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Risk factors, repair techniques and short term subjective outcome of obstetrics anal sphincter injuries at Chris Hani Baragwanath academic hospital

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RISK FACTORS, REPAIR TECHNIQUES AND SHORT TERM SUBJECTIVE OUTCOME OF OBSTETRICS ANAL SPHINCTER INJURIES AT CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

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Johannesburg, 2016

Declaration

I Salome Mokgohloe Tshabalala declare that this dissertation is my own work.
It has not been submitted before for any degree or examination purposes at this or any other university.

__SM. Tshabalala_____
(Signature of candidate)

Salome Mokgohloe Tshabalala
This day of 15 November 2016

Dedication

To my father, the late Johannes Mochamonyane Phasha, who always said:” Things cannot get better by being left alone”

Presentations arising from this study

09/03/2016: 35th Priorities in perinatal Care Conference
Session 3: Better care in pregnancy and labour.
Forever resort Warm baths Bela -Bela Limpopo.

Abstract

Background

Obstetric anal sphincter injuries (OASIS) complicates vaginal deliveries in 1-4% of patients globally. Risk factors include: Primiparity, increased birth weight > 4000g, assisted deliveries and precipitous labour amongst others.

Aims and objectives

To evaluate risk factors, describe repair methods at Chris Hani Baragwanath Academic Hospital (CHBAH) and assess outcomes post repair.

Methods

This was a prospective cohort study where 60 patients over the age of 18 with 3rd and 4th degree tears were recruited. Exclusion criteria: 1st, 2nd degree tear. Data was collected from medical files after repair. Women were interviewed telephonically at 6 and 12 weeks postpartum.

Results

The incidence of OASIS at CHBAH was 0.5%. Seventy-three percent of the study population were primigravids. End to end repair technique was popular amongst the surgeons (41.6%). Leakage of gas was the most common complaint of the patients reached at the follow up interview.

Conclusion

The low incidence of OASIS at CHBAH is similar to other studies. Primiparity was the leading risk factor in this study. Most of the patients were asymptomatic at follow up. Of those that were symptomatic, symptoms improved with time.

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Table of Contents

Declaration……i
Dedication……ii
Presentations arising from this study……iii
Abstract……iv
Acknowledgements……v
Table of Contents……vi
Abbreviations……ix
List of graphs……x
List of tables…… .xi
Chapter 1……1
Introduction……1
1.1 Problem statement……2
1.2 Justification for the study……3
Chapter 2……4
Literature review……4
2.1 Aims and objectives……4
2.2 Global incidence……5
2.3 Anatomy of the perineum……6
2.4 The identified risk factors include……7
2.4.1 Maternal risk factors……7
2.4.2 Fetal risk factors……8
2.4.3 Labor related factors……9
2.4.4 Iatrogenic related factors……10
2.5 Prevention of OASIS……10

2.6 Symptoms of OASIS……12
2.7 Signs of OASIS……12
2.8 Investigations for patients with OASIS……13
2.9 Repair techniques for OASIS……13
Summary……16

Chapter 3……17
Methods……17
3.1 Setting……17
3.2 Study Population……17
3.3 Sample size:……17
3.4 Data Management……17
3.5 Episiotomy protocol……18
3.6 The level of expertise of the surgeons repairing OASIS at CHBAH……18
3.7 Follow up……18
3.8 Tools……19
3.9 Statistics……19
3.10 Study design……19
3.11Funding……19
3.12 Ethics……19
Chapter 4……20
Results……20
4.1 Description of the study population……20
4.2 Pregnancy history……21
4.3 Labour……22
4.4 Interval between tear and repair……25
4.5 Tear Classification……26
4.6 Repair of OASIS……27
4.7 Post operation care……29

4.8 Follow up results……29
Chapter 5……37
Discussion……37
5.1 Description of the study population……37
5.2 Pregnancy history……39
5.3 Labour……39
5.4 Post operation care……43
5.5 Six and twelve week post repair follow up……44
5.6 Strengths……45
5.7 Limitations……45
5.8 Conclusion……47
5.9 Recommendations: Further research on Obstetric anal sphincter injuries……47
5.10 Recommendations: Clinical……48
References……49
Appendix A Informed Consent Form……53
Appendix B Patient information sheet……54
Appendix C Clearance certificate……55
Appendix D Stages of labour……56

Abbreviations

ART	Anti- retro viral therapy
BBA	Born before arrival
CEO	Clinical executive officer
CD4	Cluster differentiation
CHBAH	Chris Hani Baragwanath Academic Hospital
CMSA	College of Medicine of South Africa
HAART	Highly active anti-retroviral therapy
HIV	Human immunodeficiency virus
i.e.	id est (it is)
Kg	Kilogram
Min	Minute
MOU	Maternity obstetric unit
NICE	National institute for clinical excellence
OA	Occipito anterior
OASIS	Obstetrics anal sphincter injuries
OP	Occipito posterior
PDS	Polydioxanone suture
PMTCT	Prevention of mother to child transmission
RCOG	Royal College of Obstetricians and Gynaecologist
RCT	Randomised controlled trials
SD	Standard deviation
WT	Weight

List of Graphs

Page 22 Figure 4.1 - Duration of latent phase of labour

Page 23 Figure 4.2 - Duration of active phase of labour

Page 24 Figure 4.3 - Duration of second stage of labour

Page 25 Figure 4.4 - Birth weight

Page 26 Figure 4.5 - Interval between tear and repair

Page 27 Figure 4.6 - Repair of OASIS

Page 28 Figure 4.7 - Level of expertise of surgeon

Page 29 Figure 4.8 - Suture material

Page 31 Figure 4.9A - Leakage of gas

Page 31 Figure 4.9B - Leakage of gas when considering only patients reached

Page 32 Figure 4.10A – Minor bowel soiling

Page 32 Figure 4.10B -Minor bowel soiling when considering only patients reached

Page 33 Figure 4.11A – Significant bowel leakage of liquid stool

Page 33 Figure 4.11B -Significant bowel leakage of liquid stool when considering only patients reached

Page 33 Figure 4.12A – Significant bowel leakage of solid stool

Page 33 Figure 4.12 B- Significant bowel leakage of solid stool when considering only patients reached

Page 34 Figure 4.13 – Inability to defer defaecation for >15 minutes at 6 weeks

Page 35 Figure 4.14 – Inability to defer defaecation for >15 minutes at 12 weeks

Page 36 Figure 4.15A – Symptoms affects lifestyle

Page 36 Figure 4.15B – Symptoms affects lifestyle when considering only patients reached

List of tables

Page 30 Table 4.1 – Telephonic interview: Patients who answered the questionnaire

Chapter 1

This chapter introduces the subject, describes the problem statement and justification for the study.

Introduction

Obstetric anal sphincter injuries (OASIS) involve injuries to the anal sphincter, its innervation or both, following childbirth.[1] It can be a cause of considerable morbidity i.e. faecal and flatus incontinence, faecal urgency (described as inability to defer defecation for more than 15 minutes)[2] and superficial dyspareunia.[3,4,5]

It is estimated that 1- 4% of vaginal deliveries are complicated by obstetric anal sphincter injuries internationally.[6,7] The figures may be even higher, considering that a significant number of OASIS are under reported partly due to the injury being occult and only identified by endo-anal ultrasonography[1] in addition, there is poor understanding of perineal anatomy by health care workers attending to labouring women. This results in OASIS being missed. Incontinence is embarrassing for the sufferers and many times, people who suffer from incontinence do not seek help.

The risk factors for OASIS include:

- Maternal causes: Primigravidity,[3,7] certain racial groups for instance, Black and Indian women are at a higher risk than their Caucasian counterparts.[3,8]
- Fetal causes: Birth weight above 4kg,[3,7,10] large neonatal head circumference, occipito- posterior position and shoulder dystocia.[9]
- Labour causes: prolonged second stage,[10] precipitous labour.[9]
- Iatrogenic causes: assisted delivery (forceps and vacuum), epidural anaesthesia, extended episiotomy or a median episiotomy. [3,4,7,9,10]

Chris Hani Baragwanath Academic Hospital is a referral hospital which delivers approximately 22 000 women annually.[11] Women who deliver at this facility and its referring clinics and hospitals are not spared from anal sphincter injuries. To date, these have not been studied before at the institution. OASIS are repaired in theatre by doctors of different levels of training and skill. Surgeons use both an end to end technique and an overlapping technique. The suture material used is at the surgeon's discretion. The RCOG Green top guidelines recommend that repairs should be performed within the first six hours post-delivery.[12] The teaching at CHBAH is that repair of OASIS should be undertaken in the first six hours and certainly no more than 24 hours post-delivery.
Women are given stool softeners and discharged after 12 hours. These women are followed up at their local clinics.

It is not known what the incidence or associated risk factors are of OASIS at this hospital. More importantly it is not known whether these women remain symptomatic after repair. This study aims to define the incidence of OASIS, evaluate the risk factors for OASIS at CHBAH and to assess outcome post repair based on the patient's symptoms.

1.1 Problem statement

Anal incontinence in women most frequently follows
anal sphincter injuries sustained during childbirth. The sequelae thereof are significant morbidity and an altered quality of life. Women who suffer from symptoms of anal incontinence continue to suffer in silence, as they do not know where to report their symptoms and the presence of symptoms is embarrassing in the first place.
A post-natal clinic creates a venue for patients to report symptoms of anal incontinence and provides a good opportunity for clinicians to enquire about the presence of symptoms, as many sufferers do not volunteer symptoms.
Absence of a post-natal clinic at CHBAH means obstetricians rely on clinic sisters to seek symptoms from patients with anal sphincter injuries and refer the symptomatic patient to the

colo- rectal unit. If obstetricians are not following up patients that they repaired, how will they know the success/failure of the operation?

1.2 Justification for the study

- Most of the reported literature is from Europe and America, with little data about the condition in our population. The author hopes that the study will provide local data, with possibly some new insights.

- Identification of risk factors common in our hospital and referring centres will enable us to anticipate and act accordingly.

- This study is intended to highlight the need for follow up (in the form of a post-natal clinic). At this clinic, symptoms will be sought for and symptomatic patients will be referred appropriately to the colorectal department.

- More over a post -natal clinic creates an opportunity for patients to be counselled in depth about the condition and a plan of mode of delivery for future pregnancies can be made clear and be documented.

Chapter 2

Literature review

This chapter describes the aims and objectives of the study, the literature review on OASIS under the following headings: Definition, classification, global incidence, anatomy of the perineum, the risk factors for sustaining OASIS and the repair techniques used to repair these lesions.

2.1 Aims and objectives

- To determine the incidence of 3rd and 4th degree tears at CHBAH between the month of November 2012 and February 2014.
- To evaluate the risk factors for OASIS at CHBAH.
- To describe the methods used to repair 3rd and 4th degree tears at CHBAH
- To assess outcome post repair based on the patients' symptoms.

Anal incontinence is defined as any involuntary loss of faeces, flatus or urge incontinence that is adversely affecting a woman's quality of life.[14] Anal incontinence in women is mainly because of anal sphincter injuries sustained during child birth.[15] Maintaining continence largely depends on the integrity of the pelvic floor muscle and anal sphincters. Disruption to the above due to trauma sustained whilst giving birth may result in long term morbidity.[16]t Other role players in maintaining continence should also be borne in mind, including stool consistency and volume.[17] Pregnancy itself has also been implicated in the disruption of the neuro muscular function of the pelvic floor by mechanisms that include: hormonal changes and mechanical pressure on the rectum from the gravid uterus. [17] Eighty-five per cent of women who give birth vaginally will sustain some degree of perineal trauma.[18] Of these, 4 %, which involve the anal sphincter complex, are deemed severe

Sultan's classification for obstetrics anal sphincter injuries:[9,18,19]

This current classification was modified by Sultan in 1999 and has been adopted by the International Consultation on Incontinence and Royal College of Obstetricians and Gynaecologists.[9,16,]

1st degree: skin only,

2nd degree: perineal muscle injury

3rd degree: a) less than 50% external anal sphincter injury,

b) More than 50 % external anal sphincter injury

c) Anal sphincter complex (Internal and external anal sphincter) injury.

4th degree: involves injury to the rectal mucosa

5th degree: also, called the button – hole tear, the anal sphincters are intact but the anal mucosa is torn.

