A retrospective, descriptive study of neonates with Subaponeurotic Haemorrhage admitted in a public hospital in South Africa.

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A research report Submitted to the School of Clinical Medicine Faculty of Health Sciences, University of The Witwatersrand, Johannesburg, in partial fulfillment of the requirements for the degree of Master of Medicine in branch of Paediatrics 2022

DECLARATION

I Delight Nyiko Baloyi declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Medicine in the Branch of Paediatrics at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

_____

(Signature of Candidate)

11 day of November 2022

DEDICATION

To my mother

Tsakani Sophie Makhuvele

and my daughter

Vuako Andziso Baloyi

for the love and faith in me**.**

Abstract

Background

Subaponeurotic haemorrhage (SAH) is an uncommon but potentially lethal birth injury. It is associated with instrumental delivery especially vacuum extraction. At risk infants should be monitored for the development of hypovolaemic shock which is associated with mortality.

Objective

To determine the incidence, risk factors, management and outcome in neonates with SAH in a tertiary public hospital setting.

Methods

This was a retrospective, descriptive study of neonates diagnosed with SAH admitted to the neonatal unit at Chris Hani Baragwanath Academic Hospital (CHBAH) between 1 January 2016 and 31 December 2017. Maternal and neonatal demographic data, risk factors, management and outcomes to discharge were collected from the REDCap (Research Electronic Data Capture) neonatal database and hospital records. Statistical analysis was conducted using Statistica (version 14.0).

Results

The incidence was 3.5 per1000 live births. One hundred and seventy-eight neonates with SAH had data for analysis, 73.6% were male. The mode of delivery included, vacuum assisted (74, 41.6%), forceps (4, 2.25) and caesarean section after failed vacuum (9, 5%). Maternal risk factors included being primigravid (125, 70.2%) and prolonged second stage of labour (74, 75.5%). The most common comorbidities were jaundice (61, 34%) and hypoxic ischaemic encephalopathy (36, 20%). There was a decrease in head circumference (p=0.026), post treatment with fresh frozen plasma. Eleven neonates (6.2%) required a blood transfusion, 34(19.1%) required phototherapy and 3 (1.7%) developed hypovolaemic shock requiring inotropic support and demised.

Conclusion

The incidence of SAH was higher than previously reported. All neonates were treated with fresh frozen plasma irrespective of their severity and the overall mortality was low. Prompt recognition and treatment of SAH is associated with improved outcomes.

ACKNOWLEDGEMENT

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Abbreviations

aEEG	Amplitude Integrated Electroencephalogram
CHBAH	Chris Hani Baragwanath Academic hospital
CPD	Cephalopelvic Disproportion
DIC	Disseminated Intravascular Coagulopathy
FFP	Fresh Frozen Plasma
FBC	Full Blood Count
HC	Head Circumference
HDN	Haemorrhagic Disease of Newborn
HREC	Human Research Ethics Committee
HIE	Hypoxic Ischemic Encephalopathy
INR	International Normalized Ratio
IQR	Interquartile Ranges
IDM	Infant of Diabetic Mom
LGA	Large for Gestational Age
LBW	Low Birth weight
MAC	Medical Advisory Committee
MAS	Meconium Aspiration Syndrome
MOU	Midwife Obstetrics Units
NVD	Normal Vaginal Delivery
NICU	Neonatal Intensive Care
NNJ	Neonatal Jaundice
PTT	Phototherapy
PVL	Periventricular Leukomalacia
REDCap	Research Electronic Data Capture
RDS	Respiratory Distress Syndrome
RH Neg	Rhesus Negative
SBR	Serum Bilirubin
SAH	Subaponeurotic Haemorrhage
SGH	Subgaleal Haemorrhage

SD	Standard Deviation
TTN	Transient Tachypnoea of the Newborn
WCC	White Cell Count

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Main Submission

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract

The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study

Study Methods should be described in as much detail as possible so that others would be able to replicate the study should they need to.

Results should describe the study sample as well as the findings from the study itself

Discussion section will explain interpretation of findings, which should consider primary outcomes first before any secondary or tertiary findings or post-hoc analyses.

The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

Tables: Tables should be constructed carefully and simply for intelligible data representation.

Structured abstract

- This should be no more than 250words, with the following recommended headings:
    - **Background:** why the study is being done and how it relates to other published work.
    - **Objectives:** what the study intends to find out
    - **Methods:** must include study design, number of participants, description of the intervention, primary and secondary outcomes, any specific analyses that were done on the data.
    - **Results:** first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.
    - **Conclusion:** must be supported by the data, include recommendations for further study/actions. Do not include any references in the abstracts.

SUBMISSABLE FORMATTED RESEARCH REPORT

A descriptive, retrospective study of neonates with Subaponeurotic Haemorrhage admitted in a public hospital in South Africa

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Introduction

Subgaleal haemorrhage also referred to as subaponeurotic haemorrhage (SAH) is an uncommon but potentially lethal birth injury in new-borns. [1–4] It was first to described in 1819 by Naegele, when he distinguished it from a cephalhaematoma. [5] SAH is an accumulation of blood in the subaponeurotic space between the epicranial aponeurosis of the scalp and the periosteum of the bone. The subgaleal space is a potential space that is estimated to accommodate up to 260 mls of blood. It extends anteriorly to the orbital margins and posteriorly to nuchal ridge and laterally to the temporal fascia.[3] Bleeding occurs when there is rupture of the emissary veins between the scalp and the meningeal veins and dural venous sinuses.[6] In term neonates where the circulating blood volume is 82-86 ml/kg, loss of blood up to 260 mls can result in hypovolaemic shock.[7] This condition can present as a spectrum from asymptomatic bleeding to a massive haemorrhage leading to hypovolaemic shock. [8] SAH should be differentiated from other head swellings such as cephalhaematoma or caput succedaneum. A cephalhaematoma develops due to an accumulation of blood between the periosteum and skull and is limited by the sutures, while caput succedaneum is oedema in subcutaneous tissue of the skull. [9] Diagnosis of SAH is based on history and clinical examination. Clinically, there is a diffuse, gravity dependent scalp swelling which crosses skull sutures and can also track to eyelids or displace the ear. [10] Regular observation for ongoing blood loss, is recommended in at risk infants. Measurements of the head circumference should be monitored hourly for the first 6-8 hours of life as an increase of 1cm is associated with blood loss in the subgaleal space of up to 260ml, a change in colour or displacement of ears will also indicate ongoing blood loss. [3] Vital signs, perfusion and blood pressure should be monitored to identify hypovolaemic shock.

