PREVALENCE AND IMMEDIATE NEONATAL OUTCOMES OF INCIDENTAL NUCHAL CORD AT BIRTH AMONG PARTURIENTS WITH SINGLETON UNCOMPLICATED PREGNANCIES AT KENYATTA NATIONAL HOSPITAL IN 2018: A CROSS-SECTIONAL STUDY

A research dissertation in partial fulfillment of the degree in
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DECLARATION

I declare that this is an original write up. The relevant literature has been quoted for the parts where reference has been made from other sources. This is a product of my own work with guidance from my supervisors. It has not been presented in any other University for the award of a degree.

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ABBREVIATIONS

AAP	American Academy of Paediatrics
ACOG	American College of Obstetricians and Gynecologists
ANC	Antenatal Care
CS	Caesarean Section
FHR	Fetal Heart Rate
KDHS	Kenya Demographic and Health Survey
KNH	Kenyatta National Hospital
MAS	Meconium Aspiration Syndrome
MSL	Meconium Stained Liquor
NBU	Newborn Unit
NICU	Neonatal Intensive Care Unit
OVD	Operative Vaginal Delivery
SDG	Sustainable Development Goals
SVD	Spontaneous Vertex Delivery
UNICEF	United Nations International Children Emergency Fund
UON	University of Nairobi
WHO	World Health Organization

OPERATIONAL DEFINITIONS

This section provides definition of key terms used in this study. A nominal definition and relevant operational definition for each concept and how it was measured are provided.

Apgar score- This is a measure of physical condition of newborn. A total score is obtained by adding the scores in the five categories tabulated below.

Table 1: Apgar score

Parameters	**0 points**	**1 point**	**2 points**
Activity muscle tone	absent	Arms and legs flexed	Active movement
Pulse	absent	≤100BPM	>100bpm
Grimace (reflex irritability)	flaccid	Some flexion of extremity	Active motion (sneeze, cough, pull away)
Appearance (skin colour)	Blue, pale	Body pink, extremities blue	Completely pink
Respiration	absent	Slow, irregular	Vigorous cry

Birth weight has been categorized in this study as follows according to the Atlas of neonatology and WHO/UNICEF. (1,2)

Extremely low birth weight -less than 1000g

1. Very low birth weight – 1001 to1499g
2. Low birth weight -1500 to 2499g
3. Normal birth weight – 2500 to 4200g
4. Macrosomia- >4200g

Immediate neonatal period- In this study, the immediate neonatal period was considered as the first twenty-four hours of neonatal life.

Gestational age –This is a measure of length of pregnancy using the last normal menstrual period. A term pregnancy is one that has achieved gestational age of 37 weeks to 41 weeks and six days. In this study, it was categorized as early term, full term and late term according the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine. (3)

Table 2: Categories of term gestation

Gestational age	Length of gestation
Early term	37 0/7 weeks through 38 6/7 weeks
Full term	39 0/7 weeks through 40 6/7 weeks
Late term	41 0/7 weeks through 41 6/7 weeks

Adopted from 'Defining term pregnancy: recommendations from Defining "term" pregnancy workgroup. JAMA 2013

Meconium staining of liquor- This is amniotic fluid stained by fetal fecal matter. In this study, it was considered as grade 0 if amniotic fluid was clear or straw coloured; grade 1 if it was normal consistency of fluid in flow, translucent, but with yellow-green tinge in colour; grade 2 if it was opalescent with deep green and light yellow colour and grade 3 if the fluid was viscous, tenacious and contained large amount of yellow-green particulate material (opaque).

Neonatal period is the first 28 days of a newborn's life.

Neonatal resuscitation- This is the set of interventions that are used to assist the airway, breathing and circulation of a newborn.

Nuchal cord- This is the presence of a loop of the umbilical cord around the fetal neck spanning at least 360 degrees. For the purposes of this study, an incidental nuchal cord was considered as one that was first detected during delivery. A nuchal cord was considered as tight, in this study, if it could not be spontaneously unwound or had to be cut before delivery of the fetal trunk. Tightness was classified as follows.

1. loose (could be spontaneously unwound around fetal neck before delivery of the fetal trunk)
2. tight (had to be clamped and cut before delivery of the fetal trunk)

Parturient: A pregnant woman in labour.

Parity- This is the number of pregnancies reaching viable age (including live births and stillbirths). In this study, parity was considered as the number of previous deliveries. Previous ectopic pregnancies, abortions and stillbirths were not factored in. It was categorized as described by Sara Ellis et al in UpToDate(4): Nulliparity as parity of zero; low parity as parity between 2 and 4 and grand parity as parity above 5.

Spontaneous vertex delivery- This is delivery of the fetus in cephalic presentation, vaginally, without the aid of a vacuum, forceps or other instrument to aid in delivery.

Uncomplicated pregnancy- In this study, this was considered as a term pregnancy that was not complicated by maternal diseases, preterm labour, congenital malformations nor post-datism.

ABSTRACT

Background: A nuchal cord is a physiologic finding in 15 to 34% of pregnancies depending on gestation and geographical region. It is frequently blamed for adverse perinatal outcomes (perinatal asphyxia) in the absence of an obvious culprit. Studies done around it have shown conflicting findings in this regard.

Objectives: To determine the prevalence of incidental nuchal cord at birth and its association with adverse immediate neonatal outcomes among singleton uncomplicated pregnancies at the Kenyatta National Hospital (KNH), Nairobi, Kenya.

Methodology: This was a hospital-based cross-sectional study in KNH labour ward on 436 consecutively sampled women with uncomplicated term pregnancies. They were recruited in labour or just before Caesarean delivery. A brief questionnaire was administered and further data extracted from delivery records. Prevalence of incidental nuchal cord was obtained. Maternal and neonatal characteristics were summarized using proportions, percentages, means and standard deviation. Sub-group analysis was done for nuchal cord and no nuchal cord groups. Odd's ratios with 95% confidence intervals were used to determine association between nuchal cord presence and immediate neonatal outcomes. Chi-square statistic and Student T-test were used to determine level of significance for categorical and continuous data respectively.

Results: Nuchal cord prevalence was found to be 28.7%. Single and loose loops accounted for more than 80% of nuchal cord. There were no significant differences in maternal and neonatal characteristics between the nuchal cord and no nuchal cord groups. The odds of neonatal resuscitation was greater among the nuchal cord group than in the no nuchal cord group (OR=2.31, 95% CI=1.34-3.96, p=0.003).There was no significant association between presence of nuchal cord and other adverse neonatal outcomes (low Apgar score, meconium staining of liquor and NICU admission).

Conclusion: Neonatal resuscitation is commoner among neonates delivered with nuchal cord. There are no significant differences between the two groups in meconium staining of liquor, low Apgar score, NICU admission and neonatal mortality.

Recommendations: There should be anticipation and preparedness for neonatal resuscitation for neonates delivered with nuchal cord. However, presence of nuchal cord does not warrant need for Caesarean delivery.