2.2 Global incidence

Worldwide, severe perineal injuries are estimated to occur in 1-4 %,[6] but their incidence varies from institution to institution and from labour ward to labour ward. It has been suggested that the true incidence is higher than the 1-4% as a result of under-reporting. [6] There also seems to be an upward trend in the incidence of OASIS in the last decade, perhaps because of increased awareness leading to increased detection rates.[10]

Factors which may contribute to underreporting include:

a) Women feel embarrassed to seek help and they don't know where to go, where to report symptoms of OASIS. Accordingly, they suffer in silence and accept the complications as a price one pays for motherhood.[20] Results from a study done in Baltimore in 2012 revealed that patients are not adequately counselled by the clinicians post OASIS repair, thus do not know how to go about reporting symptoms.[21] Of the 19 % of patients that sustained these tears only 9% reported consulting a health care worker.[21]

b) Some injuries are occult, and can only identified by endo-anal ultrasonography. Endo-anal ultrasound has a high sensitivity and specificity, is minimally invasive and more acceptable to patients compared to electromyography.[22]

A study by Fernando found that 41% trainee doctors and 16% midwives incorrectly classified a partial /complete tear of the external anal sphincter as a second-degree tear.[23]

2.3 Anatomy of the perineum[24]

The perineum is diamond shaped, bordered anteriorly by the pubic symphysis, posteriorly by the coccyx and laterally by the ischial tuberosities on the left and right. It is further divided into the urogenital triangle anteriorly and the anal triangle posteriorly. The contents of the urogenital triangle include:

- Clitoris
- Termination of the vagina and urethra
- Ischiocavernosus muscle
- Vestibular bulb
- Bulbo spongiosis
- Bartholins gland
- Urogenital diaphragm
- Superficial and deep perineal muscles
- Central tendon of the perineum (perineal body)

The contents of the posterior triangle include:

- The termination of the anal canal
- Internal and external anal sphincter
- Ischiorectal fossa
- Blood vessels and lymphatics
- The levator ani muscles

Nerve supply to the pelvic floor is mainly the pudendal nerve arising from the sacral nerves S2, S3 and S4. The inferior rectal branch supplies parts of the levator ani, external anal sphincter and the skin of the ischio-rectal fossa. The muscular branches of the pudendal nerve supply muscles of the perineum. The posterior labial branch supplies the skin of the vulva. The terminal branch also known as the dorsal nerve of the clitoris, supplies the clitoris. The ilio -inguinal nerve (L1), together with the posterior femoral cutaneous nerve (S1, S2, S3) provide sensory innervation to the skin of the perineum.

2.4 Risk factors which have been identified include:

2.4.1 Maternal risk factors:

- Primiparity

What sets these women apart from their parous counterparts is reduced elasticity in their perineal tissues.[9,25,26] It is the leading risk factor identified by many researchers and is clearly not preventable. Having said that, delivery by caesarean section (pre labour caesarean delivery) to avoid perineal trauma is entertained in private practice universally, more and more women are requesting caesarean sections to preserve their pelvic floor. It is not only patients that are requesting caesarean sections to preserve the pelvic floor, Obstetricians themselves male and female alike, when asked their personal preference of a mode of delivery have opted for a caesarean section.[27]

A caesarean section is a major operation and it is not without risks. Caesarean sections have an overall complication rate of four times that of vaginal births.[28] The decision of choosing a caesarean section over normal vaginal delivery to avoid perineal trauma may be unjustifiable. A systemic review of the efficacy of caesarean section in the preservation of anal continence found that the number needed to treat by caesarean was 167 to prevent a single case of faecal incontinence.[29]

Multiparous women with previous caesarean section delivery are also at risk of OASIS. Multiparity with previous vaginal delivery was found to be protective against OASIS. A

prospective observational study conducted in England found that multiparity halved the risk of sustaining an OASIS.[10]

- Certain racial and ethnic groups:[29]
  A clinical audit discovered that ethnicity may be an independent risk factor towards obstetric anal sphincter tears. Anal sphincter tears were significantly more frequent in African and Indian women compared to their Caucasian counterparts. The reasons for this remain unclear.
- Maternal Diabetes mellitus, and the consequent increased frequency of fetal macrosomia is also an important predisposing factor.

2.4.2 Fetal risk factors:

- Birth weight of over 4000g and large neonatal head circumference ranks 3rd amongst the risk factors identified for OASIS in most of the literature. Big babies and big heads overstretch the perineal tissue leading to tears. Each 100g increase in birth weight was associated with a 10% increase in odds of sustaining an OASIS in a study by Smith in 2013.[10]

- Direct occipito-posterior position:

  The vertex presents in occipito-anterior position in 90% of women in the late first stage of labour which means that the occiput is in the anterior half of the pelvis. In the remaining 10% the occiput is either in the transverse or posterior position, and this malposition is characterized by minor degrees of deflexion of the head. The larger occipito-frontal diameter which measures 11.5cm then becomes the presenting diameter.[9] Women at risk of malpositions are those with pelvis that are wider posteriorly. The use of epidural anaesthesia in the latent phase of labour may also increase the chance of a malposition. Malpositions are associated with prolonged second stage of labour and severe perineal tears.[30]

- Shoulder dystocia:

  Shoulder dystocia is associated with prolonged second stage of labour and larger birth weight. The two associations are independent risk factors for OASIS.[10]

2.4.3 Labour related risk factors:

- Prolonged second stage of labour [14]

  The second stage of labour begins when the cervix is fully dilated and there is an urge to bear down, and ends with fetal expulsion. Average duration of this stage is between 1 to 2hrs.[31] Premature pushing results in maternal fatigue which will ultimately lead to unnecessary assisted delivery which is also associated with perineal tears.. This premature bearing down has also been independently implicated in the damage of bladder fascia and the pelvic floor.[32]

  Longer duration of second stage of labour independent of the size of the baby was associated with 40% increase in odds of OASIS for each minute increase in second stage of labour in a prospective observational study.[10]

- Precipitous labour

  Defined as a rapid expulsion of the fetus, the time from regular contractions to delivery occurs in less than three hours.[33]

  Precipitate deliveries can cause perineal lacerations because maternal tissues have not had enough time to adjust to the stretch of delivery forces.

  Many textbooks recommend slowing the delivery of the infants' head to protect the patient from perineal lacerations or to discourage pushing by the mother whilst the head delivers to slow down the process.[9,34]

2.4.4 Iatrogenic related risk factors:

- Instrumental delivery [4, 9, 10, 27]Vacuum and forceps have been independently associated with OASIS. There is evidence of forceps causing more OASIS than vacuum assisted delivery for the following reasons: the application of forceps, their shanks stretch the perineum, they expand the space in the pelvis by almost 10%.[28] The results of a multi-country (Asia and Africa) study found the risk for OASIS was up to 9-fold with forceps delivery compared to spontaneous delivery and up to 5-fold with vacuum when compared with spontaneous delivery.[26]

  When an assisted delivery is necessary and a vacuum not contraindicated, a vacuum delivery is the preferred method, because it is better for the maternal pelvic floor.

- Epidural anaesthesia:
  The literature does not support epidural anaesthesia as an independent risk factor, however epidurals are associated with prolonged second stage of labour and increased use of assisted delivery and those are associated with OASIS.[10]

2.5 Prevention of OASIS

- Episiotomy

  An episiotomy is an incision through perineal muscles (bulbospongiosus), deep transverse perineal muscle and superficial transverse perineal muscle) in the second stage of labour to enlarge the introitus and prevent perineal tears.[30]

  Episiotomy should only be performed when there is a clear indication such as a tight perineum, the need to expedite the 2nd stage in the case of fetal distress, assisted delivery, shoulder dystocia and in situations where a woman has been subjected to genital mutilation. Routine use of an episiotomy may produce more harm than good. According

to a study done in California between 1992 and 1997 episiotomy decreases the likelihood of 3rd degree tears but increases the risks of 4th degree tears.[25]

There are two types of episiotomy described, the median episiotomy which entails a vertical incision in the midline of the perineum from the posterior fourchette toward the anus. The advantage of it is that it is easy to repair and has improved healing, it is less painful and has less dypareunia reported. The disadvantage of it is: it has a higher risk of anal sphincter injury compared to the mediolateral episiotomy.[28] With the mediolateral episiotomy: the incision is begun at the posterior fourchette, continued downward at an angle of at least 45^0 relative to the perineal body. The advantage of a mediolateral episiotomy is that it is less likely to extend into the anal sphincter and rectum. The disadvantages of it are, increased blood loss, difficult to repair and long term perineal pain as well as dyspareunia.[35]The mediolateral episiotomy is recommended for use at CHBAH and the university of Witwatersrand affiliated hospitals.[13]

- Perineal support during crowning of the foetal head:

  Perineal support during crowning gives counter pressure to the pressure exerted on the perineal tissues by the presenting part, thus lowering the risk of an OASIS. In Laine's study on decreasing the incidence of anal sphincter tears during delivery, the results showed that perineal support decreases the number of anal sphincter injuries.[34]

- Warm compressors:

  Entails applying a warm towel to the perineal tissues during the second stage of labour to cause vasodilatation and enhance stretching of the tissues to minimize or even eliminate the risk of tearing during foetal expulsion.[16,30]

- Perineal massage:

  This technique can be started as early as 34 weeks' gestational age by a woman in preparation for delivery. The lubricants used during this procedure include: K-Y jelly, cocoa butter, olive oil and vitamin E oil.[31]

The lubricants are used so that one can avoid friction between fingers and perineal tissues. This act leads to vasodilatation to the area, thinning and enhancing stretching of perineal tissues.[31] The above techniques are cost effective, not cumbersome and acceptable to patients.

Yet some Obstetricians shy away from practicing them, arguing that the increased vasodilatation to the perineal tissues may lead to, profuse haemorrhage should an episiotomy be needed or should a tear occur,[31] and that more evidence is needed to show efficacy of these techniques. The evidence currently available on the subject is not strong enough to influence any pregnancy guidelines.

2.6 Symptoms of OASIS

- Anal incontinence, it incorporates a range of symptoms including flatus incontinence, incontinence for liquid and or solid stool that is a social or hygienic problem.[36]
- Faecal urgency defined as the inability to defer defaecation for longer than 15minutes.[2]
- Perineal pain [20]
- Superficial dyspareunia[37]
- Faecal incontinence during coitus[5]

2.7 Signs of OASIS

- Most labour wards do not have on their premises an objective tool to assess OASIS post-delivery. The attending clinician relies on his clinical examination to make a diagnosis, thus making the knowledge of the pelvic floor structures important.
- The clinical examination reveals loss of anal tone, communication between the anal canal and the vagina in the case of a fourth-degree tear.
- The ruptured anal sphincters are identified as following: the internal sphincter is a circular muscle and appears paler than the external sphincter. It lies between external sphincter and the anal epithelium. The external anal sphincter is red and often described as being analogous to red meat whereas the internal sphincter to raw fish.[19]

2.8 Investigations for patients with OASIS

The objective manner for assessing OASIS, is by using an endo-anal sonar and anal manometry. As objective as they are at assessing OASIS these tools are not readily available in the labour ward, and not all sonographers are well trained at doing and reporting on endo-anal sonars. Faltin and colleagues concluded that an anal endosonography immediately after vaginal delivery allows diagnosis of clinically undetected anal sphincter tears in a study that included 150 women who gave birth vaginally.[38] As compared to manometry, endo-anal sonography has been found to be more acceptable to patients, and quick to do with a shorter learning curve.[22]

2.9 Repair techniques for OASIS

Management of OASIS: requires a thorough knowledge and understanding of the anatomy of the pelvis.

Repair of OASIS should be done soon after delivery to avoid bleeding and contamination of the wound. The latter is associated with wound breakdown, further increasing the risk of incontinence.[14] It is not specified in most literature as to what is meant "by soon" after delivery, the time frame specified in our institution is within 6 hours post injury. The repair should not be attempted 24 hours after the injury.

Repair ought to take place in theatre, for the following reasons, theatre lights will allow better identification of the perineal anatomy, regional or general anaesthesia, causes the sphincter to relax; the retracted fibres can be pulled with a grasper without resistance.[28, 39]
A doctor trained in the repair of OASIS or a specialist should be the one repairing these lesions.

The two methods of repair for 3rd and 4th degree tears that have been studied and explored include end to end and overlapping technique for the repair of the external anal sphincter.[1]

End to end technique: The torn anal mucosa is repaired using interrupted sutures with knots tied within the anal canal. The internal sphincter is repaired separately with interrupted sutures. The torn ends of the external anal sphincter are approximated and repaired with mattress sutures.[1]

Overlap technique: the torn anal epithelium and the internal sphincter are repaired similarly to that of the end to end technique. The external sphincter is repaired by overlapping the two ends.[1]

The two important principles highlighted in most of the work done by Sultan: anatomic structures must be repaired separately i.e. the anal canal, internal sphincter and the external sphincter. When repairing the anal canal, knots must be tied within the canal.[1]

When it comes to deciding, which technique is superior between overlap and end-to-end technique, there is no consensus as to superiority. Reasons cited for these are: poor documentation by surgeons as to which method they used. Not everyone is familiar with the current classification of OASIS.