The incidence is estimated to be 0.5-3 per 1000 live births which increases to 7.6/1000 live births for those with vacuum assisted deliveries.[11,12] Risk factors for the development of SAH include primigravid women, prolonged second stage of labour and instrumental delivery; particularly vacuum delivery. The use of a vacuum is as high as 64-89% in cases with SAH. [2,4,13–15] and there is a higher risk in cases of failed vacuum extraction, difficult extraction with repeated attempts and placement of the vacuum cup. [15] There has been an associated male predominance in neonates with SAH. SAH can be classified as mild, moderate or severe based on an increase in head circumference (HC), jaundice and

hypovolaemia in previously established criteria. [2] Severe SAH is defined as an increase in HC > 3cm, jaundice requiring an exchange transfusion or hypovolaemia requiring blood products and/or inotropic support.[15,16] Management includes vitamin K administration, normal saline as a plasma expander, fresh frozen plasma (FFP), blood or cryoprecipitate in cases of a coagulopathy. [17]

Reported mortality is 12-15% usually due to massive blood loss presenting with hypovolaemic shock, often in the setting of uncorrected coagulopathy. Poor outcome has been associated with neonates that had underlying hypotension, anaemia, coagulopathy and metabolic acidosis. [4,15] Severe birth asphyxia is a contributing factor to mortality in neonates with SAH.[14] Some studies have reported on long term neurological outcomes with some neonates developing spastic or hypotonic cerebral palsy and epilepsy. These outcomes are linked to the underlying co-morbid conditions. [15] SAH continues to be a concern to paediatricians and midwives because of the associated morbidity and mortality. SAH in majority of cases can be prevented by providing education and training in instrumental delivery especially in the use of the vacuum application. Monitoring of at risk neonates is essential to reduce the incidence of SAH and its associated complications.[18] In neonates early identification and prompt treatment results in a good prognosis with no long-term consequences.[16]

This study aimed to identify the incidence, maternal and neonatal characteristics, risk factors, co-morbidities, management and outcome in neonates with SAH in a tertiary public hospital setting.

Materials and Methods

This study was a retrospective, descriptive study of all neonates with subaponeurotic haemorrhage admitted to Chris Hani Baragwanath Academic Hospital (CHBAH) neonatal unit between 01 January 2016 to the 31 December 2017. CHBAH is a public tertiary hospital in Soweto, Johannesburg, South Africa. The surrounding midwife obstetric units (MOUs), as well as the district and regional hospitals refer high risk maternal deliveries to CHBAH or

neonates post-delivery who are assessed to require tertiary care.

All infants admitted with a diagnosis of (SAH) during the study period were included. Neonates diagnosed with SAH were identified from the computerized REDCap (research electronic data capture) neonatal database. The medical records of all neonates with a diagnosis of SAH were retrieved and data extracted. Data was collected on maternal and neonatal demographics, comorbid diagnosis, management and complications and outcomes to discharge.

Data Analysis

Data was entered into a Microsoft Excel database and exported into Statistica (version 14.0) for data analysis. Categorical variables were reported as numbers and percentages. Continuous variables that were normally distributed were reported as means and standard deviations (SD) continuous variables that were not normally distributed were reported as medians and interquartile ranges (IQR). A p – value of < 0.05 was considered significant.

Ethics Statement

The study was approved by the Human Research Ethics Committee (HREC) of the University of the Witwatersrand (M180323). Approval to conduct the study was received from the hospital Medical Advisory Committee (MAC), paediatric departmental and neonatal divisional heads. This was a retrospective study thus parental consent was waivered.

Results

A total of 55 965 live births were recorded during the study period, 39 794 (71%) at CHBAH and 16 171 (28.9%) from the district. (Figure 1). Sixteen percent (9141) of the neonates were admitted to the neonatal unit. A total of 198 neonates were diagnosed with SAH during the study period, giving an incidence of 3.5 per 1000 live births. Twenty files were not located thus the study cohort was 178 (1.94%). Most of the neonates in the study cohort, were inborn 172 (96.6%) and survived to discharge n=175 (98.3%).

Maternal characteristics are presented in Table 1. Most of the mothers 125 (70.2%) who delivered neonates with SAH were primigravid. Fifty- five percent of mothers (98/178) had pregnancy complications, with prolonged second stage (75.5%) being the commonest complication. Seventy percent (125/178) of neonates were born vaginally, of these 74 (59.2%) had an assisted vaginal delivery with a vacuum device. Nine of the 41 (22%) neonates that were delivered via cesarean section had had failed a vacuum delivery.

Neonatal characteristics are presented in Table 2. The median gestational age was 39 weeks (IQR 38 – 40 weeks), with a male predominance (73.6%). Majority had a normal birth weight (84.3%), with 16 (9.0%) being large for gestational age (LGA). The median 5-minute Apgar score was 9 (IQR 8-10). Three neonates were admitted to the intensive care unit while 175 (98,3%) were admitted to the high care unit. The comorbidities of neonates diagnosed and admitted with SAH are presented in Figure 2. The most common comorbid diagnosis was jaundice 61 (34%) followed by hypoxic ischaemic encephalopathy (HIE) in 36 (20%) neonates, which was graded according to the modified Sarnat and Sarnat classification. [19]

Head Circumference Measurements

The diagnosis of SAH was made clinically, to assess severity serial measurements of head circumference were taken (Table 3). All 178 (100%) neonates had a head circumference measurement at birth. At 6 hours post-delivery, of the 168 (94%) neonates who had a head circumference measurement, a mean increase of 1cm (SD±2.7) was observed which was significant p=0.007. All 178 neonates in the study were treated with fresh frozen plasma (FFP) and vitamin K intravenously. Post management with FFP; the mean head circumference was 35.6 cm (SD± 1.4) showing a significant decrease (p=0.026). There were seventeen (9.5%) neonates who had an increase in head circumference and had a repeat dose of vitamin K and FFP.