Key words: *Nuchal cord, perinatal outcome, maternal, parturient*

1.0 INTRODUCTION

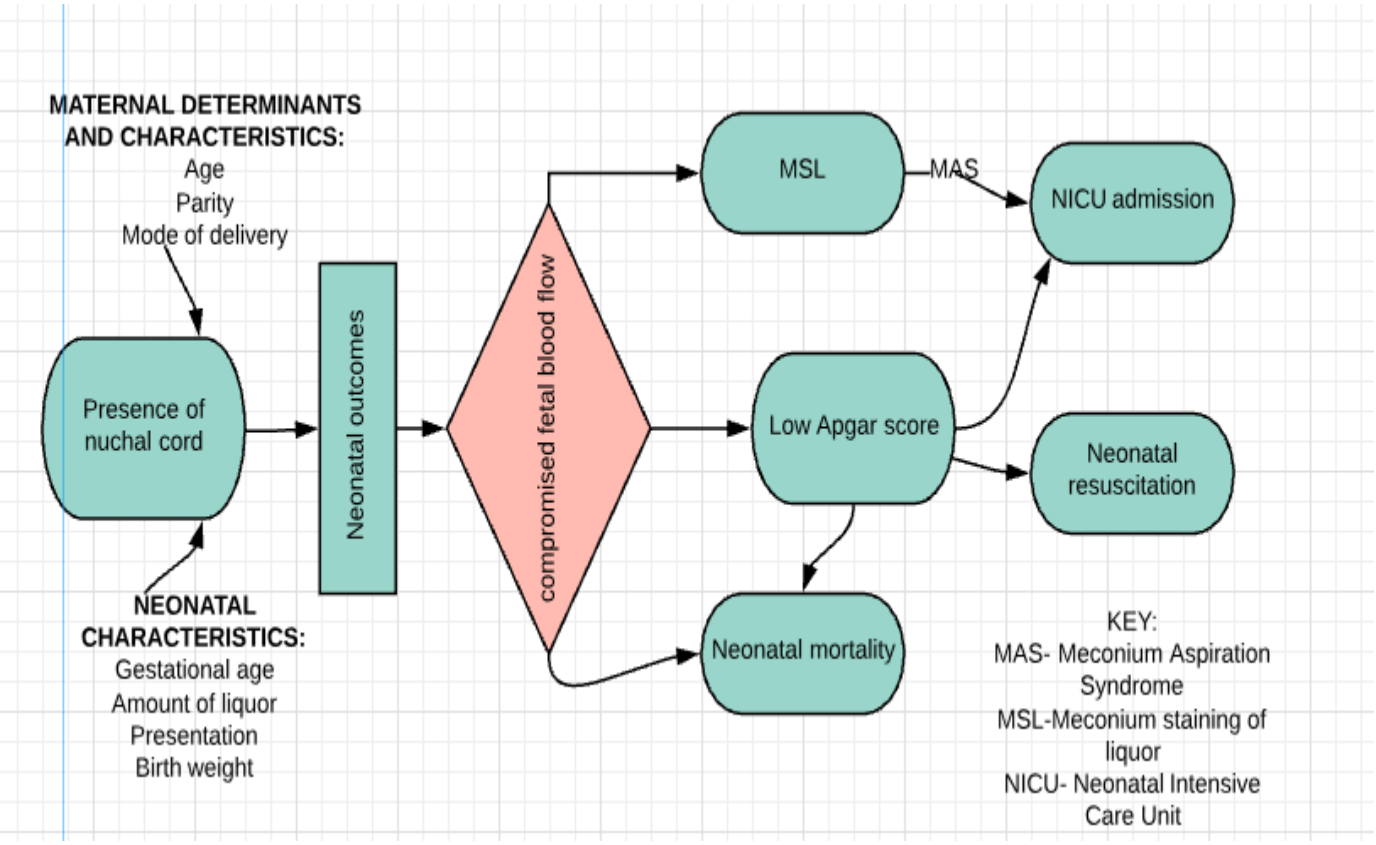
1.1 Background

The umbilical cord is the life line to the fetus whose occlusion can be detrimental. A nuchal cord is present when the umbilical cord encircles the fetal neck through 360 degrees or more. Long umbilical cord, weak cord structure, polyhydramnios and multiple gestation have been associated with increased risk of nuchal cord. There are two types of nuchal cord (Giacomello classification system). Type 1(a) can spontaneously unwind while type 2(b) cannot. It is a physiologic finding in 15 to 34%(5–8) of all pregnancies and has been associated with perinatal asphyxia. Mechanism of injury implicated is comparable to strangulation with occlusion of blood flow in the fetus leading to injuries ranging from petechial hemorrhages to hypoxic ischaemic encephalopathy and death. The occurrence increases with advancing gestational age ranging from 5.8% at 20 weeks to 29% at a gestation corresponding to 42 weeks.(9) Single nuchal cord accounts for 90% of such in the third trimester. There is limited regional data and no published local data on the prevalence of nuchal cord. If there is a nuchal cord at the onset of labor, it is very unlikely to correct itself. If there is no nuchal cord pre-labour, it is unlikely to occur during labour. In low resource settings with suboptimal fetal surveillance in labour, a nuchal cord could impact neonatal outcomes negatively compared to settings where fetal distress is easily diagnosed and promptly managed. Despite the improvement in sonographic detection prenatally(5,6,10), there is no consensus on association of nuchal cord with adverse perinatal outcomes and hence no established clinical best practices. Studies done in Uganda, India and Japan have showed association between tight nuchal cord and multiple loops (more than two) with adverse neonatal outcomes and need for operative or emergent caesarean delivery. Some studies have shown positive association between nuchal cord presence and adverse neonatal outcomes but not statistically significant and recommend delivery of such parturients in a comprehensive care unit with closer fetal monitoring. Other studies have shown no association of nuchal cord with adverse neonatal outcomes despite protraction of labour in the parturients. Most studies, however, show similar outcomes between pregnancies with nuchal cord and those without. Most radiographers opt out of reporting this finding due to both patient and caregiver anxiety partly accounting for its incidental finding. Those that are reported potentially increase the chances of operative delivery and urgent interventions.

1.2 Conceptual framework

Postulated mechanism of adverse neonatal outcome in neonates with nuchal cord at delivery is compromise of fetal blood flow before or during second stage of labour, aggravated by maternal uterine contractions. Fetal hypoxia due to compromised fetal blood flow leads to vagal collapse. Meconium passage is an indication of vagal collapse and may lead to meconium aspiration syndrome.

Figure 1: Conceptual framework



1.3 Study justification and utility

Nuchal cord is a birth event in up to 34 percent of deliveries and is mostly an incidental finding as shown in studies done worldwide. There is no published Kenyan study to quantify the burden despite the fact that most adverse perinatal outcomes among deliveries with nuchal cord are blamed on its presence in the event that there would be no other obvious cause. Studies show conflicting association between nuchal cord and adverse perinatal outcomes. Most of its association with poor outcomes is linked to perinatal birth asphyxia probably due to compromise of fetal circulation particularly during the second stage of labour.

A high prevalence of incidental nuchal cord and its proven association with poor perinatal outcomes would warrant need for establishment of protocol for antenatal detection and standardized intra-partum management of such parturients. This may include pre-labour assessment for nuchal cord and planned delivery in a comprehensive obstetric unit for close monitoring or elective delivery.

1.4 Research questions

1. What is the prevalence of incidental nuchal cord at birth at Kenyatta National Hospital among singleton uncomplicated pregnancies in 2018?
2. What are the characteristics of parturients and their neonates who are delivered with nuchal cord at KNH in 2018?
3. Is there an association between incidental nuchal cord at birth and adverse immediate neonatal outcomes at Kenyatta national Hospital (KNH) in 2018?

1.5 Null Hypothesis

There is no association between incidental nuchal cord at birth and adverse immediate neonatal outcomes at KNH.

1.6 Broad objective

To determine the prevalence and immediate neonatal outcomes of incidental nuchal cord at birth at Kenyatta National Hospital (KNH).

1.6.1 Specific objectives

1. To determine the prevalence of incidental nuchal cord at birth in singleton uncomplicated pregnancies at term among parturients at Kenyatta National Hospital (KNH) in 2018.
2. To determine the characteristics of parturients with singleton uncomplicated pregnancies and incidental nuchal cord at birth at KNH in 2018.
3. To determine the characteristics of neonates delivered with incidental nuchal cord at KNH
4. To determine the association between incidental nuchal cord and adverse immediate neonatal outcomes at KNH in 2018.

2.0 LITERATURE REVIEW

2.1 Regional perspective

2.1.1 Occurrence and patient characteristics

Nuchal cord has been found to complicate 16.2% to 55% of pregnancies in studies done in Africa. This is a higher figure compared to those quoted in studies done worldwide. Single loops have been found to be more common compared to multiple loops and patient characteristics found not to differ significantly between parturients with and without nuchal cord. A descriptive cross-sectional study done in Uganda in 2013 and 2014 found prevalence of nuchal cord of 55%. A single loop of cord was most frequent at 39%(8). A descriptive retrospective study done in Cameroon between 1992 and 2008 found nuchal cord incidence of 16.2%. The incidence of a single loop of nuchal cord was 14.18% while that of double and triple loops were 1.67% and 0.32% respectively. Of the total cases of nuchal cord, 75.81% were loose and 24.19% were tight. Mean maternal age and gestational age at delivery was similar in both deliveries with and without nuchal cord (approximate age of 30years, approximate gestational age of 39 weeks).(11)

2.1.2 Neonatal outcomes

There are conflicting findings on association between nuchal cord and adverse neonatal outcome in studies done regionally. The aforementioned descriptive cross-sectional study done in Uganda described higher rates of adverse neonatal outcomes among neonates delivered with nuchal cord than in those delivered without. All women admitted in labour at 28 weeks gestation and above with singleton fetuses in cephalic presentation and delivered during the study period vaginally or by caesarean delivery were included in the study. Documentation of presence or absence of cord around the neck was made at delivery. Neonatal resuscitation, meconium staining of liquor, Apgar score less than 7 at the fifth minute of life and NICU admission were greatest amongst neonates delivered with nuchal cord (33.2% versus 14.5%; 57.4% versus 29.1% and 4% versus 1.2% respectively). However, neonatal unit admissions were similar among those neonates delivered with a cord around the neck and those delivered without the cord around the neck (6.9% and 5.5% respectively). Cord around the neck, particularly tight cord irrespective of number of loops, was concluded to be associated with a low Apgar score at 1 and 5 minutes and increased meconium staining at birth, despite this having been a descriptive study. (8)

The aforementioned descriptive retrospective study done in Cameroon between 1992 and 2008 had conflicting findings. 9334 deliveries during the 16-year period with a gestation of 28 weeks and above were reviewed. Rates of low Apgar scores at the 1st and 5th minutes of life and transfer to neonatology unit were lower in the loose nuchal cord group than in the control group (no nuchal cord). Apgar scores < 7 at the 1st minute of life was significantly higher in the tight nuchal cord group than in the control group while that at the 5th minute was not significantly different between the two groups. This suggested good neonatal adaptation to tight nuchal cord. The rate of instrumental vaginal delivery was not significantly higher in the nuchal cord group than the control group. However, emergency caesarean delivery rate and transfer to NICU were higher among the parturients and their neonates delivered with no nuchal cord.(11)