Residual anal sphincter damage has been found in 2/3rds of cases irrespective of repair method on the endo anal sonar.[16]

The choice of suture material: Vicryl ® 3/ 0 is used and advocated for repair of the anal canal. It is rapidly absorbable synthetic suture material and it is associated with less pain and less suture dehiscence. A slowly-absorbable suture material: PDS® 3/0 (Polydioxanone suture) for the repair of anal sphincter complex to maintain tone of the sphincters. PDS® is associated with decreased risk for infection.[9,]

Poor repair techniques or no repair of perineal injuries can have debilitating effect on the patients. Even more alarming is that primary sphincter repair seems to be inadequate in at least half the women, often resulting in persistent symptoms.[20]

With regards to future deliveries, women should be counselled about the risk of anal incontinence or worsening of existing symptoms with vaginal delivery. The option of abdominal delivery should be considered and discussed with women who are symptomatic or have an abnormal manometry or abnormal endo-anal ultrasonography.[14,28]
Sadly, most of the research done on these injuries is from developed countries with little research done in developing countries.

The findings of studies from developed countries cannot be generalised to our setting. Overwhelming patient load and fewer health workers in developing countries often results in some births happening without a health care worker present. Lack of transport and late presentation may also mean women deliver in transit without assistance.

2.10 Summary

Obstetric anal sphincter injuries are rare, affecting 1-4% of vaginal births globally. The incidence might be higher than what is reported owing to cases that are missed and patients not reporting symptoms.
They are not life threatening but may cause tremendous morbidity i.e. social isolation, sexual dysfunction and an altered quality of life.
The identified risk factors include: Primiparity: it ranks as the leading risk factor in most of the literature. What sets these women apart from the multiparous patients is the reduced elasticity of perineal tissues. Increased birth weight of more 4000g, malposition such as occipito- posterior position, precipitous labour and prolonged second stage of labour.
Assisted delivery: forceps associated with a higher risk than a vacuum delivery and a median as opposed to medio-lateral episiotomy are the other risk factors for OASIS.

Interventions found to reduce the risk of OASIS are:
Antenatal: perineal massage. It is cost effective and can be done by patients themselves. It may be started as early as 34 weeks' gestational age until delivery.
Intrapartum: the use of warm towels to press on to the perineal tissues during second stage of labour, this act causes vasodilatation and enhances stretching of the perineal tissues. Perineal support during crowning and controlled delivery of the head to avoid sudden stretching are of value, as is discouraging the labouring woman from pushing during the delivery of the head.

Repair of OASIS, ought to be shortly after delivery, in theatre, where there is good lighting, under a sterile environment and where the anal sphincters are relaxed.
Post-operative care entails, prophylactic antibiotics and stool softener/ laxative.

The mode of future deliveries should be discussed with patients who should be advised that symptoms may worsen after another vaginal delivery. A caesarean section must be considered in patients with abnormal endo-anal sonar or manometry.

Chapter 3

Methods

This chapter describes the methods used in this study.

3.1 Setting:

The study was performed at Chris Hani Baragwanath Academic Hospital. CHBAH is a tertiary, academic hospital located in Soweto. The Maternity department, regarded as one of the largest in South Africa, with annual deliveries of more than 22 000 babies, is a busy hospital serving patients from the whole of Greater Soweto, Eldorado Park, Orange Farm, Lenasia, the Southern Suburbs, the Vaal region, and Heidelburg. The department also provides tertiary level support to Sebokeng Hospital, Sedibeng region, Natalspruit Hospital, Ekurhuleni, as well as Klerksdorp Hospital in the North-West Province.

3.2 Study Population:

The population was made up of women who gave birth vaginally at CHBAH, its surrounding hospitals and clinics that refer to CHBAH. The women included were those whose deliveries were complicated by 3rd and 4th degree perineal tears. Inclusion criteria: 18 years and older. Exclusion criteria: Women who did not sustain any tears, 1st and 2nd degree tears.

3.3 Sample size:

Sixty patients. This was a descriptive study and so a sample size calculation was not necessary. It is unknown what the prevalance of OASIS is in this hospital.

3.4 Data Management:

The names and hospital number of any women who had a vaginal repair in the Obstetrics theatre was looked for daily in the theatre register. The above information was used to trace the women in the postnatal wards. The study was explained to the women; they were given an information sheet and then invited to be part of this study.

Baseline demographics, weight, HIV status, antenatal characteristics, information on the labour, delivery and neonatal information was retrieved from the patient's bed letter and a telephonic interview was performed at 6 weeks and 12 weeks (see below)

3.5 Episiotomy protocol:

The hospitals protocol is that an episiotomy does not have to be performed routinely, and that it may be done only when there is an obstetric indication i.e. tight perineum in the second stage of labour. When indicated a medio – lateral episiotomy is done.

3.6 The level of expertise of the surgeons repairing OASIS at CHBAH:

The researcher classified surgeons according to their level of training into i) A consultant: Specialists in Obstetrics and Gynaecology, ii) Medical officer: This category included junior doctors, defined as doctors who had completed their internship training, but had not begun training for specialization.

The registrars were divided into junior registrar: below second year of training, and senior: second year or more of training.

3.7 Follow up:

Participants were phoned at six and twelve weeks post-delivery to establish if they were experiencing any symptoms associated with 3rd and 4th degree tears. In the event of existing symptoms women were referred to the colorectal team for further assessment and management. The follow up telephonic interview was conducted in the following manner: the researcher would try to contact the participant for a week, during the week of that case follow up interview, if by the end of the week the participant could not be reached the researcher would enter on the questionnaire "voice mail", a second attempt would be made at twelve-week post repair, if on that call the participant was reached, the interview would only be carried out for twelve weeks follow up. Lost to follow up at six weeks would thus be entered in the data for that individual. Some of the reasons for loss to follow up included: change of contact

details by the study participants without informing the researcher, study participants not answering their phones during their respective week of follow up.

3.8 Tools:

A data sheet was used to collect information from the medical notes shortly after giving birth. A telephonic interview was conducted at six and twelve weeks' post repair, where the questions used were derived from the model of the American medical system score. This scoring system was designed with the intension to evaluate the artificial bowel sphincter. We found it to be superior to other scoring systems, in that it asks about the consistency of the stool lost, the frequency and the impact the symptoms have on lifestyle. Theatre register was used to look for names of patients who had OASIS repaired.

3.9 Statistics:

Simple statistics with standard descriptive tests was used and results were presented as percentages, frequencies, means ± standard deviation (SD), medians and ranges.

3.10 Study design:

A prospective descriptive study

3.11 Funding

The only funding that was required was the cost of stationery the cost of the telephone calls. The costs of the above were incurred by the researcher

3.12 Ethics:

The study was approved unconditionally by the University of the Witwatersrand, Human Research Ethics Committee. A clearance certificate M120970 was given (see appendix) Permission to conduct research was obtained from the CEO of CHBAH (see appendix)

Chapter 4

Results

This chapter describes the population, pregnancy history, labour and outcomes thereof. It further describes the repair techniques employed during the study period and describes the short term subjective outcome of OASIS.

The study period was from November 2012 to February 2014 (15 months). A total of 123 patients with third and fourth degree tears were identified using the theatre register. Of those, 60 met the inclusion criteria and were recruited into the study, the other 63 were excluded for the reasons described below:

Age (under 18 years) was the main reason for exclusion

Incorrect classification (corrected, in theatre under anaesthesia) when the surgeons downgraded the lesion to second degree when the anal sphincter complex was found to be intact.

During the study period, there were a total of 29942 deliveries at the facility. Of those 8982 were caesarean section deliveries. The caesarean section rate during the study period was 30%.

The incidence of OASIS during this study period was 0.5%.

4.1 Description of the study population

Age:

The youngest age in the study population was 18years and the oldest age was 42. The mean age was 23.58 (SD± 5.56), a median of 22 (IQR= 20- 25).

Race:

The study sample was made up of 59 (98%) black women and 1(1, 66%) Indian.

Weight:

The weight amongst women in the study population ranged between 45kg and 126kg.

The mean weight was 66.92 (SD± 16.08), a median weight of 65.00 (IQR= 55-73).

HIV:

Fifteen (25%) were HIV positive, 45 (75%) were negative. Of the 15 positive patients 6 (40%) were on ART for their own health and 9 (60%) were on ART in the form of PMTCT. The PMTCT regimen entailed: Zidovudine 12 hourly ante-nataly from 14 weeks' gestation, Nevirapine as a stat dose once in labour and Truvada® (emtricitabine and tenofovir disoproxil fumarate) six hourly in labour as well.

CD4:

The lowest CD4 count was 89 and the highest was 611.

The mean CD4 count was 400.85 (SD± 166.59), the median 453.00 (IQR 254-487)

Duration of treatment:

The mean duration of treatment was 21.83 months (SD± 20.47), and the median was 12 (IQR 6-48)

4.2 Pregnancy history

Forty-four (73%) patients were primigravida, 17(28%) were parous.

Parity:

The mean parity was 0.4 (SD± 0.80), the median of 0 (IQR 0-1)

Gravidity:

The mean gravidity was 1.48 (SD± 0.99), the median of 1 (IQR 1-2)

Perineal massage during the ante natal period

None of the patients had ante natal perineal massage, when asked; none of them knew what it was, nor the purpose thereof.

4.3 Labour

Place of delivery:

Fifty-four (90%) patients gave birth at CHBAH, three (5%) gave birth at a clinic/ maternity obstetric unit (MOU), one (1.6%) gave birth at a district/secondary hospital and two (3.3%) gave birth at home.

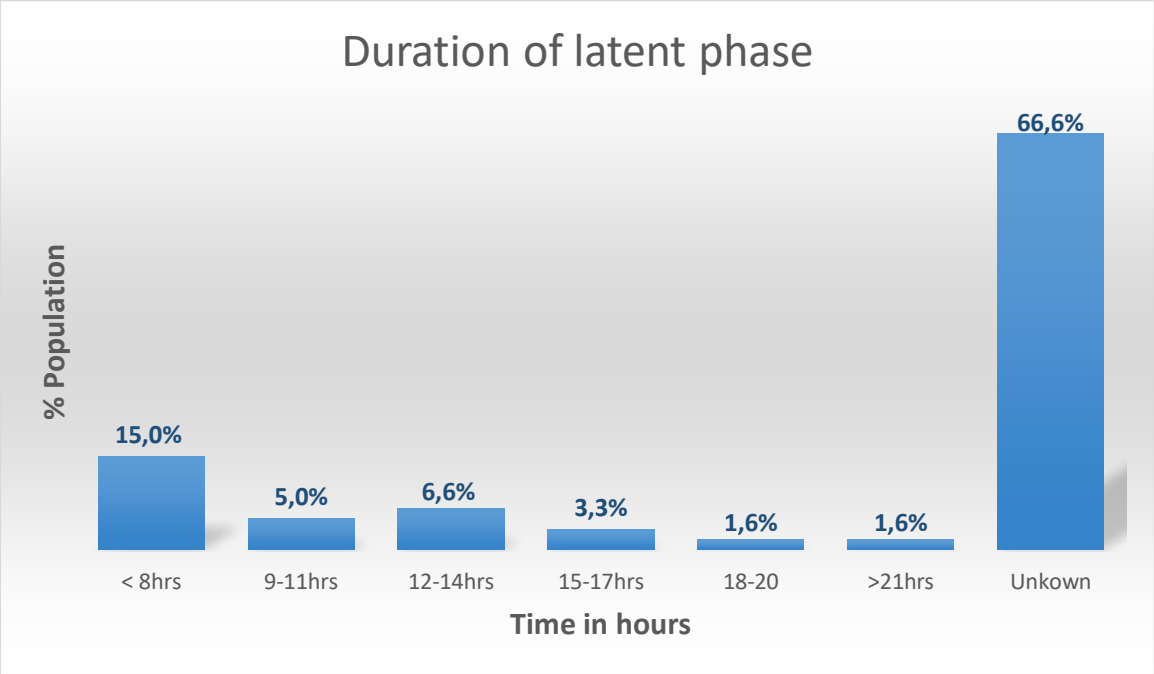


Figure 4. 1. Duration of latent phase

The mean duration of latent phase of labour was 10 hours (SD 5.76), with a median of 9 (IQR 3. 5-12.5)

The duration of latent phase of labour was unknown in 40 out of the 60 patients because most women came in in the active phase of labour.