Imaging

Thirty-one (17%) neonates had a cranial sonar. The reported abnormal findings were slit- like ventricles denoting cerebral oedema 15 (11.8%), increased brain echogenicity in 2 (1.1%) and periventricular leukomalacia (PVL) in 2 (1.1%) neonates.

Laboratory studies

Of the 152 (85%) neonates that had a full blood count (FBC) drawn the median haemoglobin was 16.1g/dL (IQR 14.5-17.4). The median white cell count (WCC) and platelets were 15.6 $X10^9$/L (IQR 12.2-18.7) and 199 $x10^9$/L (IQR 157-245) respectively. All the neonates had a serum bilirubin drawn within 24 hours with a median bilirubin of 232µmol/L (IQR190-290). The median international normalized ratio (INR) in 26 neonates (15%) was 1.0 (IQR 1.0-1.1). Table 4

Morbidity and outcomes

Three neonates with severe SAH and hypovolaemic shock required ventilation and inotropic support. Jaundice was diagnosed in 61 (65%) neonates and a third required phototherapy, no neonate had an exchange transfusion performed. Eleven of the twelve neonates diagnosed with anemia required a blood transfusion. Thirteen (7.3%) neonates had clinical seizures which were confirmed on amplitude electroencephalogram (aEEG), these neonates were treated with phenobarbitone and phenytoin.

The median length of stay was 3 (IQR 2-6) days. Neonates with jaundice had a longer length of stay. Three neonates demised giving a mortality of 1.7% and 175 (98,3%) of neonates were discharged home. Mortality was reported in neonates with lower APGAR scores and a diagnosis of HIE.

Discussion

This was a retrospective descriptive study at Chris Hani Baragwanath Academic Hospital (CHBAH) which reviewed 178 neonates with SAH, the largest cohort in the literature over a 2-year period. Our incidence of 3.5 per1000 live births was higher than that of previous studies[2,3]; this could be because CHBAH is a referral center for high-risk pregnancies but may also reflect long waiting periods for emergency caesarian sections due to the limitations

of a busy tertiary hospital in a low resourced environment. Maternal factors such as primigravidity, and prolonged second stage, were found to be risk factors for the development for SAH, this is similar to other studies.[20]

In this study, 41.6 % of neonates with SAH were delivered using a vacuum while a further 22.0% required a caesarean section after a failed vacuum attempt, in keeping with studies where vacuum delivery and the risk of developing SAH is as high as 210 per 1000 infants. [3] An increasing use of vacuum extraction to assist births has resulted in the increase of the prevalence of SAH in the high income countries (HIC) due to increased use of the forceps.[21] The authors postulate that the vacuum extractors are easier to apply and cause less maternal soft tissue trauma. [21] Our study found a relative male predominance of neonates with SAH in keeping with other studies. [4,17,20]

Monitoring of an at risk neonate at 1,6 and 24 hours in an intensive care setting was associated with the lowest mortality.[20] Colditz et al recommended that neonates at risk of SAH should be monitored at birth, 1 and 4 hours post-delivery and if hypotension or shock develops, then neonates are treated more aggressively with normal saline, packed red cell transfusions and intubation with inotropic support.[1]. In our setting, monitoring was at birth, 6 hours post treatment and prior to discharge. Head circumference measurements are used to estimate blood loss in neonates with SAH or risk factors for SAH. [3] All neonates with a diagnosis of SAH receive fresh frozen plasma as per our protocol and this was associated with a decrease in subsequent head circumference measurements.

Hypoxic ischemic encephalopathy (HIE) was the second most common co-morbid diagnosis in our study. HIE can be associated with haemodynamic instability, shock, DIC (disseminated intravascular coagulopathy) and parenchymal haemorrhage. In a study by Boo et al 15% of neonates with SAH had underlying birth asphyxia, and El-Dib et al reported 23% of neonates with SAH had neonatal encephalopathy. [10,13] Underlying HIE has been associated with poor outcome as is the case in this study where the 3 neonates that demised had lower Apgar scores and a diagnosis of HIE.[17]

Subaponeurotic hemorrhage is diagnosed clinically, imaging is rarely recommended to diagnose or classify SAH. [6] In the CHBAH study cranial sonar was indicated in the neonates with underlying comorbidities such as HIE, findings included, cerebral oedema and periventricular leukomalacia. Chang HY et al had similar ultrasound findings in 13 neonates. [4]

Coagulopathy has been reported to be associated with SAH. [2] Haemostatic disturbances have been documented in severe forms of SAH. [21] In the current study there was no evidence of a coagulopathy but the numbers were too small to attribute this as a causal effect of SAH.

Swanson et al only treated neonates with severe SAH, or underlying coagulopathy with FFP and vitamin K, in our setting all neonates with SAH were treated with FFP and vitamin K.[17] There are no randomized control trials in LMIC and HIC to compare expectant management to routine management with FFP and vitamin K administration in neonates with SAH. Monitoring in our setting can be challenging with staff to patient ratios that are suboptimal. The rationale for using FFP is the assumption that the neonate has a coagulopathy. Data to support routine use of FFP in all neonates with SAH is limited.

Mortality in neonates with SAH is associated with severe blood loss, anemia, hypovolemic shock and metabolic acidosis, with mortality as high as 15 %. [15,16] The mortality in the current study was 1.7 %, which was relatively low in comparison to some settings and may reflect our practice of treating all infants diagnosed with SAH with FFP. Neonates that demised during the study period had a similar profile as in other settings such as hypovolemic shock and underlying HIE.