2.2 Global perspective

2.2.1 Patient and healthcare provider perspectives on impact of nuchal cord

Zhao F. et al carried out a questionnaire survey in Hong Kong, China, between August and October 2012 to assess pregnant women's views on impact of nuchal cord on pregnancy outcomes. The study showed anxiety among women attending the facilities with a finding of nuchal cord. Approximately 87.5% of participants thought that nuchal cord would reduce the chance of successful vaginal delivery and 56.4% thought that it would increase the chance of assisted vaginal delivery. 68.8% thought that it was necessary to deliver the fetus early and 72.8% thought that caesarean section must be performed in the presence of nuchal cord. Many thought that nuchal cord would lead to adverse fetal outcomes, affect the mode of delivery, and require special management. It was concluded that misconceptions should be addressed and proper education of women was needed. (12) A retrospective study done in April 2016 in Lebanon on 44 cases of prenatally diagnosed nuchal cord showed that parental anxiety, despite normal findings during fetal monitoring, contributed to increased rates of caesarean delivery. (13)

2.2.2 Occurrence and patient characteristics

Most global studies have been done in Asia and India. Most studies have shown single nuchal cord loops to be commoner than multiple loops, higher incidence of nuchal cord among neonates to previously nulliparous women and no significant differences between groups with nuchal cord at birth and those without. A comparative cross-sectional study done in Lahore, Pakistan showed that the mean age of the women who delivered with nuchal cord was 24.03 years and those without was 23.97 years. The mean gestational age at delivery was 38.65 weeks and 38.79 weeks respectively.(14) In a retrospective study between 2009 and 2010 in India, 15.54% of all deliveries had nuchal cord. The incidence of a single coil of the umbilical cord around the neck was 81.67% and 86.67% of these were loose. There were no significant differences in the maternal age, race nor parity between the two groups. The mean age of the mothers in both groups was around 21 years and the majority were nulliparous (43%).(15) The incidence of nuchal cord was 19.76% in a cross-sectional study done in India. Most cases of nuchal cord were found to complicate pregnancies of women between 21 and 25 years of age in the same study.(16) A prospective comparative cross-sectional study in Kathmandu, Nepal in South Asia found a nuchal cord incidence of 22.85%. Incidence of single nuchal cord was highest (18.95%).(17) In a retrospective case-control study carried out in South Asia spanning a period between 2010 and 2011, the incidence of nuchal cord was 6.57% among preterm deliveries, 49.13% among term deliveries, 39.79% among postdated pregnancies and 4.5% among post-term pregnancies. The incidence of nuchal cord was not affected by caste, parity, gestational age, antenatal visit, neonatal intensive care unit admission and other perinatal complications. 62.98% parturients whose neonates were delivered with nuchal cord were previously nulliparous and 85.12% had vaginal delivery.(18) A retrospective study done between 2008 and 2011 in Warabi, Japan found that 39.85% neonates had nuchal cord. 58.7% of those with nuchal cord were nulliparous. There were no significant differences in maternal age, gestational age, birth weight, parity nor fetal sex between the group with nuchal cord and that without.(19)

Few studies have been published in Europe and the United States of America. A retrospective analysis of the effect of nuchal cord on term and post term pregnancies between 1995 and 2004 was carried out in Switzerland. The incidence of nuchal cord in term and post term deliveries was 33.7% and 35.1%, respectively. Multiple nuchal cord loops were present in 5.8% of term and 5.5% of post term deliveries.(20) A similar study was carried out between 2005 and 2010 in the western

part of the United States of America to compare the outcomes of neonates born with and those without nuchal cords. The group with a tight nuchal cord had slightly older gestational age, lower birth weight, preponderance of male fetuses, previously nulliparous women, singleton pregnancies and shoulder dystocia.(21) A retrospective case-control study done in Houston (Texas) between 2001 and 2002 showed that 17.51% of the neonates had nuchal cord. 89.16% of those with nuchal cord had a single loop while 10.84% had more than one nuchal cord loop. (22)

2.2.3 Neonatal outcomes

Conflicting findings on effect of nuchal cord on perinatal outcomes have been deduced in studies done globally. In the comparative cross-sectional study done in Lahore mentioned above, patients in the third trimester of pregnancy were investigated for presence of nuchal cord by Doppler sonography and outcomes of interest were noted. This study suggested that presence of nuchal cord does not affect neonatal outcome in the form of Apgar score and NICU admission despite higher rates of caesarean delivery (26.7% versus23.4%) and greater incidence of grade 1 and grade 2 meconium staining of liquor among the nuchal cord group.(14) In a retrospective case-control study of term neonates done in Houston (Texas), control group comprised neonates delivered with no nuchal cord and cases comprised the group delivered with nuchal cord. There were no significant differences in the mean birth weight, the frequency of non-reassuring fetal heart rate patterns, operative vaginal deliveries, nor 5-minute Apgar scores of < 7 between the nuchal cord and no nuchal cord groups. The cesarean delivery rate was the highest among the group of women whose fetuses had no nuchal cord. A nuchal cord at term was therefore not associated with untoward pregnancy outcomes.(22) Similar conclusions have been arrived at in most studies conducted in other parts of India, Switzerland and USA .(17,20,21,23,24)

Some studies have shown association between nuchal cord and poor outcomes. In a retrospective case-control study carried out in South Asia between 2010 and 2011, labour registry was reviewed in Kathmandu University Hospital for all deliveries including preterm and post-term deliveries. Caesarean section had to be done in 10.38% of the women with fetuses with nuchal cord. 2.8% of the neonates who had nuchal cord required neonatal intensive care unit admission for prematurity. It was concluded that confirmation of presence of nuchal cord was crucial in suspected pregnancies from non-engagement of fetal head, decreased fetal movement and fetal distress with management in a comprehensive obstetric care facility in case of need of emergent delivery after close monitoring with cardio-tocography.(18) A retrospective study was carried out between 2008 and

2011 in Warabi, Japan, to evaluate effect of nuchal cord on perinatal complications. There was a higher risk of non-reassuring fetal heart rate patterns, instrumental delivery, caesarean delivery and severe meconium in amniotic fluid in the nuchal cord group compared to the group with no nuchal cord. There was no significant increase in the risk of Apgar score of <7 points at 1 minute nor 5 minutes, nor need for neonatologist care in the nuchal cord group. Despite the wide confidence interval for odds of caesarean section ranging from almost no difference in risk to almost two and a half times risk, the substantial risk of non-reassuring fetal patterns was notably significant enough. In conclusion, nuchal cord was associated with perinatal complications and antenatal evaluation for its presence was ruled as important.(19) A population-based case-control study was carried out in Washington (United States of America) between 1992 and 1993 to assess the risk factors and outcomes associated with nuchal cord. Increased risk of nuchal cord was associated with induction of labor. After exclusion of selected obstetric complications, the risk of nuchal cord associated with induction of labor increased. Nuchal cord was associated with increased risks of fetal distress, meconium staining, five-minute Apgar score < 7 and assisted ventilation.(25) Similar conclusions were arrived at in studies done in Khozhikode (India), Greece and Ontario (Canada).(26–28)

Other studies showed that only tight nuchal loops were associated with poor neonatal outcomes. A retrospective study was carried out between 2009 and 2010 in India to study the effect of nuchal cord on mode of delivery and fetal outcome. It showed that fetal distress was higher among the nuchal cord group (13.3% versus 12.3%). Analysis of the two subgroups with tight nuchal cord and loose nuchal cord showed statistically significant higher vacuum delivery rates, meconium stained liquor, fetal distress and low Apgar scores at the first minute of life in tight nuchal cord group. It was concluded that nuchal cord did not increase the chances of cesarean delivery despite the fact that tight cord around the neck may have resulted in low Apgar scores and increased incidence of fetal distress leading to cesarean section.(15) A comparative cross-sectional study done in India had similar findings.(16)

2.2.4 Pathogenesis, diagnosis and management

In a study done in Jerusalem, Israel it was concluded that poor outcomes in fetuses with cord accidents, reduced fetal movements and changes in fetal heart rate were due to a diminished blood flow in the cord vessels as a result of gradual cord compression. In three of 1,094 cases of cord complications the mothers experienced reduction of fetal movements until cessation. In these three instances the fetal heart beat was audible but changes appeared on the fetal heart rate monitor. The course of loss of fetal movements resembled that seen in cases of placental insufficiency.(29)

Variable decelerations on cardio-tocography has been shown to be suggestive of nuchal cord. Ultrasonography has been shown to be the gold standard in diagnosis of nuchal cord when combined with colour Doppler imaging with greatest sensitivity after 36 weeks gestation (93% vs. 67%). A "divot" sign is diagnostic on high-resolution ultrasound.(30) Prenatally, nuchal cord can be diagnosed clinically by a test that involves trans-abdominal manual compression of the fetal neck. If compression of fetal neck elicits fetal heart rate decelerations (FHR), the test is considered positive. Studies have shown that this noninvasive test has sensitivity of 82.3% and specificity 89.1%.(31) Vibro-acoustic stimulation (electronic artificial larynx) at particular frequencies of vibrations seem to elicit fetal heart rate decelerations. Vibro-acoustic stimulation used during second stage of labor has been shown to elicit acceleration followed by decelerations when a nuchal cord is present.(32) Nuchal cord may be suspected prior to delivery when there is 'shouldering' or 'double variable' or 'W pattern' on cardiotocography.(5)

There are no universal guidelines on management of nuchal cord. The approach depends upon fetal status, number of involved nuchal loops, the amniotic fluid index, the gestational age, and the fetal growth, among other factors. Some obstetricians opt to deliver early when multiple nuchal cord loops are noted on fetal scans. Presence of variable decelerations during fetal heart rate monitoring is indicative of possible presence of nuchal cord. Intra-partum management includes avoiding early cord clamping, bringing the loose loop of over the fetus' head and proceeding with normal delivery. A nuchal cord may not impede the descent and delivery of the body and indeed rarely does. When the cord is short and tight, or there are several loops around the neck, further descent of the body after delivery of the fetal head and before the trunk may be limited and another approach may be necessary. Cutting the umbilical cord before delivery of the trunk is an intervention that has been associated with hypovolemia, anemia, shock, hypoxic-ischemic

encephalopathy, and cerebral palsy.(33,34) Somersault maneuver followed by delayed cord clamping for management of nuchal cord at birth has been recommended.(32,33)

3.0 STUDY METHODOLOGY

3.1 Study design

A cross-sectional study was carried out to achieve the objective.