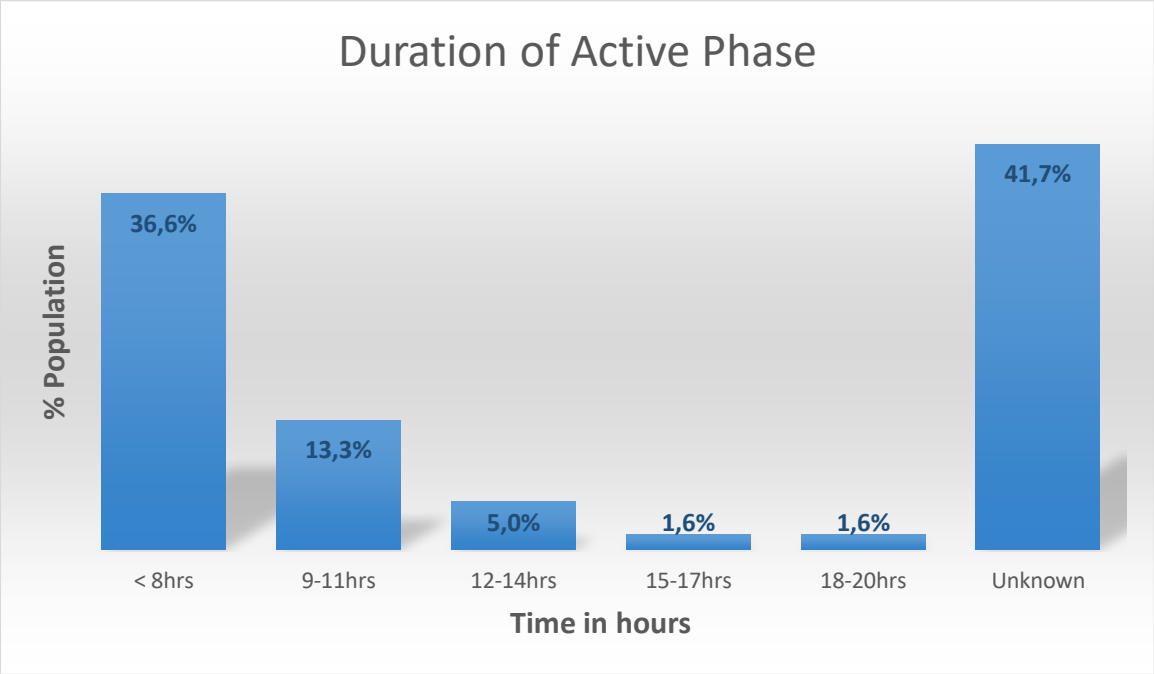


Figure 4.2. Duration of active phase

The duration of active phase ranged from 1hr to 18 hrs.

The "unknown "in the graph describes that group within the study sample whose length of duration of active phase of labour was unknown.

The mean duration of the active phase of labour was 7.40 (SD 4.03), with a median of 7.00 (IQR 4-10)

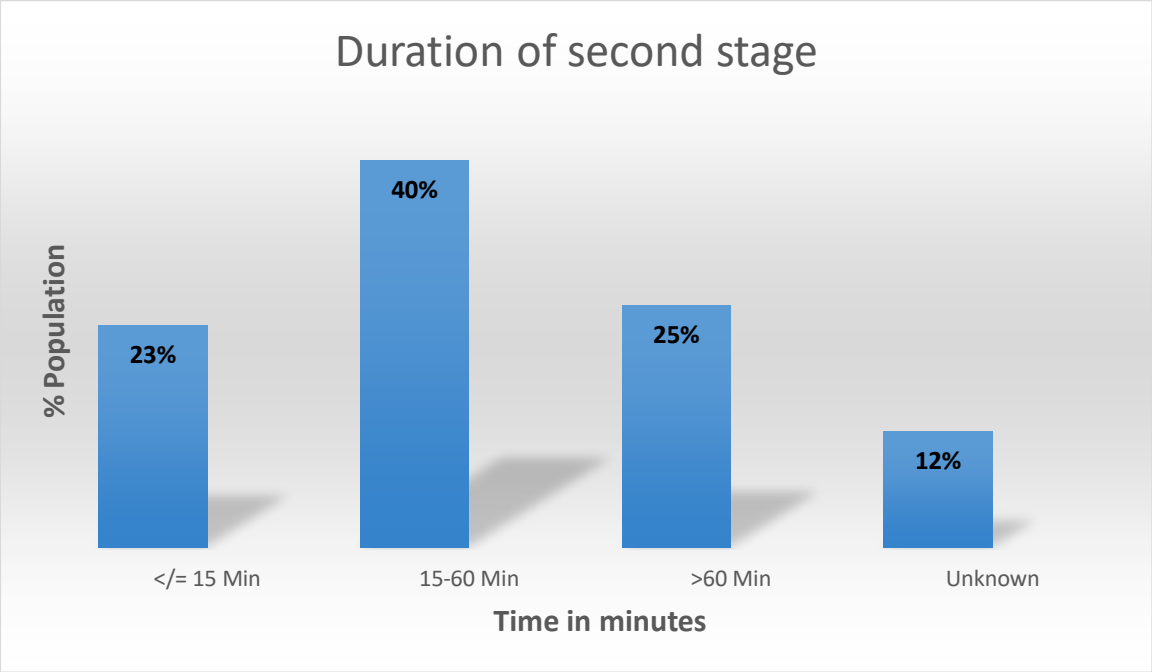


Figure 4.3. Duration of second stage

The "unknown" in the graph describes those whose duration of second stage was unknown to the researcher because of patients presenting for the very first time already in the second stage or poor recording in the patients' bed-letter of the beginning or the end of the various stages of labour.

The mean duration of second stage of labour was 52.16 minutes (SD 43.16), the median of 35.00 minutes (IQR 15-70)

Position of presenting part:

The position of the presenting part was not stated in 54 (90%), OA was documented in 5 (8.3%) patients and OP was documented in one (1.6%) patient.

Episiotomy:

Episiotomy was performed in 22(36.6%) patients and not done in 38(63.3%) patients

Instrumental delivery:

Vacuum delivery was done on 11(18%) patients and forceps delivery on 2(3.3%) patients

Perineal massage intrapartum

It was not performed in any of the 60 patients.

Perineal support during crowning:

Perineal support during crowning of the fetal head was documented as having being done in 2(3.33%) patients, not done in 3(5%) patients not documented in 55 (91.66%)of patients.

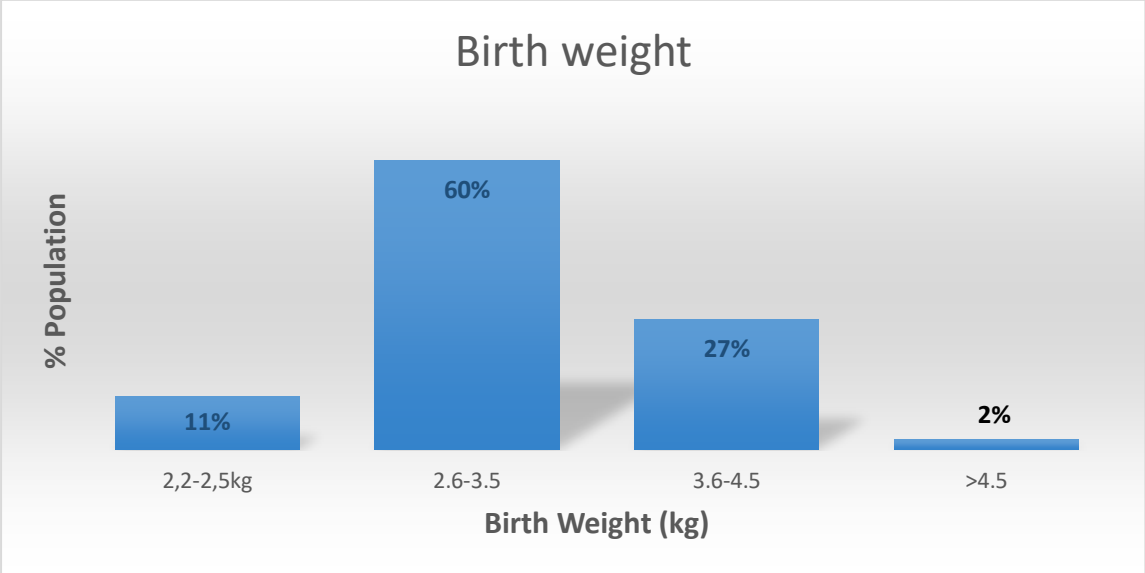


Figure 4.4. Birthweight

The mean birth weight was 3363.42g (SD 496.15), the median of 3370.00g (IQR 3135-3680)

Baby's head circumference:

The head circumference ranged from 31cm to 38cm

The mean head circumference was 35.12 cm (SD 1.58), the median of 35.00cm (IQR 34-36)

4.4 Interval between tear and repair

The graph below describes in hours the duration between the tear and repair of the tear. Twenty-three per cent (23%) patients were repaired within 6hrs of sustaining the tear. Of those one was repaired immediately post-delivery, as the delivery took place in theatre. The majority (66%) were repaired after 6 hours but no more than 24 hours after the tear.

One patient (2%) was repaired after 24hours. The “other” 9% of patients in the graph depicts those that were not repaired because of wound contamination, or interval could not be accurately calculated, because the patients gave birth at home and could not give a proper account of the time of delivery.

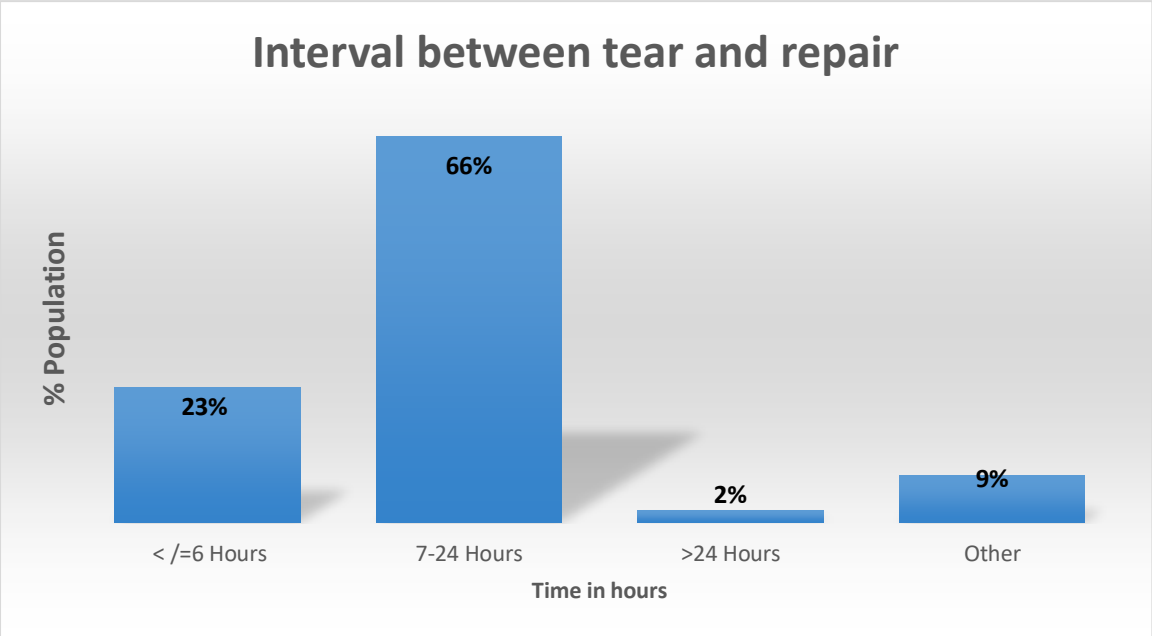


Figure 4.5. Interval between tear and repair

4.5 Tear classification

There were 26(43%) that were classified as a 3rd degree tear and 6(10%) classified as a 4th degree tear. There were those that further classified the extent of the 3rd degree: six (10%) 3c, 9(15%) 3b, eleven (18.33%) 3a and two (3.3%) were never repaired.