Limitations

This is a retrospective study with missing data for some neonates as 20 files could not be retrieved. Monitoring of head circumference and documentation thereof was not consistently recorded in all neonates.

Conclusion

Symptomatic SAH is a rare neonatal emergency with potentially serious complications, leading to morbidity and mortality. SAH has a good prognosis provided there are no associated co-morbidities. To reduce mortality early identification of at-risk neonates and constant monitoring for potential complications is imperative. Aggressive management of shock is important to reduce mortality. Long-term follow up of neonates with SAH and comorbidities would be a future recommendation.

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Conflicts of Interest

The authors have no conflicts of interests.

Authorship

DNB, AvK, FLN conceptualized the study. DNB wrote the first draft. DNB, AvK and FLN reviewed and edited the manuscript. All authors approved the submission of the final manuscript.

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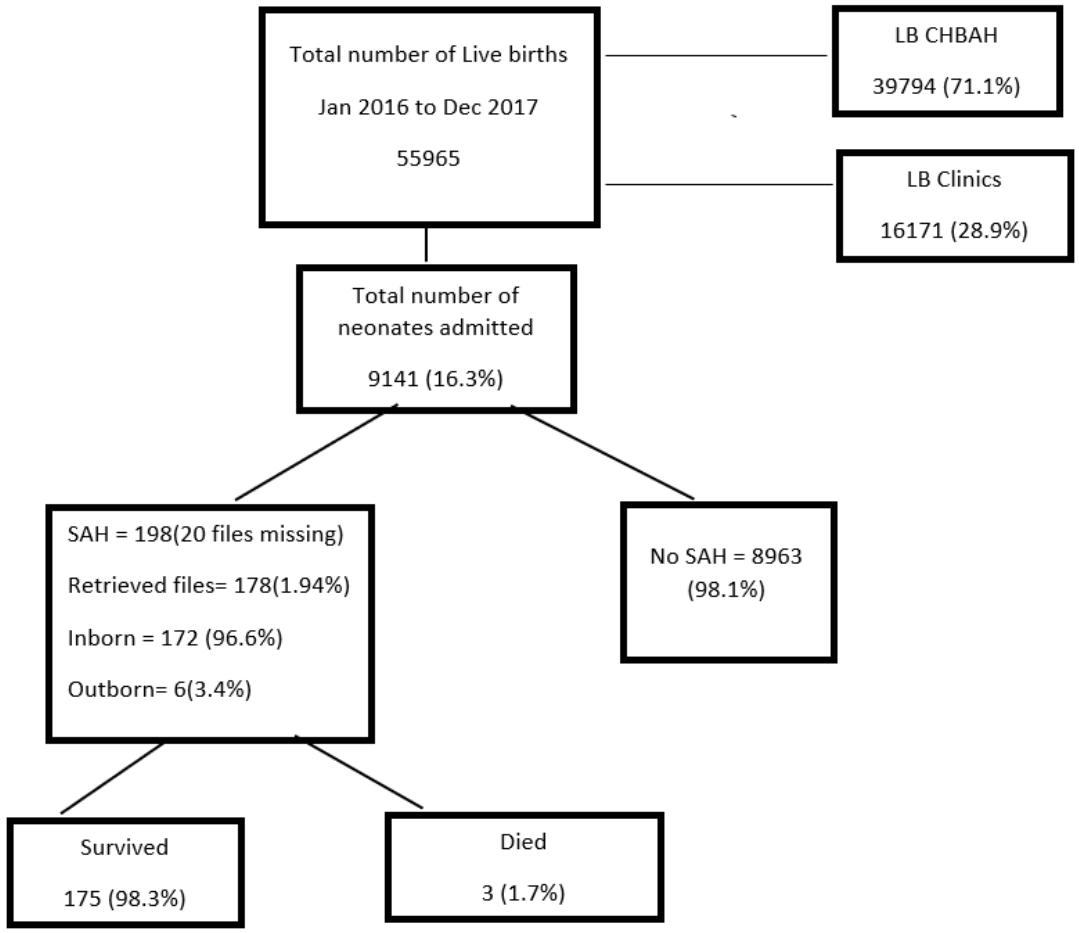