3.2 Study setting and population

The study was carried out at Kenyatta National Hospital, a referral and teaching hospital affiliated to the University of Nairobi. It is located in Nairobi County, the capital city of Kenya. Approximately 10,000 deliveries are conducted in the hospital's labour ward annually. The hospital offers comprehensive obstetrical care with 50 consultant obstetricians and a fully-fledged newborn unit and neonatal intensive care unit. The study population was drawn from parturients (and their neonates) who fulfilled the eligibility criteria. All neonates to these parturients were studied for outcomes of interest.

3.3 Eligibility criteria

3.3.1 Inclusion criteria.

Study participants fulfilled the requirements below.

1. Pregnant woman at a point in labour at which cervical dilation does not exceed 6cm or one who is due for Caesarean delivery
2. Pregnant woman who had a singleton pregnancy with fetus in cephalic presentation having completed a full-term gestational age (37 to 41weeks plus 6 days)
3. Neonate delivered by a woman who fulfilled the eligibility criteria

3.3.2 Exclusion criteria. Any pregnancy that was complicated by the following condition was excluded due to potential for serving as confounders to the outcomes of interest.

1. Maternal diabetes, hypertension, preeclampsia
2. Antepartum hemorrhage
3. Fetal mal-presentation
4. Multiple gestation
5. Congenital malformations
6. Anaemia in pregnancy
7. Any hematological conditions
8. Chorioamnionitis
9. Malaria

3.4 Sample size

Sample size was calculated using the Statcalc Epi info app Fleiss formula. Various assumptions were used to calculate the sample size to ensure that the study was powered to detect difference in Apgar score at the first, fifth, tenth minute of neonatal life, meconium staining of liquor, neonatal resuscitation and neonatal mortality between the group with and that without nuchal cord. Table 4 below shows the different sample sizes powered for the outcomes. The main outcomes of interest were Apgar score at the 1st minute of life and immediate neonatal resuscitation. This sample size was also powered to detect difference in meconium staining of liquor.

The assumptions were as follows:

Two-sided confidence level (1-alpha) = 95

Power (1-Beta, percentage chance of detecting) =80

Ratio of unexposed to exposed =1

Percent of unexposed with outcome from Ugandan study(8)=9.1

Percent of exposed with outcome from Ugandan study(8) =18

Odds ratio =2.2

With the following assumptions, using a similar study done in Uganda(8), the sample size was **436** as shown in table 3 below. The Apgar score was less than 7 in 18.3% of the neonates delivered with nuchal cord, and 9.1 percent in the unexposed group. 15% of neonates delivered without nuchal cord required neonatal resuscitation compared with 33% of those delivered with a cord.

Table 3: Sample size calculation

Start | Enter | Results | Examples | Help

Sample Size:X-Sectional, Cohort, & Randomized Clinical Trials

Two-sided significance level(1-alpha):	95
Power(1-beta, % chance of detecting):	80
Ratio of sample size, Unexposed/Exposed:	1
Percent of Unexposed with Outcome:	9.1
Percent of Exposed with Outcome:	18
Odds Ratio:	2.2
Risk/Prevalence Ratio:	2
Risk/Prevalence difference:	9.2

	Kelsey	Fleiss	Fleiss with CC
Sample Size - Exposed	219	218	239
Sample Size-Nonexposed	219	218	239
Total sample size:	438	436	478

References

Kelsey et al., Methods in Observational Epidemiology 2nd Edition, Table 12-15
Fleiss, Statistical Methods for Rates and Proportions, formulas 3.18 &3.19
CC = continuity correction
Results are rounded up to the nearest integer.
Print from the browser menu or select, copy, and paste to other programs.

Results from OpenEpi, Version 3, open source calculator--SSCohort
Print from the browser with ctrl-P
or select text to copy and paste to other programs.

Sample size was powered for different outcomes as shown below from the Ugandan study (MSL, neonatal resuscitation and Apgar score) and a western study (NICU admission) (21):

Table 4: Sample sizes powered for different neonatal outcomes

	unexposed with outcome (Percent)	**exposed with outcome (Percent)**	**Sample size (Kelsy)**	**Sample size (Fleiss)**
MSL	29.1	57.4	98	96
Neonatal resuscitation	15	33	178	176
Apgar score<7 at 1 minute	9.1	18.3	438	436
Apgar score<7 at 5 minutes	1.2	4	1016	1014
NICU admission	5.9	6.6	35,902	35,900

3.5 Sources of data

Sources of data comprised interview of parturients, antenatal clinic attendance books, maternal files and neonatal records.

Data collection tools were as follows

1. Eligibility criteria checklist
2. Interview form
3. Data extraction form

3.6 Sampling method, participant recruitment and data collection procedure

The research team comprised the principal investigator and two research assistants (one clinical officer and one midwife). Consecutive sampling was used to recruit the study participants from the labour ward triage room, and the rooms assigned for first stage of labour. The eligibility criteria checklist was ticked against and a written consent obtained from those who satisfied the criteria. Information that was entered into the eligibility criteria checklist was obtained from the maternal

records. Those who declined to participate in the study were replaced by the consecutive parturient. A brief interview on socio-demographic and obstetric characteristics was administered to those who consented to participate (see annex 2). The files of the recruited participants were marked by blue stickers and unique patient identifier which matched that on the interview form and data extraction form, in a four-digit numerical form for ease of traceability of records and anonymity after data extraction. The study participants were thereafter attended to as usual by the primary healthcare caregivers. Posters were put up in the labour ward delivery rooms and maternity theatre as a reminder to the primary medical caregivers for proper documentation of variables of interest and as a guide for assessment of nuchal cord tightness, meconium staining of liquor and Apgar scoring. Information was extracted from the maternal and delivery records into the data extraction form after the woman delivered. A ward visit was made on every following day after delivery to inquire on neonatal status after 24 hours from the parturients.

3.7 Data variables

The primary independent variable was presence of nuchal cord, number and tightness of loops of cord at the time of delivery. Dependent variables comprised maternal socioeconomic status; age; parity; antenatal clinic attendance; onset of labour; mode of delivery, diagnosis leading to caesarean delivery, neonatal sex, birth weight, gestational age, meconium staining of liquor; neonatal Apgar score at the 1st, 5th and 10th minute of life; need for neonatal resuscitation; NICU admission and neonatal mortality.

3.8 Data management and analysis

3.8.1 Data management. Data was received in hard copies, as filled in questionnaires and data extraction form. Verification was done by the principal investigator on a daily basis. The data extraction forms had unique identifier codes. This data was transferred into an excel spreadsheet. Data analysis was done using SPSS analytical package version 22. Summary maternal and neonatal characteristics was done using proportions, percentages, means and standard deviation. Sub-group analysis was done for nuchal cord and no nuchal cord groups using logistic regression. Odd's ratios with 95% confidence intervals were used to determine association between nuchal cord presence and immediate neonatal complications. Chi-square statistic and Student T-test were used to determine level of significance for categorical and continuous data respectively.

3.9 Ethical consideration

Ethical approval and permission to conduct the study in KNH was obtained from the Ethical research committee, University of Nairobi and Kenyatta National Hospital (KNH/UON ERC protocol number: P486/07/2018 and Reproductive health registration number: 249/2018). Written consent was obtained from the parturients who fulfilled the eligibility criteria. The study objectives were explained to the parturients and both advantageous and detrimental effects made clear. The data extraction forms had unique identifier numbers for anonymity. The lack of prior knowledge on presence or absence of nuchal cord by the principal investigator and assistants limited mismanagement by virtue of withholding information.

3.10 Study limitations

The likelihood of improper grading of meconium staining of liquor and incorrect Apgar scoring was circumvented by attaching posters in the labour ward as guidance for the healthcare providers.

4.0 RESULTS

This was a cross-sectional study in which a total of 681 parturients in the month of October and November 2018 were assessed for eligibility for the study. 245 parturients were excluded as shown in Figure 2 below.