4.6 Repair of OASIS

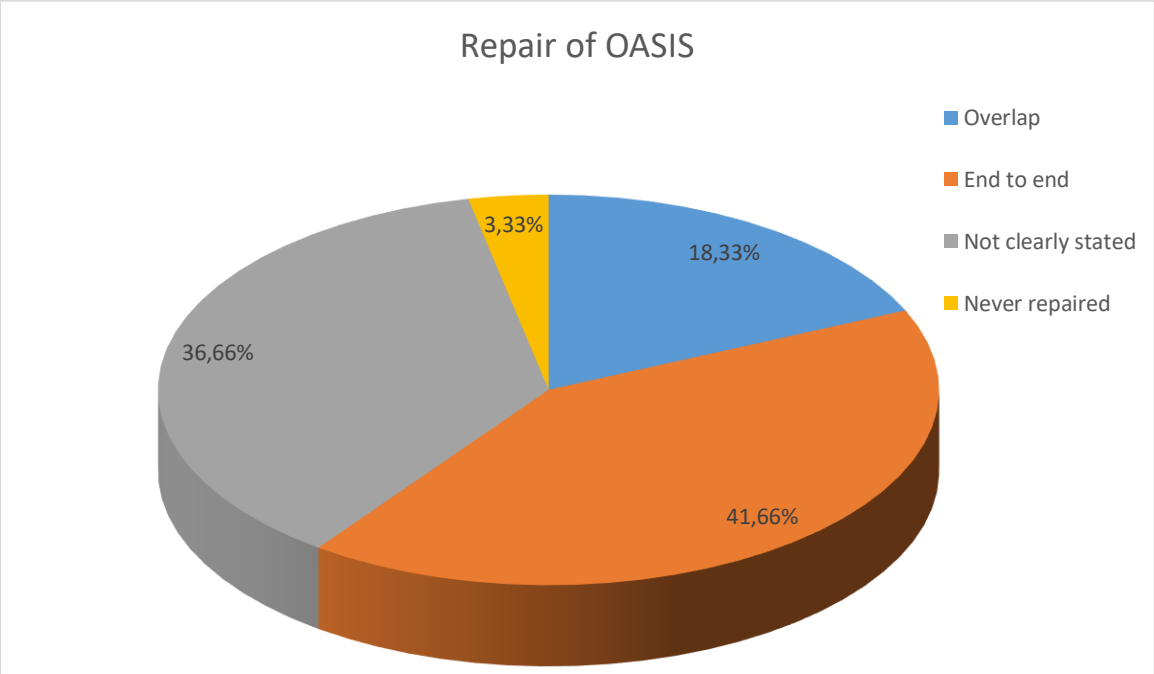
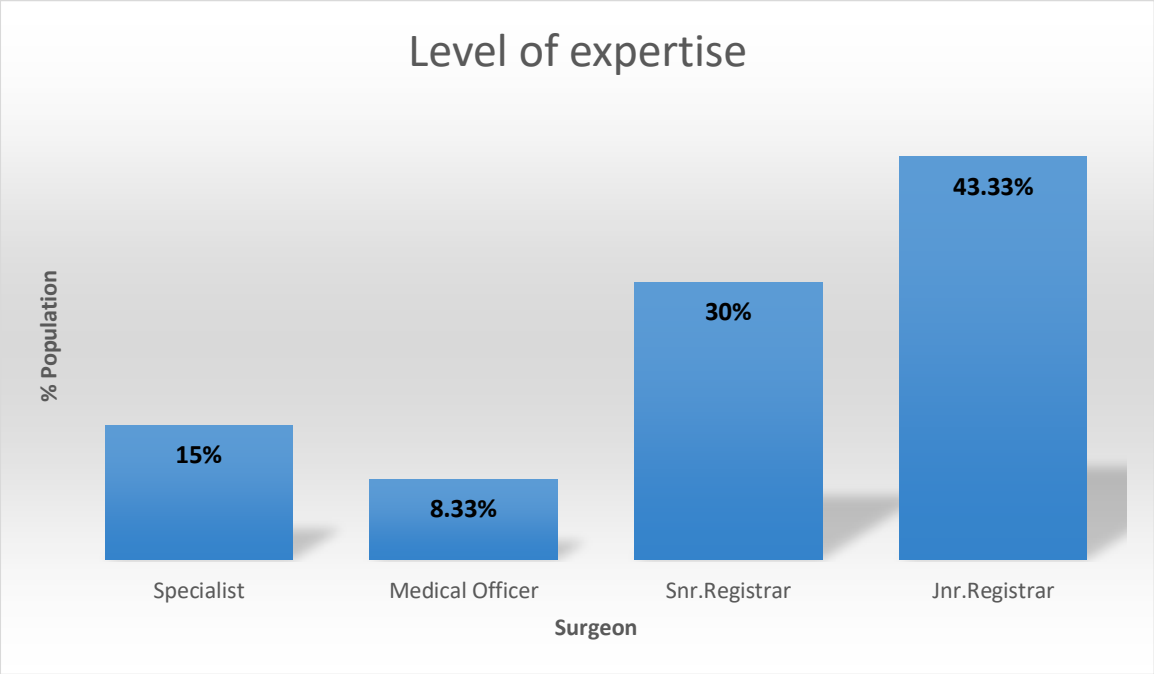


Figure 4.6. Repair of OASIS

The overlap suturing technique for suturing the external sphincter was used by 11(18.33%) surgeons; the end to end technique was used by 25 surgeons (41.66%). The surgical technique used, was not clearly stated in 22(36.66%) of cases, and 2(3.33%) were not repaired primarily.

Level of expertise of surgeon:

Twenty-six patients (43.33%) were repaired by the junior registrar, 18(30%) were repaired by the senior registrar, 9(15%) were repaired by a consultant, 5 (8.33%) were repaired by a medical officer. Two (3.33%) were not repaired primarily.



Graph 4. 7 Level of expertise

Suture material:

Vicryl® was used to repair OASIS for 31 (51.66%) patients, the suture material used was not specified in 22 (36.66%) patients, PDS® was used in 5 (8.33%) 2 (3.33%) were not repaired primarily

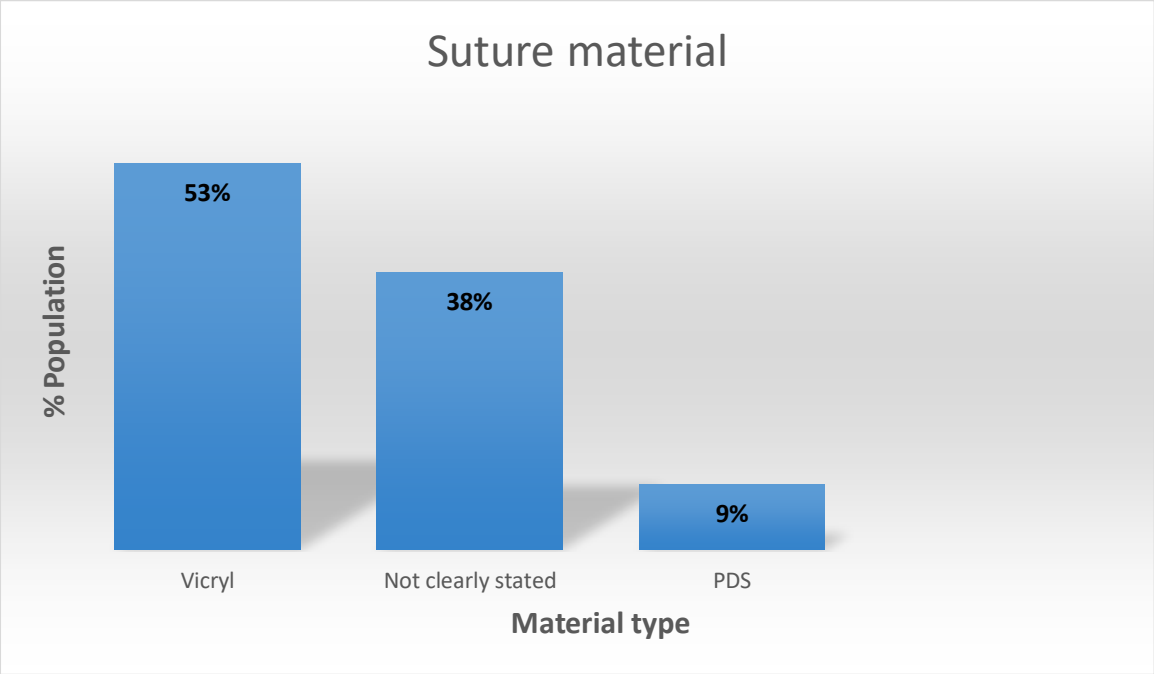


Figure 4. 8 Suture material

4.7 Post operation care

Antibiotic cover:

Fifty (83.33%) patients received antibiotics (prescribed by the surgeon administered by the nursing staff in the post- natal ward), 10 (16.66%) did not receive antibiotics (not prescribed by the surgeon).

Laxative/stool softener:

Thirty-seven (61.66%) patients received laxative/stool softener, twenty-three (38.33%) did not.

4.8 Follow up results: six and twelve weeks' post repair

We enrolled sixty patients into study, an attempt to contact all at 6 and 12 weeks' post repair was done to establish if any symptoms of anal incontinence were present.

At six weeks, we could reach 42(70%) patients and at twelve weeks we managed to reach 40(67%) patients. It is important to note that the patients we could contact at 12 weeks were not necessarily the same patients we were able to contact at six weeks.

Telephonic interview: patients who answered the questionnaire

At 6 weeks only	At 12 weeks only	Both 6 and 12 weeks	Not reached at 6 & at 12 weeks
6(10%)	2(3%)	37(62%)	15(25%)

Table 4.1 Telephonic interview: patients who answered the questionnaire

The above table demonstrates the number of patients reached and those not reached at the follow up telephonic interview. Those that answered the questionnaire at six weeks only were 6(10%), those that were not reached at six weeks but were successfully contacted at 12 weeks were 2(3%). The majority 37(62%) of patients were successfully contacted at 6 and 12 weeks' post repair and answered both questionnaires. Fifteen (25%) were not reached telephonically on both occasions.

Analysis of the 37(62%) patients that we could reach on both occasions

Eleven patients (30%) were symptomatic at 6 weeks and the symptoms persisted at 12 weeks' post repair. Of the eleven leakage of gas was the symptom reported the most 9 (82%). One patient reported daily leakage of gas, daily minor bowel soiling, daily leakage of liquid stool and solid stool. That patient was not repaired primarily; she was discharged 24 hours after OASIS with secondary repair by the colo-rectal team having been arranged.
However, twelve weeks' after injury she had not yet been operated upon.
Protocol at the facility suggests that OASIS ought to be repaired in the first 24 hours, failing which the patient gets discharged and repaired secondarily by the colorectal surgeons. The most common reason why patients with OASIS do not get repaired in the first 24 hours is the lack of theatre time. The facility runs a 24 hour two obstetric theatre and the average number cases done per day are thirty to thirty- five.

One patient reported leakage of gas for the first time at 12 weeks' post repair. Twenty-five (68%) of patients were asymptomatic at six weeks and remained asymptomatic 12 weeks' post repair of OASIS.

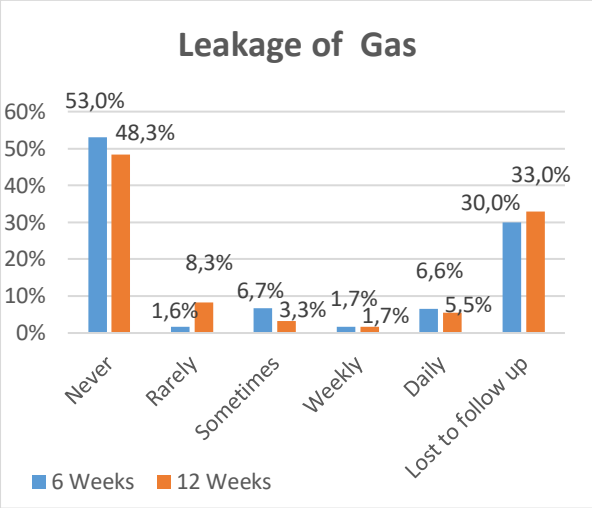


Figure 4.9A Leakage of gas

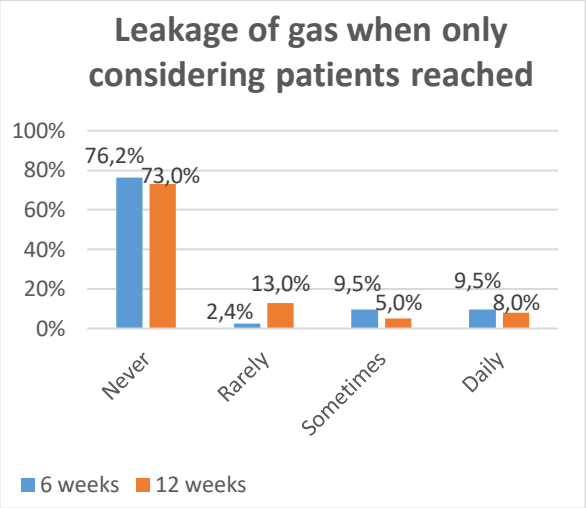


Figure 4.9B Leakage of gas when only considering patients reached

In the above graphs, most patients were asymptomatic at six weeks and at twelve weeks for leakage of gas. Fifty-three percent reported that they never leaked gas. The number declined by 5% at twelve weeks. There was an overall 30% loss to follow up at six weeks rising to 33% at 12 weeks. There were fewer patients that rarely experienced leakage of gas at six weeks (1.6%) the percentage increased at 12 weeks to 8.3%