Figure 1: Flow Diagram of Neonates with SAH at CHBAH

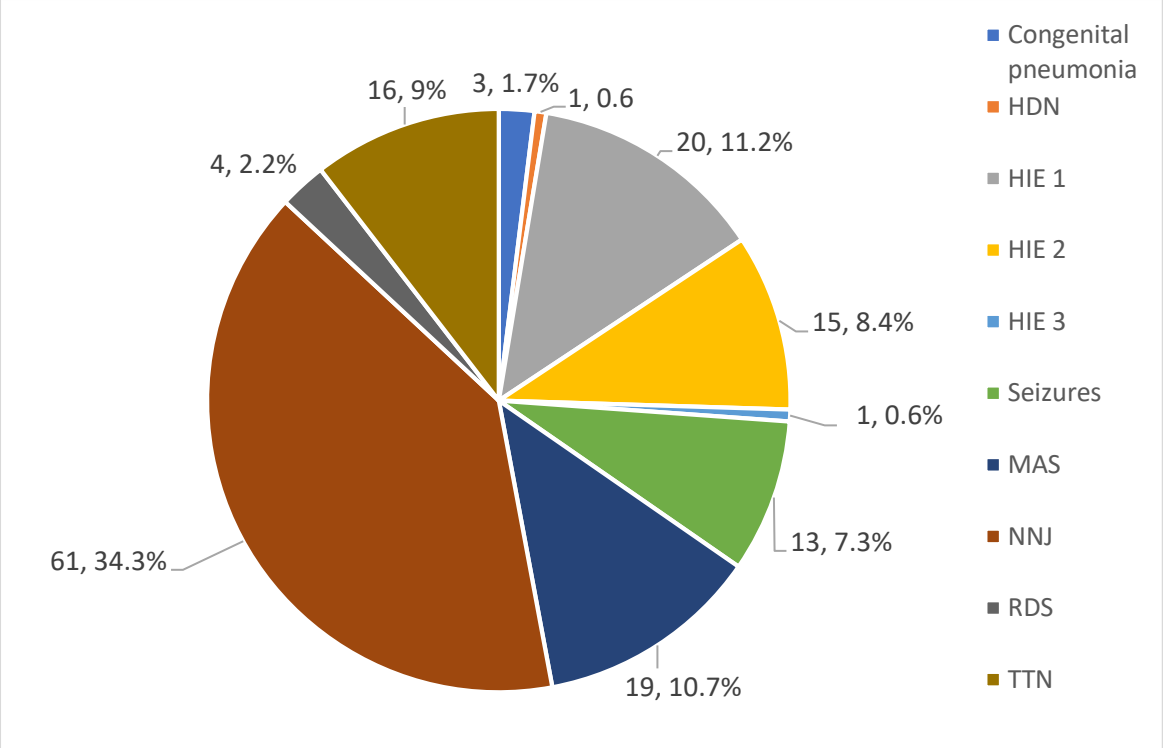

Figure 2: Co morbid Conditions of Neonates Admitted with SAH

HIE- Hypoxic Ischemic Encephalopathy, HDN- Haemorrhagic Disease of Newborn IDM -Infant of Diabetic Mom, LBW -Low Birth Weight, MAS - Meconium Aspiration Syndrome, NNJ -Neonatal Jaundice, RH neg- Rhesus Negative, RDS- Respiratory Distress Syndrome TTN- Transient Tachypnoea of Newborn

Table 1: Maternal Characteristics

Maternal Characteristics	**Number (%) n=178**
Parity	
Primigravidae	125 (70.2)
Multiparous	53 (29.8)
Pregnancy complications n=98	
Prolonged Second Stage	74 (75.5)
CPD	24 (24.5)
Mode of Delivery	
Spontaneous NVD	47 (26.4)
NVD assisted	
Vacuum	74 (41.6)
Forceps	4 (2.2)
Caesarian Section	41 (23.0)
Forceps	3 (1.7)
Failed vacuum	9 (5.1)

NVD normal vaginal delivery, CPD cephalopelvic disproportion

Table 2: Infant Characteristics

Infant Characteristics	Number (%)
Place of Birth	
Inborn	172 (96.6)
Outborn	6 (3.4)
Gestational age*	39 (38-40)
Birthweight	
<2500g	12 (6.7)
≥2500g – 4000g	150 (84.3)
>4000g	16 (9.0)
Apgar score <7*	
1 minute	7 (6-9)
5 minute	9 (8-10)
Gender	
Female	47 (26.4)
Male	131 (73.6)
Admission ward	
NICU	3 (1.7)
High Care	175 (98.3)
Complications	
Anaemia(<10g/dl)	12 (6.7)
NNJ requiring PTT	34 (19.1)
NNJ not requiring PTT	27 (15.1)
Hypovolemic shock	3 (1.7)
Seizures	13 (7.3)
Length of stay (days)*	3 (2-6)
Outcome	
Discharged	175 (98.3)
Died	3 (1.7)

*Median and interquartile ranges (IQR), NICU neonatal intensive care unit, PTT phototherapy, and NNJ neonatal jaundice

Table 3: Serial Head Circumference measurements at different time intervals

Time intervals of head circumference measurements	N (%)	Mean (SD) (cm)	p value
At birth	178 (100)	36 (±2.1)	
At 6 hours	168 (94)	37 (±2.7)	0.007
Post FFP	123 (69)	35.6 (±1.4)	0.026
At 24 hours	56 (31)	35 (±1.21)	0.039
At discharge	33 (19)	35 (±0.89)	

SD – Standard deviation, FFP – Fresh Frozen Plasma

Table 4: **Laboratory Results of Neonates admitted with SAH**

Variable	N (%)	Median (IQR)
White cell count $X10^9$/L	144 (81)	15.6 (12.2 – 18.7)
Haemoglobin (Hb) g/dl	152 (85)	16.1 (14.5 – 17.4)
Platelet $X10^9$/L	143 (80)	199 (157 - 245)
SBR µmol/l	178 (100)	232 (190 - 290)
INR	26 (15)	1.0 (1.0 – 1.1)

SBR – serum bilirubin, INR – international normalized ratio

APPENDICES

Appendix A Protocol

A CLINICAL PROFILE, MANAGEMENT AND OUTCOME OF INFANTS WITH A SUBAPONEUROTIC HAEMORRHAGE IN CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

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Outline

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STUDY TOPIC

A CLINICAL PROFILE, MANAGEMENT AND OUTCOME OF INFANTS WITH A SUBAPONEUROTIC HAEMORRHAGE IN CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

1. INTRODUCTION

Subgaleal haemorrhage is an uncommon but potentially lethal condition found in newborns. In 1819 Naegele was first to describe the lesion whilst differentiating true sub periosteal heamatoma from false heamatoma. Subgaleal haemorrhage is also known as subaponeurotic haemorrhage (SAH). [(1)] This condition can present as a spectrum from asymptomatic bleeding to a massive haemorrhage leading to hypovolemic shock. It is often underreported and may be misdiagnosed.[(2)] This condition can result in bleeding under the aponeurosis which if not recognized can compromise the affected neonate. SAH continues to be a concern to pediatricians and midwives because of the associated mortality and morbidity. Prompt recognition and appropriate management improves the outcome of the affected neonates.[(3)]

2. LITERATURE REVIEW

Subaponeurotic haemorrhage (SAH) occurs because of birth trauma due to the shearing forces on the scalp during delivery. This results in the accumulation of blood between the skull periosteum and galeal aponeurotica. [(4)] Anatomically the scalp is made of 5 layers' skin, connective tissue, galeal aponeurotica, loose connective tissue and periosteum. SAH occurs when the emissary veins in subgaleal space rupture. Rupturing of these veins can occur after twisting or torsion of scalp. This is then followed by blood accumulating between the epicranial aponeurosis and the periosteum. This potential space can hold up to 260mls of blood leading to volume depletion. A term neonates total blood volume is about 80mls/kg[(5)].