Figure 2:Flow chart of inclusion of patients in the study

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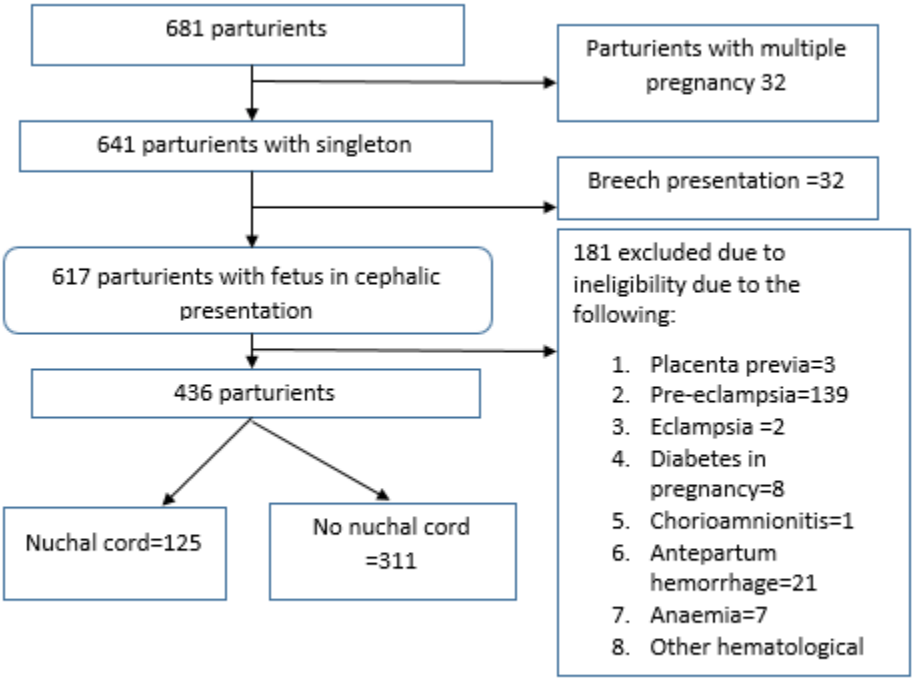

Prevalence of nuchal cord among term uncomplicated pregnancies at Kenyatta National Hospital, Nairobi, Kenya was found to be 28.7% (95%CI 24.5-33.2%). Single nuchal cord loops accounted for 93% of all loops while multiple loops accounted for 7% of all loops. 87% of nuchal cord loops were loose and 13% were tight.

Table 5 below illustrates the maternal characteristics of parturients who delivered neonates with and without nuchal cord. Most parturients had attended secondary level of education. This was the only statistically significant finding. 63.7% of the no nuchal cord group parturients were previously of low parity and 58.4 % of those who delivered with an incidental nuchal cord were of a similar category. 84.2% and 87.2% of the no nuchal cord and nuchal cord group parturients had attended four to seven antenatal clinics, respectively. More than 55% of parturients in each group had a sonogram performed at or after a gestation corresponding with 20 weeks. The differences in all the latter characteristics between the groups were however not statistically significant.

Table 5 : Characteristics of parturients who delivered neonates with and without incidental nuchal cord

	NO NUCHAL CORD N (%)	NUCHAL CORD N (%)	P- VALUE
MEAN AGE (YEARS)	28.1 (SD 5.5)	27.1 (SD 4.9)	0.12
EDUCATION LEVEL			
PRIMARY LEVEL	24(7.7)	2(1.6)	
SECONDARY LEVEL	204(65.6)	82(65.6)	0.035
TERTIARY LEVEL	83(26.7)	41(32.8)	0.019
PARITY			
NULLIPARITY	111(35.7)	51(40.8)	
LOW MULTIPARITY	198(63.7)	73(58.4)	0.312
GRAND PARITY	2(0.6)	1(0.8)	0.945
ANC ATTENDANCE			
NONE	3(1.0)	1(0.8)	0.951
<4	39(12.5)	14(11.2)	
4-7	262(84.2)	109(87.2)	0.657
≥8	7(2.3)	1(0.8)	0.408
SONOGRAM AT OR AFTER 20 WEEKS			
YES	183(58.8)	80(64.0)	
NO	128(41.2)	45(36.0)	0.32
MODE OF DELIVERY			
SVD	201(64.6)	103(82.4)	
OVD	2(0.6)	0(0.0)	NA
ELECTIVE CAESEREAN SECTION	98(31.5)	19(15.2)	<0.001
EMERGENCY CAESEREAN SECTION	10(3.2)	3(2.4)	0.424
ONSET OF LABOUR AMONG SVD			
INDUCED	14(4.5)	8(6.4)	
SPONTANEOUS	189(60.8)	95(76.0)	0.781

As illustrated in table 5 above, elective Caesarean section was significantly commoner among the group with no nuchal cord than among the nuchal cord group (31.5%, 15.2%, $p<0.001$). Spontaneous vertex delivery was commonest mode of delivery in both groups (64.6% and 82.4% respectively). Table 6 and Figure 3 below illustrate that SVD was the commonest mode of delivery generally (70%) and in both groups.

Induction of labour was commoner among the nuchal cord group. Emergency Caesarean delivery rates were higher among the no nuchal cord group. This was however statistically insignificant. The most common indication for emergency CS delivery among the nuchal cord group was

previous uterine scar followed thirdly by fetal distress. All the aforementioned findings were, however, not statistically significant.

Table 6: Overall rates of each mode of delivery in Kenyatta National Hospital

MODE OF DELIVERY	N=425	PERCENTAGE
SVD	304	70
EMERGENCY CS	117	27
ELECTIVE CS	13	13
OPERATIVE VAGINAL DELIVERY	2	0

Figure 3: Bar graph: Mode of delivery in the nuchal cord and no nuchal cord groups

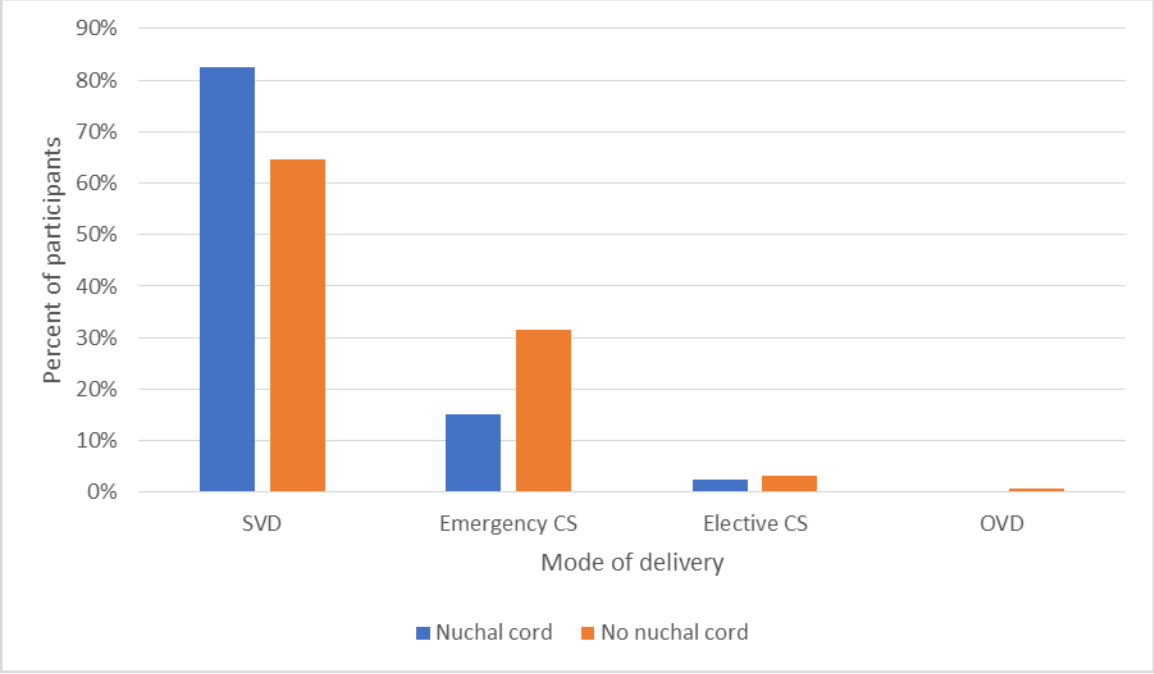

Table 7: Characteristics of neonates delivered with and without incidental nuchal cord at Kenyatta National Hospital

	NO NUCHAL CORD n (%)	NUCHAL CORD n (%)	p- value
GESTATIONAL AGE			
EARLY TERM	99(31.8)	38(30.4)	
FULL TERM	183(58.8)	70(56.0)	0.988
LATE TERM	29(9.3)	17(13.6)	0.24
BIRTH WEIGHT			
NORMAL (2500-4200G)	300(96.5)	120(96.0)	
LOW (<2500G)	9(2.9)	4(3.2)	0.863
>4200G	2(0.6)	1(0.8)	0.856
NEONATAL SEX			
MALE	140(45.0)	59(47.2)	
FEMALE	171(55.0)	66(52.8)	0.679

Table 7 above illustrates that there were no statistically significant differences in neonatal characteristics between the two groups in terms of gestational age, weight and sex. Nonetheless, for both groups, most neonates achieved full term gestational age with normal birth weights. Low birth weight neonates (3.2%) and neonates delivered at a later gestation (13.6%) were commoner among the nuchal cord group. This was however not statistically significant.