In figure 4.9B data was analysed considering only the patients that were reached at six and twelve weeks follow up questionnaire. Where n=42 at six weeks and n=40 at twelve weeks. The graph illustrates better that most patients remained asymptomatic for leakage of gas. Overall symptom improved over time except in the subcategory of those that initially reported leakage of gas rarely, a significant increase from 2.4% to 13.0%

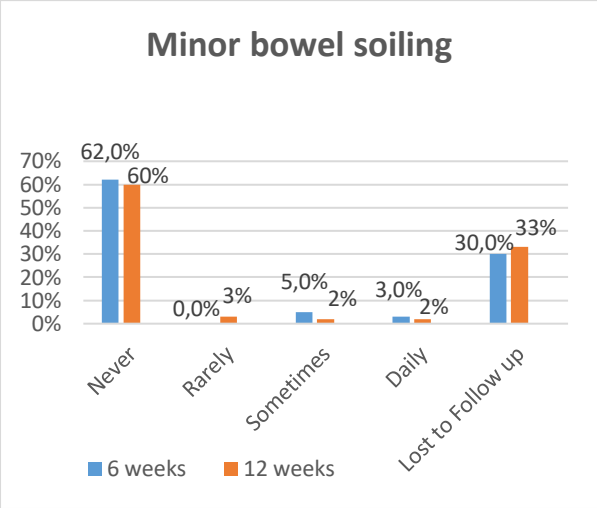


Figure 4.10 A Minor bowel soiling

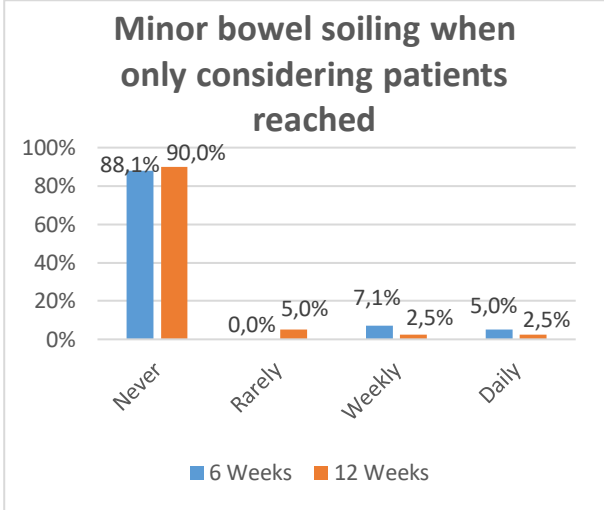


Figure 4.10 B Minor bowel soiling when only considering patients reached

The majority (62% and 60%) of the patients did not have minor bowel soiling at six and twelve weeks follow up. None of the patients said that they "rarely have minor bowel soiling" at six weeks however 3% reported this symptom for the first time at twelve weeks. Those that reported to minor bowel soiling occurring sometimes and daily, those symptoms improved with time, from 5% and 3% at six weeks to 2% and 2% at twelve weeks.

When analysing data (figure 4.10B) patients reached at follow up, at 6 weeks n=42 and 12 weeks n=40, most patients were asymptomatic for minor bowel soiling. In the few cases that were symptomatic, symptoms improved with time.

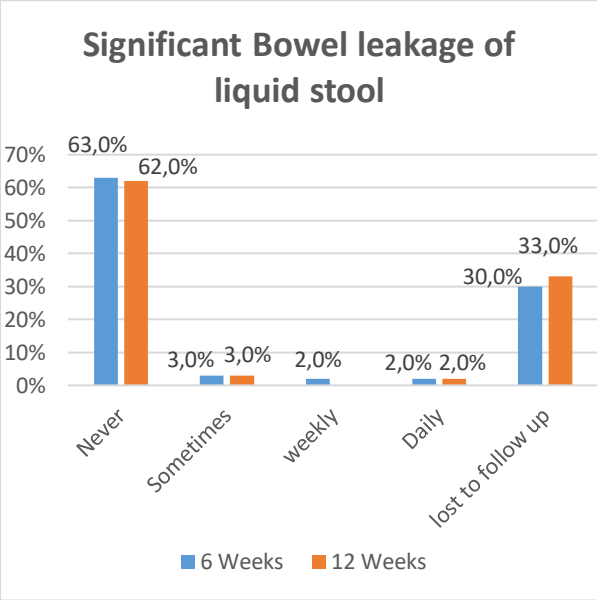


Figure 4.11 A Significant bowel leakage of liquid stool

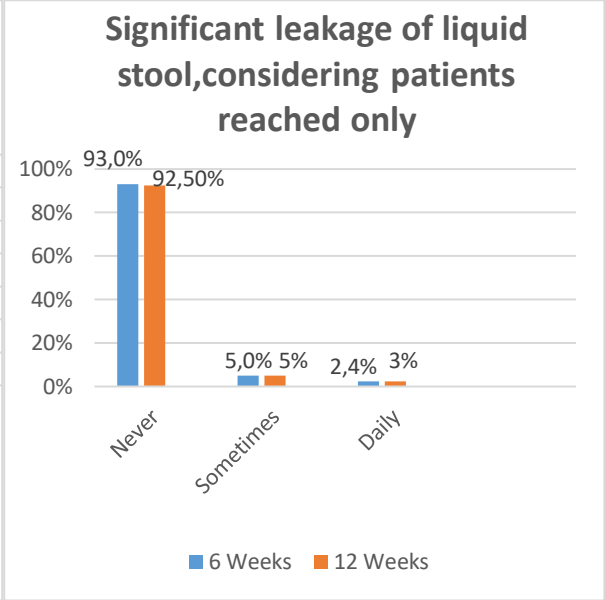


Figure 4.11B Significant leakage of liquid stool, considering patients reached only

A minority of patients reported significant leakage of liquid stool,

The trend remained the same at 12 weeks follow up.

In figure 4.11B, we analysed data using the patients we could reach on both occasions. Where n=42 at 6 weeks and n=40 at 12 weeks. Over ninety percent of patients were asymptomatic to significant leakage of liquid stool

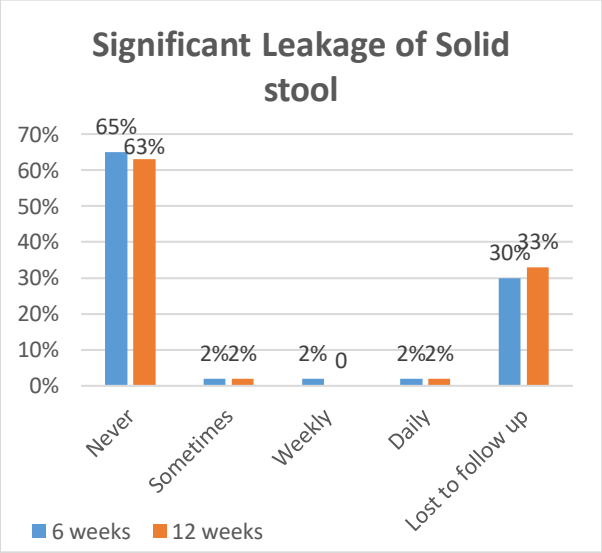


Figure 4.12 A Significant leakage of solid stool

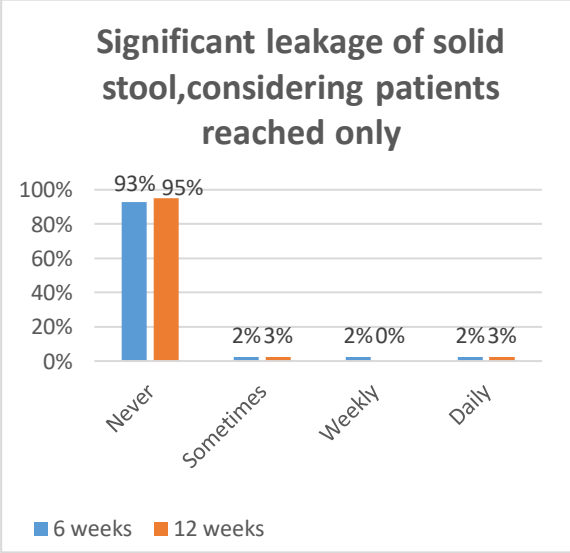


Figure 4.12 B Significant leakage of solid stool, considering patients reached only

Less than 2% of patients reported significant leakage of solid stool and the majority never experienced significant leakage of solid stool.

The value remained below 2% at six and at 12 weeks.

Figure 4.12B: analysis of data when subtracting the 'lost to follow up' where n=42 at six weeks and 40 at 12 weeks. The percentage for symptomatic patients remained constantly low, both at six and at 12 weeks follow up.

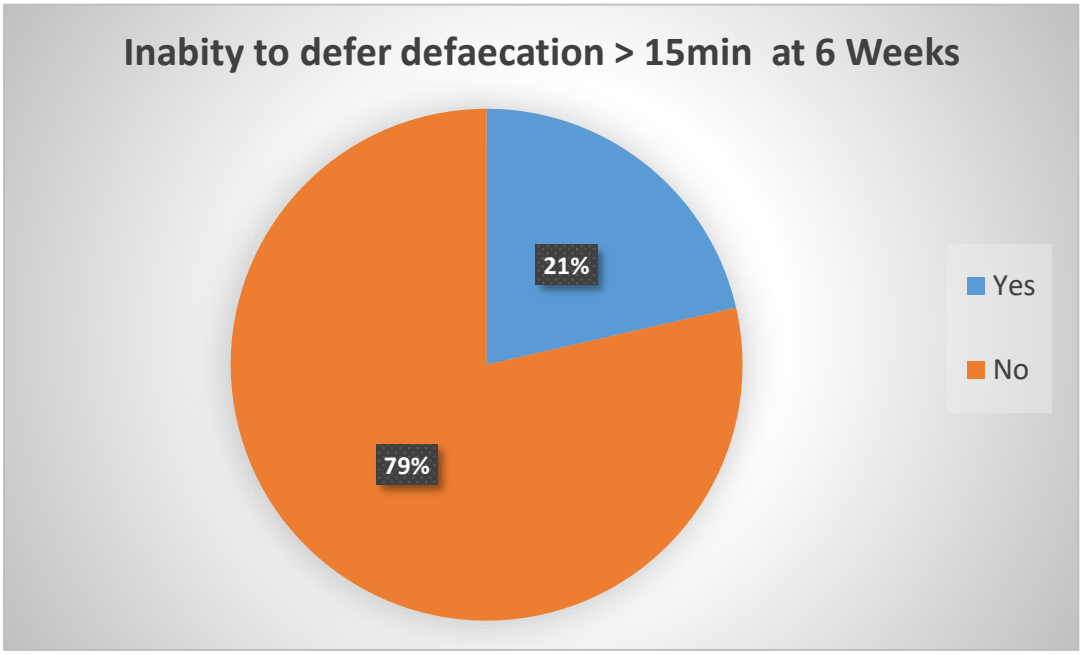


Figure 4.13 Inability to defer defaecation >15 min at 6 weeks

Of the patients that were reached at six weeks' post repair 21 % said that they were unable to defer defaecation for more than 15 minutes. The majority (79%) could defer defecation for more than 15 minutes.