In a study by McQuivey it was suggested that the potential space of a newborn during a bleed can accommodate 50 to 80% of the blood volume which can be catastrophic. [(6)] The severity of a SAH was also assessed by looking at head circumference, jaundice as well as hypovolemia. These parameters were used to determine if the SAH was mild, moderate or severe.[(7)] Mild SAH is determined by increase of head circumference without jaundice or hypovolemia. On the other spectrum moderate is determine by increase of head circumference by at least 1-3cm with use of plasma expander. Severe SAH is characterized by increase in head circumference >3cm and use of blood and plasma expander this may also lead to one or more blood transfusion.

Due to the enclosed blood loss, this condition is probably underestimated, in a study by Chadwick the incidence was noted to be 0.2- 0.3 per live birth. [(2)] Another study by Reid quoted the incidence in the developing countries such as Africa as 0.8 per 1000 live births. Scotland a developed country had a higher incidence of 1.02 per 1000 live births this may reflect better methods of data collection.[(8)] The highest incidence of 3 per1000 births was noted by Cebremarium in Ethiopia [(9)]. The causes of SAH in this study was attributed to

difficult, traumatic deliveries and incorrect vacuum technique. In a public hospital in Cape Town studies showed an increase in SAH amongst the African (Black) population, related to traumatic deliveries especially in primigravida, as well as vacuum assisted vaginal deliveries. [10] The increase risk in the African population was also related to an increase incidence of haemorrhagic disease of newborns.[11] The incidence of SAH in spontaneous delivery were between 0.1 to 0.6 per 1000 vaginal deliveries [12-14]

The extraction of a neonate by ventouse was described first in 1705 by Dr Yonge. It continued gaining popularity by the 1950s following studies which were done in Sweden. By the 1970s it seems to have gained popularity compared to assisted forceps delivery in most European countries.[15] Over the years with an increased use of the vacuum as a mode of delivery it has been associated with an increased number of patients with SAH. Whilst it is more likely associated with instrument\or assisted deliveries it can also occur in spontaneous deliveries. [6] Other risk factors include macrosomia, prolonged second stage of labour, fetal distress, primigravida, prematurity, shoulder dystocia, precipitous labour and neonates with congenital coagulopathy. [5,8,16]

In a Malaysian study by Boo et al the incidence of SAH was higher in neonates with weight greater than 4000g [16] .The larger infants had increased force against the maternal pelvis which did increase the risk of vascular stretching associated with an SAH. [17] In primiparous women due to increase of heavy perennial muscle stretching on the scalp, can lead to tears in the emissary vein.[8] This muscle resistance is a factor for assisted deliveries such as vacuum mode of delivery in primigravida patients, is associated with prolonged second stage is associated with increase time of interstitial fluid accumulation which then had increased tissue vulnerability to injury in SAH. in the premature infants the risk was related to the factors leading to premature delivery.

In a study conducted in African neonates with SAH highlighted association of assisted delivery, weight greater than 3Kg, these infants had symptoms within 4 -48 hours of delivery and received a blood transfusion as part of their management .[11].

Vacuum use was noted to be as high as 60 to 89% in cases with SAH.[18] The risk with vacuum use was noted to be higher with in cases of failed vacuum, difficult extraction (repeated attempts) as well as the placement of the vacuum. [1] Failed vacuum occurs when there is failure to deliver a baby within at least 15- 30 minutes, this must be with the correct application of the vacuum with at least 2- 3 pop offs or 3 sets of pulls. Doronjski et al also described a case of a neonate with hemophilia A who developed SAH as a first presentation. Coagulopathy has been described in neonates with SAH. Male infants had increased risk of developing SAH as compared to females as males had an higher risk of developing bleeding disorders.[19]

An SAH presents with a boggy, fluctuant mass under the scalp an increased head circumference [13] . It crosses suture lines, extends to involve the anterior neck and the superior orbital ridges.[20] The diagnosis can be made within the first 4 – 6 hours of life. It is a progressive injury; the skin may change to bluish – blackish bruising which can be seen in the

occipital and frontal areas. For these reasons it has been recommended that neonates with a difficult vacuum should be monitored for at least 8 hours. [21]

Infants with increased risk factors need to be monitored for signs of hypovolemic shock such as tachycardia, tachypnoea, acidosis and hypotension. [16] [1] once diagnosis of SAH has been made Serial head circumference measurements at least (at birth , an hour later , 6 hours and after 24 hours) [19] blood pressure and ongoing monitoring. Investigations in an infant with SAH include full blood count (FBC) and platelet count bilirubin levels as well as coagulation studies form part of monitoring and investigations. [16]

Imaging is not indicated as a method of investigation, Ultrasound a simple method used however does not give any information regarding the nature of the fluid. In patients with severe disease, a Computerized tomography (CT) scans of the skull showed low density enhancement in the region around the head. It was also useful to detect other associated injuries such as skull fractures. CT did reveal amount of extra osseous bleeding and extent of damage in the intracranial structures.[22] MRI was a better method in neonates with SAH, it confirmed the nature of the subgaleal fluid in comparison to other imaging modalities.[23] Imaging was at times indicated in cases with other comorbidities such as intraventricular haemorrhage (IVH), subarachnoid haemorrhage , periventricular leukomalacia and subdural haemorrhage[4] which when missed can lead to the rapid decompensation of a newborn with an SAH. Imaging is indicated in neonates with other comorbidities.