Table 8: Association between nuchal cord and immediate neonatal outcome

	NO NUCHAL CORD n (%)	NUCHAL CORD n (%)	OR (95% CI)	P-VALUE
APGAR SCORE AT 1 MINUTE				
<7	5 (1.6)	3 (2.4)	1	
≥7	306 (98.4)	122(97.6)	1.5 (0.35-6.39)	0.58
APGAR SCORE AT 5 MINUTES				
<7	1(0.3)	2(1.6)	1	
≥7	310 (99.7)	123 (98.4)	5.04 (0.45-56.10)	0.188
APGAR SCORE AT 10 MINUTES				
<7	1(0.3)	2(1.6)	1	
≥7	310 (99.7)	123(98.4)	5.04 (0.45-56.10)	0.188
MSL GRADE				
≥1	84(27)	32 (25.6)	1	
0	227(73)	93(74.4)	0.93(0.58-1.49)	0.002
NEONATAL RESUSCITATION				
YES	36 (11.6)	29(23.2)	1	
NO	275 (88.4)	96(76.8)	2.31(1.34-3.96)	0.003
NICU ADMISSION				
YES	6(1.9)	2(1.6)	1	
NO	305 (98.1)	123(98.4)	0.75(0.14-3.74)	0.721
MORTALITY				
ALIVE	309 (99.4)	123 (98.4)	1	
DEAD	2(0.6)	2(1.6)	2.51(0.35-18.03)	0.36

Table 8 above illustrates the association between nuchal cord and immediate neonatal outcomes. There was no significant association between nuchal cord presence and Apgar score of less than 7 at the first, fifth and tenth minutes of neonatal life; meconium staining of liquor; NICU admission and neonatal mortality. The odds of neonatal resuscitation was 2.31 times greater among the nuchal cord group than their counterparts (OR=2.31, 95%CI=1.34-3.96, p=0.003). When this was adjusted for maternal and neonatal characteristics, the association remained significantly positive (OR=2.81, 95%CI=1.49-5.29, p<0.001).This study was however not powered to detect significant differences between the two groups in Apgar score at 5 and 10 minutes of neonatal life, NICU admission and neonatal mortality.

Table 9: Number of nuchal cord loops and immediate neonatal outcome

	SINGLE LOOP n (%)	MULTIPLE LOOPS n (%)
MSL GRADE		
≥1	33 (28.4)	0(0.0)
0	83 (71.6)	9(100)
APGAR SCORE AT 1 MINUTE		
<7	1(0.9)	2(22.2)
≥7	115(99.1)	7(77.8)
APGAR SCORE AT 5 MINUTES		
<7	0(0)	2(22.2)
≥7	116 (100)	7(77.8)
APGAR SCORE AT 10 MINUTES		
<7	0(0)	2(22.2)
≥7	116(100)	7(77.8)
NEONATAL RESCUSCITATION		
YES	27(23.3)	2(22.2)
NO	89 (76.7)	7(77.8)
NICU ADMISSION		
YES	2(1.7)	0(0)
NO	114(98.3)	9(100)
IMMEDIATE NEONATAL MORTALITY		
ALIVE	116(100)	7(77.8)
DEAD	0(0)	2(22.2)

Table 9 above illustrates the findings among the nuchal cord group with regards to number of nuchal loops. Apgar score <7 at the first, fifth and tenth minutes of neonatal life were commoner among the group with nuchal cord that had multiple loops than the single loop group (22.2% versus 0.9%; 22.2% versus 0% and 22.2% versus 0% respectively). Meconium staining of liquor was commoner among the single loop group compared to the multiple nuchal loops group (33% versus 0). The multiple loops group had higher rates of immediate neonatal mortality than the single loop group (22.2% versus 0%). Neonatal resuscitation and NICU admission were commoner among the single loop group compared to the multiple nuchal loops group.

Table 10: Nuchal cord tightness and immediate neonatal outcome

	LOOSE NUCHAL CORD n (%)	TIGHT NUCHAL CORD n (%)
MSL GRADE		
≥1	29(26.9)	3(17.6)
0	79(73.1)	14(82.4)
APGAR SCORE AT 1 MINUTE		
<7	0(0)	3(17.6)
≥7	108(100)	14(82.4)
APGAR SCORE AT 5 MINUTES		
<7	0(0)	2(11.8)
≥7	108(100)	15(88.2)
APGAR SCORE AT 5 MINUTES		
<7	0(0)	2(11.8)
≥7	108(100)	15(88.2)
NEONATAL RESUSCITATION		
YES	23(21.3)	6(35.3)
NO	85(78.7)	11(64.7)
NICU ADMISSION		
YES	1(0.9)	1(5.9)
NO	107(99.1)	16(94.1)
IMMEDIATE NEONATAL MORTALITY		
ALIVE	108(100)	15(88.2)
DEAD	0(0.0)	2(11.8)

Table 10 above illustrates the findings among the nuchal cord group with regards to tightness of nuchal loops. Apgar score<7 at the first, fifth and tenth minutes of neonatal life were commoner among neonates delivered with tight incidental nuchal cord compared to the loose counterparts. NICU admission and immediate neonatal mortality were commoner among the tight nuchal cord loop group than in the loose loop category.

4.0 DISCUSSION

Prevalence of nuchal cord among term uncomplicated pregnancies was found to be 28.7%. This is comparable to prevalence in a cross-sectional study done in India at 23%. (17) It is however higher and lower than 16.2% ,39.6% and 55% reported in Cameroon, Japan and Uganda respectively.(8,11,19). This could be attributable to inclusion of pregnancies from 28 weeks gestation in the Ugandan study, larger sample size in the Japanese study and retrospective analysis in the Cameroon study. More than 80 percent of all nuchal cord loops were found to be single and loose. Similar findings were reported in Cameroon. (11)

There were no statistically significant differences between the two groups in terms of gestational age, birth weight and neonatal sex. A retrospective review done in Japan had similar findings.(19) A case-control study done in United States of America found positive association between higher neonatal birth weight and nuchal cord presence. (25) Our study found nuchal cord to be commoner among low birth weight neonates. The difference could be attributable to higher sample size in the aforementioned study. Previous studies done in Japan and U.S.A found that male neonates had significantly higher rates of nuchal cord.(19,25). In this study nuchal cord was commoner among female neonates. This was however not statistically significant.

There were no significant differences in maternal characteristics between the two groups in terms of age and parity. Previous studies done in Cameroon and India had similar findings. (11,15) Studies done in Japan and U.S.A however showed higher rates of nuchal cord occurrence among nulliparous women. (19,25)

The rate of SVD delivery was higher than Caesarean delivery generally (70 % versus 27%). This may not be a generalizable finding as the study population was not inclusive of complicated pregnancies. There was a significantly increased rate of elective Caesarean delivery in no nuchal cord group than in nuchal cord group. This could be accounted for by the inclusion of parturients who were due for elective caesarean section for other obstetrical reasons. A study done in Greece found increased rates of emergency Caesarean section and operative vaginal delivery among nuchal cord group. (27)

In our study, the odds of need for neonatal resuscitation in the nuchal cord group was more than twice that in the no cord group (OR 2.31; 95% CI 1.34-3.96; p value=0.003). This association

increased when adjusted for maternal and neonatal characteristics (OR 2.81; 95% CI 1.49-5.29; p<0.001). The findings were comparable to those from studies done in Uganda, Japan and U.S.A .(8,19,25) Neonatal resuscitation was commoner in the tight NC group compared to loose NC group which was a similar finding to findings in Uganda and Cameroon .(8,11)

The association between nuchal cord presence and low Apgar scores at first, fifth and tenth minutes of neonatal life was not statistically significant. A previous study done in Japan had similar findings.(19) Some studies showed association between nuchal cord and low Apgar scores at first and fifth minutes of life. (8,25,27). The rates of Apgar score <7 at the first, fifth and tenth minutes of neonatal life were higher in the multiple nuchal cord loops group than in the single nuchal cord loops group. This is comparable to findings from other similar studies. (8,11)

Rates of meconium staining of liquor and NICU admission were not significantly different between both cord groups. This is similar to findings from the Ugandan cross-sectional Study. (8) A study done in the U.S.A found that MSL was higher in the nuchal cord group. (25) .There was no significant difference in neonatal mortality between the nuchal cord group and the no nuchal cord group. This was a similar finding as in the study done in U.S.A.(25)

5.0 CONCLUSION AND RECOMMENDATIONS

In conclusion, incidental nuchal cord is a common birth occurrence in KNH with 28.7% prevalence among term singleton uncomplicated pregnancies. There are no significant differences in characteristics between parturients who deliver neonates with and without nuchal cord. There are no significant differences in characteristics among neonates delivered with and without nuchal cord. Nuchal cord is associated higher rates of neonatal resuscitation. However, there are no significant differences in neonatal outcomes in terms of Apgar score, NICU admission nor neonatal mortality.

Therefore, anticipation of need for resuscitation among neonates delivered with nuchal cord is recommended. However, nuchal cord should not be an indication for Caesarean delivery. A study with a larger sample size powered for the rare outcomes of interest like NICU admission and neonatal mortality should be carried out.