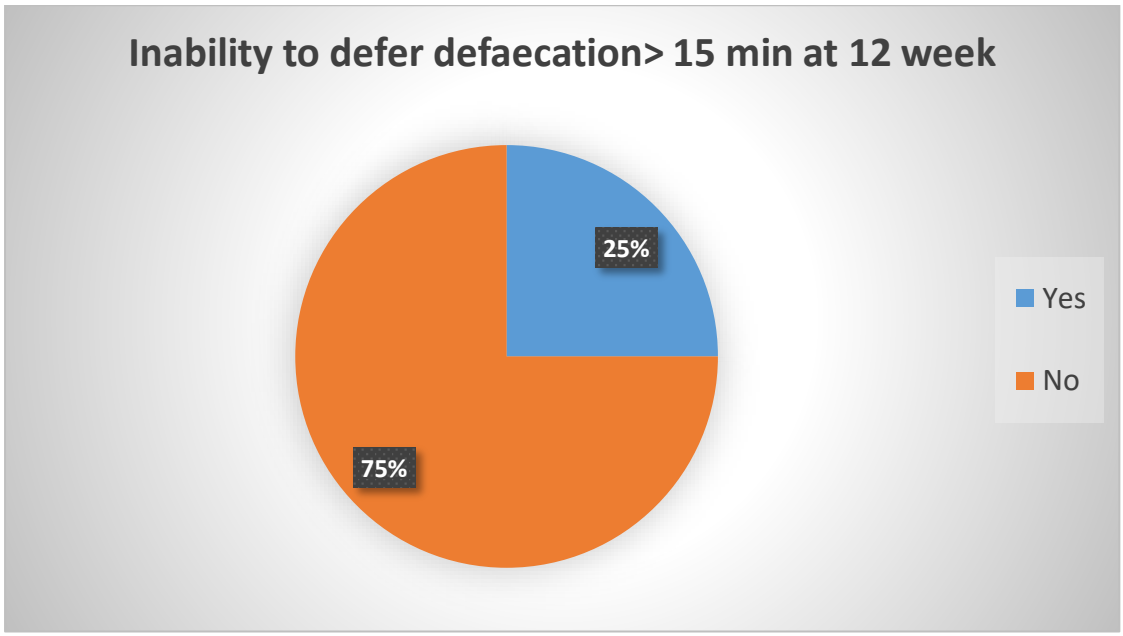


Figure 4.14 Inability to defer defaecation >15 min at 12 weeks

At twelve weeks' after repair, the percentage increased slightly from 21% to 25% for those that reported inability to defer defecation for more than 15 minutes.

Symptoms affects lifestyle

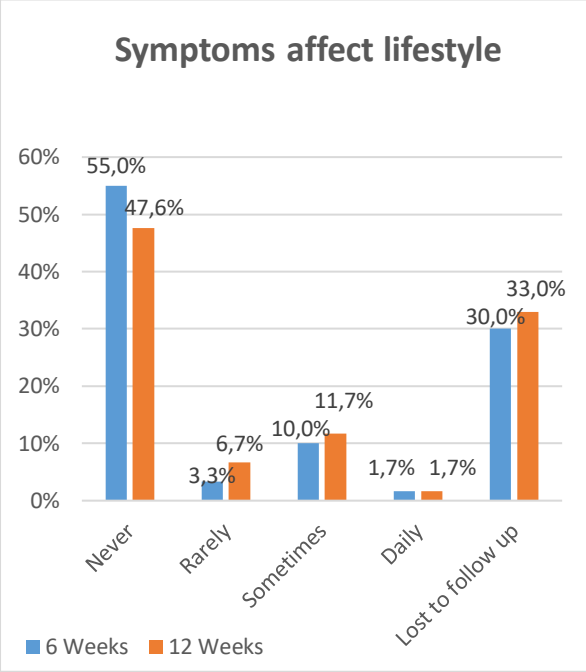


Figure 4.15 A Symptoms affect lifestyle

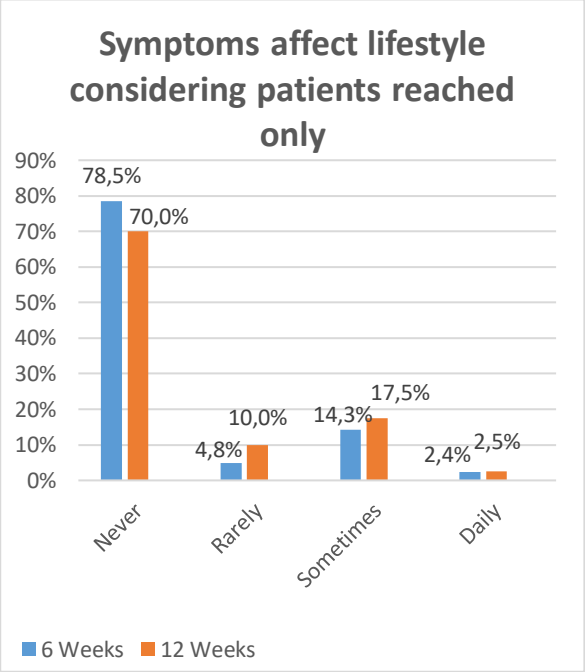


Figure 4.15 B Symptoms affect lifestyle considering patients reached only

When asked overall if symptoms affected lifestyle, most of the patients answered ‘never’ to the question. Those that replied by saying rarely or sometimes were few.
Of note, the numbers increased in each category at 12 weeks.

Although a small number complained of symptoms at follow up, one of the patients that had gross symptoms further elaborated by saying they found themselves always wanting to know where the toilet is when they found themselves in unfamiliar places, or sitting close to an exit when in church for example.

Chapter 5

Discussion

The results of this study are discussed in this chapter under the following sub headings: description of the study population, pregnancy history, labour events, repair techniques and subjective outcome at six and twelve weeks' post repair.

5.1 Description of the study population

The incidence of OASIS at CHBAH was 0.5% for the 15 months of the study period. The incidence was calculated by including all women who sustained an OASIS during child birth, regardless of age or whether they fulfilled the study criteria. The total number of women who delivered vaginally at the institution is also included. In the calculation, we excluded those that sustained OASIS but delivered outside of Chris Hani Baragwanath Academic, in other words patients referred to Chris Hani Baragwanath Academic Hospital for repair purposes only. The low incidence of OASIS at CHBAH and referring centres is similar if not lower to that described in local and international studies. The incidence of anal sphincter injuries varies from country to country and is reported to occur in 0.5% of vaginal births in the United Kingdom, 1.4% in Japan, 2.5% in Denmark and 9% in Canada.[4] Under-reporting, the use of different classification systems and missed lesions are some of the reasons why there are such marked differences in incidences found in different countries**.** One can certainly also attribute the rise in incidence to an increase in awareness of these lesions.

We expected a higher rate of OASIS because our hospital sees mainly black women. CHBAH, is in Soweto, where most people residing there are black.

There is literature that has found a high number of OASIS in certain racial groups. The black and Indian races have been found to have a higher risk of OASIS compared to their Caucasian counter parts. [10] We cannot comment on this in our study as the facility whereupon the study took place caters for black patients mostly.

There were patients younger than 18 years that sustained OASIS during the study period but were not part of the study because of their age.

The mean age in the study population was 23. The mean age of patients in other studies in the Obstetrics Department was between 26 and 27.[41] OASIS are high in the younger age group. The mean age may have been younger than 23 had the 18 years of age and below been included in the study.

The weights of the women enrolled in the study reflect the weights of a Soweto pregnant population.

HIV infection is a well-known risk factor for fistula formation and poor healing in the peri-anal area.[42] We found that 25% of the patients who sustained an OASIS were HIV positive. It would be interesting to find out how many of the 25 % HIV positive population go on to incur a fistula or poor healing secondary to the HIV status. The 25% HIV positivity rate is lower than the antenatal prevalence of 29% at the hospital.[11] Of the 15 positive patients 6(40%) were on treatment and 9(60%) were not on treatment. The ones not on treatment, were on the old (pre-April 2013) PMTCT programme which entailed: Zidovidine antenatally and Neviripine and Truvada® in labour.

The lowest CD4 count was 89 in one patient. Of note is that the same patient was on treatment for the last four years.
The duration of treatment ranged from 5months to 48 months in our study population. The management of HIV positive pregnant women has evolved since the study took place. The current guidelines stipulate that every HIV positive pregnant woman should be started on full treatment regimen regardless of CD4 count or gestational age.[40] Not only that but treatment should be on going long after delivery and breast feeding.
These guidelines are not only concerned with prevention of HIV infection to the infant but with the overall wellbeing of the mother.

There is an increase in perineal disease i.e. fistula formation in HIV positive women, and the effects of ART on this are unclear. There isn't an increased risk of OASIS in these women at CHBAH.

5.2 Pregnancy history

Primigravidity (73%) ranked the highest risk factor for OASIS in our study. This phenomenon is consistent with all the other studies done on anal sphincter injuries following child birth both locally and internationally.[9,40,25]

The concept of perineal massage started as early as 34 weeks' gestational age by patients was unknown in our study population. It is patient driven and a cost-effective intervention once patients are taught how to do it. It is something that can be taught to the high-risk population i.e.: Primigravida. It results in thinner stretchable perineal tissues, thus decreasing the risk of OASIS, however more work still needs to be done before it can be incorporated in the Obstetric guidelines.

5.3 Labour

In our study the 90% of OASIS incurred were CHBAH deliveries. This can be explained by: CHBAH is a tertiary hospital accepting referrals from surrounding clinics; MOU's and level two hospitals of complicated labour. The low 5% OASIS occurring at the MOU's could be explained by the uncomplicated deliveries occurring at the clinics compared with complicated deliveries seen at a tertiary hospital. Three percent of the OASIS occurred in patients that gave birth at home, their labour unmonitored and perineum's unsupported during the second stage of labour. In both cases the patients said there was no transport to get them to the hospital in time for their delivery. An observational study 2013, found occurrence of OASIS higher in hospital than in community settings i.e. clinics, MOU's and home deliveries. This was attributed to the absence of assisted deliveries and of epidural anaesthesia[10]at that level of care.

In 66% of the study population the duration of the latent phase of labour was unknown because the patients would arrive at the facility already in the active phase.
As a result of a large percentage of unknown duration of latent phase of labour in our study population, it is difficult to label prolonged latent phase of labour as an independent risk factor for an OASIS.
The duration of active phase of labour was unknown in 41% of the study population owing to patients arriving already in the active phase, or those that gave birth in other facilities and were referred to CHBAH for repair of the tear only. The records of events of their labour did not accompany the patient. In some patients, there was poor documentation of the beginning of the second stage of labour, thus an overlap between the active phase of the 1st stage and the 2nd stage of labour. The active phase was less than 8 hours in 37% of the study population. A minority of 20% fell in the range of between 9 and 17 hours of active phase of labour. The duration of active phase of labour was more than 18 hours in 2% of the study population.
We could not identify prolonged active phase of labour as an independent risk factor for OASIS, as most of the women in whom the duration of active phase was known had an active phase of less than 8 hours.

The duration of second stage of labour in our study ranged from 5 minutes to 150 minutes. In a significant proportion (23%) of women the duration of second stage was less than 15 minutes, implying that a short duration of second stage of labour could also pose a risk of an OASIS. The proposed explanation would be that this does not allow the perineal tissues time to stretch adequately and allow easy passage of the foetal head. Only 10% of patients had duration of second stage longer than the acceptable one hour. The duration of second stage was unknown in 12% of patients because of poor documentation in the patient's bed letter, or missing information from referring clinics and MOUs. In some instances, there was no information in the patients' bed letter, particularly those patients that had given birth at home unassisted prior arriving at a clinic or hospital.

Whilst we cannot come to any conclusions regarding the length of latent, active and second stage of labour, Zetterstrom in his Swedish study, as well as a local study by Juul demonstrates that extremes of duration increase the risk of an OASIS.[1,9]

The position of the presenting part was not documented in 90% of patients. Perhaps if the maternity files used in labour ward could have a slot where position of the presenting part is documented this would yield better documentation of the position of the presenting part, and t health care workers should be educated into correctly documenting their finding and the importance thereof.

The position of the presenting part was documented in 10%, and documentation was more frequent in the assisted deliveries.

It is interesting how there were fewer episiotomies performed (36.6%). Sixty-three (63.3%) per cent of our study population delivered without an episiotomy. The protocol at CHBAH, with regards to an episiotomy, is that no routine episiotomies are performed. They are carried out when there is a clinical indication i.e. a tight perineum, assisted delivery, shoulder dystocia etc. Mediolateral episiotomies are done and never a median episiotomy.[13] The work by Twidale et al demonstrates a decrease in OASIS with an increase in mediolateral episiotomy.[7]

Twenty-two percent of the study population had an assisted delivery. This is much higher than the institutional rate for vacuum and forceps, and the vacuum extractor was preferred. The reasons for this could be the readily available disposable vacuums in the form of Kiwis in labour ward unlike forceps that need to be fetched from the CSSD (Central sterile services department) at the time of need. Doctors are hesitant to perform forceps deliveries because of lack of experience and the knowledge of increased OASIS with forceps as compared to vacuum delivery.

The indications for a vacuum is more liberal than for forceps - for instance one can perform a vacuum assisted delivery at less than fully dilated cervix of 9 cm, while full dilatation is an absolute must have before one can proceed with forceps assisted delivery. The institutions

protocol allows an attempt with a vacuum with a head above pelvis of no more the 2/5th and zero fifths above brim when it comes to forceps assisted delivery forceps.
The rise in litigation in the field of Obstetrics has yielded to a rise in caesarean section delivery and a decline in operative vaginal delivery.