Boo et al described complications in patients with an SAH 32.7% developed anaemia 9.1% developed severe haemorrhage and shock requiring blood transfusion. 56.4 % of these patients had unconjugated hyperbilirubinemia and of the neonates with hyperbilirubinemia 7% required an exchange transfusion.[19] Other complications described by Chang include seizures, impaired renal and liver function, and in severe cases disseminated intravascular coagulopathy(DIC) which is related to consumption of clotting factors. [13] Persistence of hypovolemic shock was mostly implicated in development of severe complications. A rare complication of infected SAH has been reported, this was seen in patients that had a traumatic scalp laceration [24]Lifelong complications include epilepsy, impaired auditory function and cerebral palsy. These are associated with comorbidities and or the complications associated with an SAH

There are no randomized control trials to compare management however the standard management recommended is the use of fresh frozen plasma (FFP) as well as Vitamin K. The transfusion of FFP has been regarded as a mode of treatment to correct DIC. [25] In cases where bleeding did not stop despite giving FFP, platelet transfusion was considered as a modality of treatment. Recombinant activated factor VII has been used to correct the coagulopathy in patients with increased risk of development of coagulopathy. Head wrapping has been suggested as a method of treatment. This is difficult to use [26] and contributes to an increased intracranial pressure. [27]

In other centers some neonates were managed in NICU, these included neonates with seizures, hypoxic ischemic encephalopathy (HIE) and respiratory distress. Patients with poor

outcomes were noted to have coagulopathy, impaired renal function, renal vein thrombosis and severe anaemia, hemoglobin less than 10g/dl. These patients were noted to have an increased length of hospital stay.[13]

A high index of suspicion needs to be maintained in patients with risk factors for SAH as well as treated to avoid morbidity and mortality. In a Taiwanese study with 41 neonates with SAH about 31% percent of patients had poor outcome, which included patients who (5,12,1%) died, (4,10%) had epilepsy, (1,2,4%) with renal vein thrombosis and (2,5%) had cerebral palsy. A delay in diagnosis, failure to recognize deterioration, and misdiagnosis have been noted to be contributing factors to mortality. Patients with the worst outcome required transfusion, ventilator support, NICU admission as well as prolonged hospital stay. Mortality attributed to volume loss, anaemia, coagulopathy and shock, multiple organ failure and severe encephalopathy was reported up to 22.8%.

In a previous study recorded mortality of about 11,8% out of 34 neonates with SAH, this was attributed to volume loss anaemia coagulopathy and shock. [28] intracranial haemorrhage, subarachnoid haemorrhage and skull fractures which are related to morbidities in neonates with SAH.[28] Monitoring of neonates after instrumental delivery has also been associated with increased earlier identification as well as appropriate treatment of this condition.[1]

In Chris Hani Baragwanath Academic Hospital (CHBAH) being one of the largest hospitals in Southern Africa. CHBAH is a tertiary/ quaternary center that accepts referrals from maternal obstetric units (MOUs), surrounding district and regional hospitals of mothers that require specialized care. There are 2 obstetric theatres with an average of 20000 deliveries a year. There are 4000 admissions to the neonatal unit with several term babies admitted. SAH is diagnosed in several term neonates admitted in the unit. This study will assist in quantifying the burden of neonates presenting with risk factors as well as management practices and outcomes of SAH in the neonatal unit. The study will also highlight the impact SAH has on mostly term neonates focusing on complications clinicians can avoid as well as treat promptly

3. AIM OF STUDY

To determine the clinical profile, management and outcomes of neonates admitted with SAH to the Chris Hani Baragwanath neonatal unit. Additionally, to explore the management strategies used in Chris Hani Baragwanath Academic Hospital and identify better ways to monitor these neonates to reduce mortality and morbidity.

4. STUDY OBJECTIVES

1. To describe the incidence of neonates with SAH in Chris Hani Baragwanath Academic Hospital
2. To describe demographics of neonates with subaponeurotic haemorrhage at Chris Hani Baragwanath Academic Hospital

3. To identify common risk factors in neonates with SAH such as instrumental delivery, prolonged second stage of labour, CPD etc.
4. To describe morbidity defined as anaemia, jaundice, exchange transfusions, shock and length of stay in neonatal unit
5. To describe treatment strategies of neonates admitted with SAH
6. To estimate number of newborns with SAH who developed complicated anaemia requiring transfusion as well as those with severe hypovolemic shock needing NICU admission
7. To describe outcomes of neonates in association to the identified risk factors

5. SAMPLE SIZE

The study will include all neonates admitted with SAH to the Chris Hani Baragwanath Academic Hospital neonatal unit between period of January 2016 to December 2017. An estimate of +/- 150 patients with SAH have been identified in the neonatal redcap data base system.

6. METHODS

This will be a descriptive retrospective cohort study. This study will include all babies with SAH admitted to the unit between January 2016 until December 2017.Patient information will be obtained from computerized neonatal database of neonates admitted to Chris Hani Baragwanath Academic Hospital Neonatal Unit. Redcap (research electronic data capture) system will be used to access data from Chris Hani Baragwanath academic Hospital database. The files of patients with an SAH will be retrieved and included to the study. The demographics of the patients will be collected as per data sheet (Appendix A)

7. DATA ANALYSIS

The statistics will be mainly descriptive. Data will be entered into an Excel spreadsheet. Thereafter, the data will be analyzed utilizing Statistica (version 14.0). Categorical variables will be reported as numbers and percentages. Continuous variables will be reported as means and standard deviations if not normally distributed, if not normally distributed the data will be represented as medians and interquartile ranges. Comparative statistics, student –t tests or Mann-Whitney U tests will be used for continuous variables and Chi squares and Fischer exact tests will be used for categorical values to compare groups 1) those who survived to the ones who demised 2) those with different treatment modalities e.g. treated with vitamin K and FFP to those treated with Vitamin K, FFP and blood transfusion 3) those who were ventilated compared to those who were not ventilated. A p value <0.05 will be considered as significant.