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1.0 ANNEXES

Annex 1: Consent form

PARTICIPANT INFORMATION AND CONSENT FORM

Title of the study: Prevalence of incidental nuchal cord during delivery and association with immediate neonatal outcomes at Kenyatta National Hospital

Principal investigator: Dr. Sharon Ayore

Co-investigators and institutional affiliation: Professor Eunice Cheserem (University of Nairobi), Dr Kireki Omanwa (University of Nairobi), Dr. Goerge Gwako (University of Nairobi), Dr. Francis Kagema (Kenyatta National Hospital)

INTRODUCTION

Dr. Sharon Ayore is a post graduate student in the department of Obstetrics and Gynecology, University of Nairobi, currently carrying out a study on the prevalence and early neonatal outcomes of incidental nuchal cord during delivery at Kenyatta National Hospital. The purpose of this consent form is to give you the information that you will need to decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, possible risks and benefits, your rights as a volunteer and anything else in this form that is not clear. When we have answered all your questions, you may decide to be in the study or not. This process is called the "informed consent". You are invited to participate in this study and can take all the time you need to make the decision. Kindly take time to read through the information provided. If there are any questions, comments or clarifications, please feel free to ask the principal investigator or the research assistants.

May I continue? YES/NO

This study has been approved by the Kenyatta National Hospital-University of Nairobi Ethics and Research committee protocol No._____

WHAT IS THIS STUDY ABOUT?

Dr. Ayore Sharon is interviewing mothers who come to deliver at Kenyatta National Hospital. The aim of this study is to collect information and find out the prevalence and early neonatal outcomes of incidental nuchal cord during delivery at Kenyatta National Hospital. This would help guide future management of such incidents. Participants in this study will be asked questions about their age, attendance to antenatal clinic, number of previous deliveries and any ultrasonography done during the current pregnancy. Information on your mode of delivery and well-being of your baby will be obtained from your records. There will be approximately three hundred and eighty one participants in this study, consecutively chosen. We are asking for your consent, to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study you will have to sign and also date the consent form. A copy of the completed form will be made and given to you to keep. The research team will collect information from your records. Some of the information may need to be obtained directly from you in a private room where you feel comfortable. This will include your age, level of education, occupation, marital status, antenatal clinic attendance, previous radiological studies and deliveries. This will take approximately 15 minutes. You will be managed in labour like the rest of the mothers and followed up for 7 days following your delivery.

ARE THERE ANY RISKS, HARMS OR DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

There will be no procedures nor tests done on you apart from by your primary caregiver which will be done in privacy. This will include examination of your baby in utero and vaginal examinations to monitor your labour. Therefore, no embarrassing situations are anticipated. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You may benefit by receiving free counselling and health information. We will refer you for specialized care and support where necessary. Also, the information you provide will help us better understand the prevalence of nuchal cords and whether it has an impact on neonatal outcomes. This information is a contribution to science and future policy formulation to achieve best neonatal outcomes.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

You will not be charged any extra fee for your participation in this study.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No

I agree to provide contact information for follow-up: Yes No

Participant printed name:

_____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: _____ Date: ____ _____

Signature

_____

Role in the study: _____ [i.e. study staff who explained informed consent form.]

For more information contact the following-

Dr. Sharon Ayore
Principle investigator
P.O box 243 (00242)
Kitengela
Tel: 0724369152

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Honorary Lecturer, university of Nairobi

Prof Mark L. Chindia,
Secretary, KNH-UoN ERC
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Tel: (254-020) 2726300-9, Email: uonknherc@uonbi.ac.ke

FOMU YA IDHINI YA UTAFITI

Sehemu ya kwanza: Maelezo

Mada ya Utafiti: Kuenea kwa tukio la kamba la uzazi kuzingira shingo la mwana kabla ya kuzaliwa na matokeo ya watato wachanga katika hospitali kuu ya Kenyatta.

Mtafitii Mkuu: Daktari Sharon Ayore, Mwanafunzi katika idara ya uzazi na magonjwa na wanawake

Utangulizi

Daktari Sharon Ayore ni mwanafunzi wa Chuo Kikuu cha Nairobi. Anaangazia maswala ya uzazi na afya ya wanawake kwa jumla. Ninafanya uchunguzi kuhusu kuenea kwa, na Uhusiano kati ya kamba la uzazi kuzingira shingo la mwana kabla ya kuzaliwa na matokeo ya watato wachanga katika hospitali kuu ya Kenyatta.

Maudhui ya ridhaa hii ni kukupa maelezo utakayohitaji kutumia katika uamuzi ya kushiriki au kutoshiriki katika uchunguzi huu. Uwe huru kuuliza maswali yoyote kuhusu lengo la utafiti huu, nini kinachotokea ukishiriki katika utafiti, faida na hasara ya kushiriki,na haki zako kama aliyejitolea kushiriki, na chochote kile ambacho hakieleweki vyema. Tutakapo kuwa tumejibu maswali yako yote,utaamua kushiriki katika uchunguzi au la. Mchakato huu unaitwa ridhaa ya maelezo, maanake “informed consent.” Unakaribishwa kushiriki katika uchunguzi huu na waweza chukua muda wowote unayoitaji kufanya uamuzi wa kushiriki ni kwa hiari yako. Kama kuna maswali yoyote au ufafanuzi utakao hitajika, kuwa huru kuwasiliana na mdadisi mkuu au manaibu wake.

Je, naweza kuendelea? NDIO/ LA

Utafiti huu umekubaliwa na kamati ya maadili ya utafiti ya hospitali kuu ya Kenyatta na chuo kikuu cha Nairobi.

LENGO LA UTAFITI/ UTAFITI WAHUSU NINI?

Utafiti huu una nia ya kukusanya taarifa ili kutambua kuenea kwa tukio la kamba la uzazi kuzingira shingo la mwana kabla ya kuzaliwa na matokeo ya watato wachanga katika hospitali kuu ya Kenyatta. Hii itasaidia kuunda msingi wa kukabiliana na matukio kama haya kwa wakati ujao. Washiriki katika utafiti huu wataulizwa maswali kuhusu miaka yao, kuonekana katika liniki ya wajawazito, uzazi wao na kupigwa picha ya kujulia mtoto hali kabla ya kuzaa. Taarifa kuhusus njia ya uzazi na wema wa mwana utapatikana katika rekodi yako na utaweza pigiwa simu kutujulisha hali yake. Kutakuwa na takribani washiriki mia tatu, themanini na moja. Tunaomba ushiriki na idhini yako.

NAMNA / NINI KITAKACHOTOKEA UKISHURIKI?

Ukikubali kushiriki katika utafiti huu, utahitajika kuweka saini na tarehe katika idhini. Utapewa nakala ya idhini ili uweke. Timu ya utafiti itakusanya maelezo kutoka kwa rekodi zako. Unaweza pia kuulizwa maswali kuhusu maswala ambayo hayatapatikana katika rekodi zako. Mahojiano utafanyiak pahali pa faraja. Washiriki katika utafiti huu wataulizwa maswali kuhusu miaka yao, kuonekana katika liniki ya wajawazito, uzazi wao na kupigwa picha ya kujulia mtoto hali kabla ya kuzaa. Muda wa mohojiano hautazidi dakika thalathini. Utapewa huduma hospitalini kama kawaida.

UWEZEKANO WA HATARI NA USUMBUFU

Utafiti wa matibabu unaweza kuwa na athari kisaikologia na kwa uhai. Juhudi za kupunguza madhara haya lazima ziwekwe. Kupoteza faragha ni moja yao. Tu.taweka siri kila jambo ambalo utatuelezea. Tutatumia nambari ya msimbo kukutambua katika kompyuta lilo na nenosiri na taarifa lolote ambalo litakuwa limeandikwa litafungiwa pahali siri. Hata hivyo, hakuna mfumo ambao ni salama kabisa.

Ikiwa una wasiwasi wa kujibu swali lolote, una haki ya kukataa kujibu.

Hakuna vipimo au utaratibu utakaofanywa mbali na yale ya huduma ya msingi, ambayo yatafanywa kwa faragha. Wahuduma wote ni wataalamu katika huduma ya wanawake wanaojifungua.

FAIDA INAYOTARAJIWA

Utafaidika kwa kupata mafunzo ya habari za afya. Matokeo ya uchunguzi huu yana lengo la kutoa matibabu bora kuboresha afya kwa vizazi vijavyo.

JE, KUSHIRIKI KWENYE UTAFITI UTAKUGARIMU CHOCHOTE?

Hakuna gharama lolote la ziada utakalopata kwa kushiriki katika utafiti huu.

HAKI YA KUKATAA/ WAWEZA KUJIONDOA KWENYE UTAFITI?

Kushiriki katika uchunguzi huu, ni kwa kujitolea kwa hiari yako. Una haki ya kujitoa kwa uchunguzi wakati wowote bila ya madhara yoyote, na matibabu yako bado yataendelea kwa njia mwafaka bila matatizo yoyote. Kutoshiriki ni haki yako, na haki hii itaheshimiwa.

SEHEMU YA PILI: MAKUBALIANO (TAARIFA YA IDHINI)

Taarifa ya mshirika.

Nimesoma na nikaelewa ujumbe ulioko hapa juu. Nimeelezewa kikamilifu kuhusu utafiti huu na nilipata nafasi ya kuuliza maswali yaliyojibiwa kwa ukamilifu kutumia lugha ninayoielewa. Nimeelezewa kuhusu faida na hasara ya utafiti. Nimekubali kushiriki katika utafiti huu bila kulazimishwa ama kupewa hongo,na naweza kuchagua kutoshiriki wakati wowote.

Naelewa kwamba juhidi zote zitafanywa kuweka usiri kuhusu habari yangu ya kibinafsi.

Nimekubali kushiriki kwenye utafiti	NDIO	HAPANA/LA
Nimekubali kutolewa sampuli ya damu cha utafiti	NDIO	HAPANA/LA
Nimekubali kutoa habari ya mawasiliano ya kufuatiliwa	NDIO	HAPANA/LA

Jina la Muhusika: …… AU Alama ya Kidole…….

Saini ya Muhusika: ……

Tarehe: ……..

Saini ya Shahidi: …… Tarehe: …….

Taarifa ya Mdadisi

Nimewaelezea wahusika kuhusu utafiti na nikawapatia nafasi ya kuuliza maswali. Nimeyajibu maswali yote niwezavyo. Nimehakikisha kuwa wanaohusika wamekubali kwa hiari yao.

Jina la mdadisi: ……..……

Saini: ……..

Tarehe: ……**…**

Kuwasiliana

Kwa maswali yoyote au ufafanuzi wowote wasiliana na:

Daktari Sharon Ayore
Mtafiti mkuu
Nambari la posta 243 (00242)
Kitengela
Nambari ya simu: 0724369152

Profesa Eunice Cheserem- Msimamizi mkuu
Profesa, Idara ya uzazi na magonjwa ya wanawake,
Chuo kikuu cha Nairobi,
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Nambari ya simu: (254-020)2726300-9
Barua Pepe: uonknh_erc@uonbi.ac.ke

Annex 2: Data extraction form

PREVALENCE AND IMMEDIATE NEONATAL OUTCOMES OF INCIDENTAL NUCHAL CORD AT BIRTH AT KENYATTA NATIONAL HOSPITAL: A CROSS-SECTIONAL STUDY

Date…… Identification number…….....

Section A: Eligibility criteria checklist

All parturients to be enrolled should satisfy the criteria below

Requirements for eligibility	**Tick if satisfactory**
Singleton pregnancy	
Gestational age by dates and or first trimester ultrasound 37+0 days to 41+6 days (any pregnancy with a gestation below 37 weeks or beyond 41 plus 6 days is excluded from the study)	
Cephalic fetal presentation (by ultrasound or clinical examination)	
No maternal diabetes, hypertension nor preeclampsia	
No antepartum hemorrhage	
No congenital malformation	
No clinically diagnosed anaemia nor a hemoglobin concentration of <10g/dl on antenatal record or maternal file	
No diagnosis of chorioamnionitis, malaria nor hematological disease	

Section B: Interview

1. What is your age in completed years? _____

2. When is your birth date?

____/_____/_____

Day/ Month/ Year

3. What is your marital status?

Single□ Married□ Divorced □

4. What is the highest level of education you have attained?

Primary □Secondary□

University □

5. How many pregnancies have you had and carried to term? _____

6. When was the first day of your last normal menstrual period?

____/_____/_____

Day/ Month/ Year

7. Did you attend antenatal clinic? Yes□ No □

8. If yes to above, where did you attend the clinic?

KNH □

Other public facility □

Private facility □

Specific_____

9. How many visits did you make?'

Specific_____

None□ <4 □ 4-7 □ ≥8□

10. Was antenatal ultrasound done after your fifth month of pregnancy?

Yes □ No□

11. Do you have the ultrasound scan and report?

Yes □ No□

Please provide the report

Section C: Data abstraction from delivery records

Maternal characteristics	
Prenatal ultrasound performed after 20 weeks gestation (check for the report)	Yes □ No□
Gestation(as reported in the scan)at which the ultrasound above done	Specific
Prenatal reporting of nuchal cord made by sonographer (for those with incidental cords)	Yes□ No□
Mode of delivery	SVD □ OVD□ Emergency Caesarean □ Elective CS□
If caesarean delivery, diagnosis leading to this mode	Prolonged/protracted/arrested labour□ Cervical dystocia □ Fetal distress □ Cephalo-pelvic disproportion□ Shoulder dystocia □ Obstructed labour □ Failed attempted VBAC □ Maternal request □ Placenta previa □ Abruptio placenta □ Cephalopelvic disproportion□ Macrosomia □ Placenta previa □

	Vulvo-vaginal fistula repair □ HIV □ Active herpes □ Repeat CS □ Other □ specify…….
Induction of labour done or not (use of cervical ripening medication e.g misoprostol to induce labour)	Yes □ No□
Fetal characteristics	
Gestational age at delivery (completed weeks and days)	Specific……. Early term: 37 weeks to 38 6/7 weeks □ Full term: 39 weeks to 40 6/7 weeks □ Late term: 41 0/7 to 41 6/7 weeks □
Neonatal birth weight (in grams)	Specific…… Extremely low birth weight (<1000g)□ Very low birth weight (1001-1499g) □ Low birth weight (1500-2499g) □ Normal birth weight (2500-4200g) □ >4200g □
Neonatal sex	Male□ Female □

Incidental nuchal cord at birth (wrapping of the umbilical cord around the fetal neck at least 360 degrees)	Present □ Absent□
If present, tightness of nuchal cord	Loose(could be spontaneously unwound before delivery of fetal trunk) □ Tight (need to be clamped and cut to deliver fetal trunk) □
If present, number of nuchal cord loops	Specific…… Single □ Multiple(≥2) □
Neonatal outcomes	
Meconium staining of liquor grade (see attached poster for guidance)	0□ 1□ 2□ 3□
Apgar score at 1st minute (see attached table for guidance)	Specific……. <7□ ≥7□
Apgar score at 5th minute	Specific……. <7□ ≥7□
Apgar score at 10th minute	Specific…….
Need for neonatal resuscitation (Need for airway support, mechanical ventilation or circulatory resuscitation including cardiac massage by neonate after delivery)	Yes □ No□
NICU admission after delivery	Yes □ No□
Neonatal status within 24 hours of delivery	Alive □ Dead□

Annex 3: Poster

PREVALENCE AND IMMEDIATE NEONATAL OUTCOMES OF INCIDENTAL NUCHAL CORD AT BIRTH AT KENYATTA NATIONAL HOSPITAL: A CROSS-SECTIONAL STUDY

This is to bring to your attention that the study above is ongoing. The principle researcher is Dr. Ayore Sharon, a postgraduate student at university of Nairobi pursuing obstetrics and gynaecology. Approval has been obtained from KNH/UoN ERC. Your assistance and compliance is greatly appreciated.

This is a guide and reminder to some of the neonatal and maternal data to be collected with the assistance of the primary care provider.

You are kindly requested to document all the information listed below for the mother and the neonate:

1. **Maternal: Inquiry on prenatal ultrasounds done with retention of copies in the file, induction of labour and mode of delivery**
2. **Neonatal: presence of nuchal cord, tightness and number of loops, gestational age, neonatal sex, birth weight in grams, Apgar score at the 1st, 5th and 10th minute, meconium staining of liquor, if neonatal resuscitation was performed, if the neonate was transferred to NICU or not**

A guide and reminder on grading of meconium stained liquor:

1. Grade 0 if amniotic fluid clear or straw coloured
2. Grade 1 if normal consistency of fluid in flow but with yellow-green tinge in colour (translucent)
3. Grade 2 if thicker and darker in colour (opalescent)
4. Grade 3 if fluid viscous, tenacious and contains large amount of yellow-green particulate material (opaque)

A reminder on Apgar score for the neonate:

	0 points	1 point	2 points
Activity muscle tone	absent	Arms and legs flexed	Active movement
Pulse	absent	≤100BPM	>100bpm
Grimace (reflex irritability)	flaccid	Some flexion of extremity	Active motion (sneeze, cough, pull away)
Appearance (skin colour)	Blue, pale	Body pink, extremities blue	Completely pink
Respiration	absent	Slow, irregular	Vigorous cry
Total of the points from the five categories gives total score			

Nuchal cord

Presence of a loop of the umbilical around the fetal neck spanning at least 360 degrees. A nuchal cord will be considered as tight if it cannot be spontaneously unwound or has to be cut before delivery of the fetal trunk. Tightness will be classified as follows.

1. loose (can be spontaneous unwound around fetal neck before delivery of the fetal trunk)
2. tight (has to be clamped and cut before delivery of the fetal trunk)

Your compliance and assistance in achieving the goal of the study is greatly appreciated

Yours

DR. SHARON AYORE

Annex 4: Study timeline/time frame

ACTIVITIES	FEB 2018	MAR 2018	APRIL 2018	MAY 2018	JUN 2018	JUL 2018	AUG 2018	SEP 2018	OCTOBER 2018	NOV 2018	DEC 2018	JAN 2019
PROPOSAL PREPARATION AND PRESENTATION												
ETHICAL REVIEW												
DATA COLLECTION												
DATA ANALYSIS												
RESULTS PRESENTATION												
FINAL DISSERTATION PREPARATION												

Annex 5: Budget and budget justification

COMPONENTS	Units of measure	Number/duration	Cost (Ksh.)
Personnel			
Research assistants		2	80000
Statistician		1	50000
Printing			
Consent forms		450	10000
Data extraction forms		450	10000
Manuscript development		150	5000
Other expenditure (airtime, stickers, travel)			10000
Dissemination			
Registration, transport and accommodation			50,000
Total Estimated Expenditure			215,000