Perineal support and intra partum perineal massage is poorly documented. Perineal support was only documented in 7.33% whereas intrapartum perineal massage was not documented at all. This is not to say that it does not get done. The midwives and doctors at the facility routinely support the perineum during crowning

Most our patients gave birth to babies of weight between 2.6 -3.5kg. Only 2% gave birth to babies of more than 4.5kg. This is not to say that OASIS are associated with smaller birth weight than larger birth weight. It may be that most of these women with babies of more than 3.5kg are delivered by caesarean section because they have poor progress of labour or cephalo- pelvic disproportion. Further research into this is necessary.
The majority (33%) of the OASIS were repaired within 7 to 10 hours, 23 % were repaired within 6 hours of the injury. Most guidelines do not specify the time frame for primary repair, we should certainly aim for 6 hours and certainly no more than 24 hours of sustaining the tear. Due to lack of theatre time (priority given to caesarean sections, ectopic pregnancy etc.), there were two patients that were not repaired 24hrs post injury, their wounds were deemed contaminated. They were discharged with referral letters to the colorectal departments for secondary repair.

A high proportion of these injuries were not sub classified by the surgeons into 3A, 3B or 3C; this is attributed to lack of knowledge of the classification by Sultan, adopted by the Royal college of Obstetricians and Gynaecologist.
The lack of knowledge on the classification system may very well result in some OASIS being missed. A survey by Stepp KJ concluded that trainee specialist in their fourth year of

training had not received a formal training in pelvic floor anatomy, episiotomy or perineal repair and there was little supervision when it came to repair of perineal injuries.[16]

The popular suturing technique for repair of the external sphincter was the end to end technique (42%) in preference to the overlap technique (18.33%). The hospital does not have a strict protocol as to which method should be used. The decision is based on the surgeon's preference and experience. The technique was not described in 37% of cases, a lack of knowledge of the different types of repair techniques could be the reason for this.
The majority (43.33%)of the cases were repaired by the junior registrars. A junior registrar is trained initially and supervised once deemed capable they are then allowed to operate on OASIS on their own. It is the junior registrars that work in theatre most of the time whilst the senior registrars are left to run the labour ward and high care area. The senior registrars get called into theatre for difficult cases.

The preferred suture material used to repair OASIS in our study was Vicryl® (52%), this is consistent with what is described in the literature: Obstetricians use Vicryl® whereas the colorectal surgeons use PDS® to repair the external sphincter.[19] Another reason why surgeons in the department opt for Vicryl ® over PDS ® is that the protocol book, last revised in 2013 stipulates Vicryl® as the suture material of choice.[13] The protocol book is undergoing revision. The benefits of PDS® are that it has a longer half-life than Vicryl® it is associated with decreased wound sepsis and has better tensile strength.[9,19]

5.4 Post operation care

Knowledge and importance of antibiotics post repair is less than required at CHBAH: 83% of patients received antibiotic post repair. However, the figure should be 100% considering it is stipulated in the Wits protocol book as well as a recommendation of the RCOG.[12,13]
The same can be said for laxative/stool softener post repair, 62% of patients received laxative/stool softener. There is room to improve, amongst clinicians the practice of mandatory laxative/ stool softener post repair.

5.5 Six and twelve weeks' post repair follow up

The majority (62%) of patients were reached both at six and twelve weeks' post repair, this allowed us to see the trend of symptoms over time, unlike those that were reached once off or not at all.

We can appreciate that leakage of gas was the most problematic sequalae of OASIS in our study when this group was analysed on their own.

Leakage of gas: The analysis of the entire study population showed that leakage of gas didn't seem to be a problem in the majority (53% at six weeks and 48.3% at twelve weeks) of patients. What is striking though is that a low 1.6% rarely reported leakage of gas at six weeks, the percentage increased to 8.3% at twelve weeks. It seems therefore, that leakage of gas worsens with time. The trend however remains low or even lower at twelve weeks in those that reported sometimes, weekly and daily. A study by Brummen et al found that 42% of their women reported flatus incontinence late in the pregnancy,[44] supporting the evidence that says pregnancy itself is a risk factor for anal incontinence. The pressure of the gravid uterus on the pelvic floor as well as the hormonal changes that are associated with pregnancy render the women vulnerable to anal incontinence.[17]

Minor faecal soiling: Most patients were asymptomatic; this is better expressed on the graph that analyses data looking only at the patients we could contact for the follow up interview. Over 80% were asymptomatic. Again, with the few that were symptomatic, symptoms improve with time.

Significant leakage of liquid and solid stool: once again majority of our patients were asymptomatic, with a small minority reporting significant leakage of liquid and solid stool sometimes and daily, the values are constantly low both at six and twelve weeks.

Inability to defer defaecation: Again, a large proportion of our patients had good anal continence and could defer defaecation longer than 15 min, 79% at six weeks and 76% at twelve weeks.

What is of concern though is that with time the percentage of those that were unable to defer defaecation increased from 21% at six weeks to 25% at twelve weeks suggesting that not all symptoms improve with time, a conclusion found in this study and many similar studies on OASIS. The works of Johannessen et al revealed the correlation between urgency (defined as inability to defer defaecation for more than 15 minutes) and instrumental deliveries but not with OASIS.[17] They propose that urgency may have a different aetiology altogether. If indeed they are correct, (more clinical trials are needed), then it explains why most of our study population did not experience urgency, and those that did, did not improve with time as expected.

The two patients with overt symptoms make us to appreciate the importance of surgical repair. Not only is repair important but that it must be done primarily. With no repair at six and twelve weeks' patients experienced a whole spectrum of symptoms and in their severity. These patients experienced daily leakage of gas, liquid and solid stool and inability to defer defaecation, thus affecting quality of life.

5.6 Strengths

1. 1 It's a prospective study
2. Follow up at six and 12 weeks' post repair by the same researcher
3. Able to communicate in the patient's language.

5.7 Limitations

- Small sample size
- Follow up at 6 and 12 weeks was done by means of a telephonic interview, where study participants were asked questions from a questionnaire to establish if symptoms of incontinence were present. Failure to contact some participants resulted in incomplete follow-up.

- Hawthorne effect: behaviour patterns may have changed as soon as doctors learnt of an ongoing study
- Pre-delivery symptoms of anal incontinence were not sought prior to enrolling patients into the study
- We excluded women under the age of 18, for ethical reasons. Minors would require their parents to consent to be enrolled into the study.
- There was no information about intrapartum perineal massage or perineal support in the second stage of labour.
- Further dividing of Medical officer into senior and junior would have enabled the study to see if the level of training and experience matters when it comes to repairing OASIS
- It would have also been fruitful to be able to track down the symptomatic patients post repair to the surgeon as per level of expertise.
- It would have been worthwhile to have a control group: patients that did not sustain OASIS.

Conclusion

The low prevalence of OASIS at CHBAH is like, if not lower than that found locally and internationally.[3,5,9] Primiparity, was identified by this study as a risk factor for women sustaining OASIS.

This study could not conclude that prolonged latent phase, active phase and second stage of labour were risk factors for women sustaining OASIS, because of poor documentation of beginning and endings of the various stages of labour in the maternity records. Majority of the patients were asymptomatic at follow up, of those that were symptomatic, symptoms improved with time.

The institution is struggling to get patients in theatre for repair in less than 6 hours of sustaining an OASIS owing to the burden of emergency caesarean sections.

Not all doctors who repair OASIS at CHBAH are familiar with the current and recommended classification system, the repair techniques and the post operation care of such patients.

Recommendations: Further research on Obstetric anal sphincter injuries

- A similar study with a larger study population or even a case control study
- A longer follow up duration i.e. 6 to 12 months follow up post repair
- Future observational studies could include a question to the health worker involved in the delivery whether perineal massage and support were done.
- An interventional study where at the first follow up symptomatic patients are divided into those that will be taught pelvic floor exercises to strengthen the pelvic floor and those that will not be taught and later asses the results post intervention

Clinical recommendations

- A more effective follow up, could be done by having patients come to a post-natal clinic where symptoms of anal incontinence can be sought for and perhaps an endo anal sonar and manometry can be done for symptomatic patients.
- For all surgeons involved in the repair of OASIS, to clearly document the technique used as well as the suture material used
- For all surgeons to classify and document OASIS using the current and recommended guideline.

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Appendix A

Informed Consent Form

Study title: Risk factors, repair techniques and short-term subjective outcome of obstetric anal sphincter injuries at Chris Hani Baragwanath Academic Hospital.

Researchers Dr. Salome Mokgohloe Tshabalala and Dr. A.B Oyebajo

With your permission; we would like to access your hospital records to answer relevant questions (such as age; number of children and duration of labour) this will happen +/- 48 hrs of giving birth. Thereafter a second questionnaire will be administered six weeks and again at twelve weeks post-delivery by means of a telephonic interview. You will be asked in the questionnaire for example: Did you experience accidental leakage of gas or bowel leakage?

There are no risks or discomforts from participating in the study. There will be no cost to you if you participate in this study nor will there be any personal benefit from your participation, but the knowledge received will be of value to humanity. Your participation is voluntary. Refusal to participate or withdrawal of your consent or discontinued participation in the study will not result in any penalty or loss of treatment or rights to which you are entitled. The principal investigator may at her discretion remove you from the study for any of several reasons. In such an event, you will not suffer any penalty or loss of benefits or rights which you are entitled to.

You will not receive any monetary compensation for your participation in this study. Efforts will be made to keep personal information confidential. Absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the Research Ethics Committee and the Medicines Control Council (where appropriate). If results are published, may lead to individual / cohort identification.

Wits Research Ethics Committee has approved the procedures of this study.

Should you have any queries about this study please contact **Dr S.M Tshabalala on 0799835752**

For reporting complaints/ complements and/or any queries regarding your rights as a participant please feel free to contact: **Wits Research Office, 10th Floor Senate House, East Campus at 011-717-1234 Fax: 011-717-12657594** This study is funded by Dr. S.M Tshabalala (principal investigator), who is supporting the costs of this research. There will be no financial gain to the researchers by conducting this study.

I understand the nature of this study and agree to participate. I received a copy of this form. I give the principal investigator and her associates' permission to present this work in written and/or oral form for teaching or presentation to advance the knowledge of science and/or academic without further permission from me provided that my name or identity is not disclosed.

_____ _____

Participants of Signature Date

_____ _____

Signature of Witness Date

Appendix B

Patient information sheet

Study title: Risk factors, repair techniques and short-term subjective outcome of obstetric anal sphincter injuries at Chris Hani Baragwanath Academic Hospital.

Hello. My name is Dr SM Tshabalala. I am a doctor at this hospital and I am training to become a specialist in Obstetrics and Gynaecology. We are required to do research as part of our training. Research is just the process whereby we gather information, analyse and interpret it to learn the answer to a question. In this study, we want to understand more about perineal injuries, following child birth (why they occur, how are they repaired and results after a repair has been done) This research project does not form part of routine care. Information that will be gathered will enable us to get answers to questions pertaining to our health care services.

We are inviting you to take part in this research study. It is a prospective study and 59 other patients like you will also be invited to participate. Your involvement in the study entails: giving us permission to your hospital records to answer questions found in the first data sheet, this will happen within +/- 48hrs of giving birth. Thereafter a second questionnaire will be administered at six weeks and again at twelve weeks post-delivery by means of a telephonic interview.
You will be asked in the questionnaire for example: Did you experience accidental leakage of gas or bowel leakage? Should you have significant symptoms, you will be referred to the relevant department for further assessment and management.

In taking part in this study you will not have to experience any uncomfortable or painful procedures.

There will be no direct benefit for participating in this study but what we find out about your condition will help others in the future.

You will be given pertinent information on the study while involved in the project and after the results are available.

Participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the subject may discontinue participation at any time without penalty loss of benefits to which the participant is otherwise entitled.
Efforts will be made to keep personal information confidential. Absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law.
Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the Research Ethics Committee and the Medicines Control Council (where appropriate).
If results are published, may lead to individual / cohort identification.
You can contact me at any time for further information or reporting of study related adverse events.
My contact number is: 0799835752
Contact details of REC (Research ethics committee) administrator and chair – for reporting of complements /complaints or problems is 011 717 1234.

Appendix C

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Mokgohloe S Tshabalala

CLEARANCE CERTIFICATE	**M120970**
PROJECT	Risk Factors, Repair Techniques and Short Term Subjective Outcome of Obstetric Anal Sphincter Injuries at Chris Han1 Baragwanath Academic Hospital (change of title)
INVESTIGATORS	Dr Mokgohloe S Tshabalala.
DEPARTMENT	Department of Obstetrics & Gynaecology
DATE CONSIDERED	28/09/2012
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 16/01/2013 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr AE Oyebajo

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

Appendix D: Stages of labour