8. ETHICS

Consent will be obtained from the national department of health to obtain approval to conduct the study. Ethics approval will be requested from the Human Research Ethics committee from the University of Witwatersrand. The data obtained from the neonatal unit's files shall be handled with utmost security, will remain a product of the University of Witwatersrand as well as Chris Hani Baragwanath Academic Hospital (CHBAH). Patient identifiers will be kept separately from patient's demographics. The two data sources will be linked by a study number.

9. RISK AND BENEFITS

1. This study will serve to highlight the burden of SAH in our unit and assist in identifying knowledge to clinicians in the unit to be aware of the morbidity as well as mortality of neonates with SAH. The information obtained will assist in identifying infants with higher risk to complicate. No risk to any of the participants as most data will be obtained from Chris Hani Baragwanath Academic Hospital neonatal records.

746 10. TIMELINE:

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Year	2017			2017				2018				2019				
Activity	June	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept
Literature Review																
Preparation of protocol																
Submission to Ethics																
Submission of protocol																
Data collection																
Data analysis																
Write up of research report																

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Year	2019							2020-2021	2022				
Activity	June	Jul	Aug	Sep	Oct	Nov	Dec	Mar-Dec	Jan	Feb	Mar	Apr	May
Literature Review								Covid					
Preparation of protocol								Covid					
Submission to Ethics								Covid					
Submission of protocol								Covid					
Data collection								Covid					
Data analysis								Covid					
Write up of research report								Covid					

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11. FUNDING

The costs involved in the study will be borne by the researcher

12. LIMITATIONS

This will be a retrospective study and information is dependent on the practitioner attending patient and completing the medical records accurately.

13. REFERENCES

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Appendix B

DATA SHEET: SAH

1 Infant details

Study No _____

Place of birth 1 CHBAH 2 Clinic 3 Home 4 Other Hosp

Place of Admission: TICU/ NICU.

Gestational Age: _____Gender: M/F Birth Weight _____

APGARS: 1 min _____ 5 Min _____

Mode of delivery: NVD [] Forceps [] Vacuum [], Number of attempts____ C/section

2. Maternal

Primigravida: YES /NO

Prolonged second stage: YES /NO CPD: YES / NO

3. **MONITORING**

Head circumference: Increase _____ CM ____/Static_____ Decrease ___

Time of Head Circumference: birth ___ 6 hours_____, 24 Hours___

Head Circumference post treatment ____/Discharge____

4. Investigation

Bloods: FBC WCC___ HB___ Platelet_____ SBR: Total bilirubin YES/NO _____

INR/PTT_____

Urea and Electrolytes: NA __, K__, CL____, Urea ___, Creatinine___, HCO3____

IMAGING YES/NO

IMAGING: ultrasound YES/NO CT scan YES/NO MRI YES/NO

Findings of imaging _____

5. Management

Ventilated Yes / no Indication for ventilation_____

Vitamin K _____ FFP _____, No of infusions_____, Packed red cells _____

Platelet transfusion _____phototherapy _____ UREA AND ELECTROLYTES_____

6. Morbidity

Jaundice [] Anaemia [] Hypovolemic shock [] Hypotension [] Inotropes [] Neurological Impairment []

7. Diagnosis

HIE [] MAS [] IVH [] Intracranial bleeds []

7. Outcome

Discharged Home YES/NO

Died YES /NO

Appendix C Turn-It-In Report

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ORIGINALITY REPORT

10%	8%	11%	2%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	LM CHADWICK. "Neonatal subgaleal haematoma: Associated risk factors, complications and outcome", Journal of Paediatrics and Child Health, 6/1996 Publication	2%
2	Bmcpediatr.Biomedcentral.Com Internet Source	1%
3	sajch.org.za Internet Source	1%
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7	Mohamed El-Dib, Melanie P Parziale, Lise Johnson, Carol B. Benson et al. "Encephalopathy in neonates with subgaleal	1%

hemorrhage is a key predictor of outcome", Pediatric Research, 2019
Publication

8	www.seslhd.health.nsw.gov.au Internet Source	1 %
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Exclude bibliography	On		

Appendix D Ethics Clearance Certificate Approved Post Protocol Submission

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Dr ND Baloyi

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M180323

NAME: (Principal Investigator)	Dr ND Baloyi
DEPARTMENT:	School of Clinical Medicine Department of Paediatrics and Child Health Neonatal Unit Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	A clinical profile, management and outcome of neonates with a subaponuerotic haemorrhage in Chris Hani Baragwanath Academic Hospital Neonatal Unit
DATE CONSIDERED:	06/04/2018
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr F. Nakwa and Dr A. Van Kwawegen
APPROVED BY:	Professor CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	17/04/2018

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on 3rd floor, Philip V Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **March** and will therefore be due in the month of **March** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix E Application for Title Change

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

29 August 2022
Person No: 0601018E
TAA

Miss ND Baloyi
P O Box 8213
Elandsfontein
1406
South Africa

Dear Miss Nyiko Baloyi

Master of Medicine in Paediatrics: Change of title of research

I am pleased to inform you that the following change in the title of your Research Report for the degree of **Master of Medicine in Paediatrics** has been approved:

From:	**A clinical profile, management and outcome of infants with subaponeurotic haemorrhage in Chris Hani Baragwanath Academic Hospital**
To:	**A retrospective, descriptive study of neonates with subaponeurotic haemorrhage admitted in a public tertiary hospital in South Africa**

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix F: Ethics Clearance Certificate, Tittle Changed

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr ND Baloyi

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M180323

NAME: (Principal Investigator)	Dr ND Baloyi
DEPARTMENT:	School of Clinical Medicine Department of Paediatrics and Child Health Neonatal Unit Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	A retrospective, descriptive study of neonates with subaponeurotic haemorrhage admitted in a public tertiary hospital in South Africa
DATE CONSIDERED:	06/04/2018
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr F. Nakwa and Dr A. Van Kwawegen
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	17/04/2018 (Initial approval) ; 30/08/2022 (Change of title)

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Philip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **March** and will therefore be due in the month of **March** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES