OBSTETRIC AND NEONATAL OUTCOMES OF WOMEN IN LABOUR UNDERGOING ADMISSION CARDIOTOCOGRAPHY VERSUS INTERMITTENT AUSCULTATION AT KENYATTA NATIONAL HOSPITAL:

A RANDOMIZED CONTROL TRIAL

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DECLARATION

This dissertation is my original work and has not been presented for a degree in any other University. Where reference was made from other sources, the literature sources have been cited.

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i

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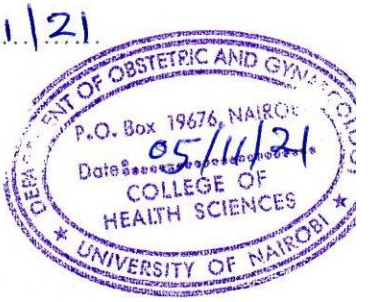

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DEDICATION

I dedicate this dissertation to the Lord Almighty my strong pillar, source of strength and inspiration through whom this was possible.

To my loving wife Esther you always encouraged, took great care of me and prayed for me all through and gave me hope beyond measure to achieve this and much more.

To my dear children Hailey, Edward and Malkia for having to bear with the endless hours of research to allow me to accomplish this.

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LIST OF ABBREVIATIONS AND ACRONYMS

ACTG	Admission Cardiotocography
ANC	Antenatal Clinic
BPM	Beats per Minute
BR	Baseline Rate
BV	Baseline Variability
cCTG	Continuous Cardiotocography
CTG	Cardiotocography
ED	Early Decelerations
EFM	Electronic Foetal Monitoring
FHR	Foetal Heart Rate
HIE	Hypoxic Ischemic Encephalopathy
IA	Intermittent Auscultation
IUGR	Intrauterine Growth Restriction
KDHS	Kenya Demographic and Health Survey
KNH	Kenyatta National Hospital
LD	Late Decelerations
NBU	New Born Unit
NICU	Neonatal Intensive Care Unit
SDG	Sustainable Development Goals
SGA	Small for Gestational Age
SPSS	Statistical Package For Social Sciences
VD	Variable decelerations

DEFINITION OF OPERATIONAL TERMS

Electronic Foetal Monitoring:	Electronic foetal heart rate recording
Cardiotocography:	Technical means of recording the foetal heartbeat and the uterine contractions during pregnancy as a pattern on a strip of paper.
Auscultation:	Act of listening to sounds from the foetus in the uterus
Fetoscope:	Device used to listen to the foetal heart
Foetal Heart Rate:	Number of heartbeats in the foetus that occur in a given time
Normal Foetal Heart Rate:	110 to 160 beats per minute (bpm)
Parturient:	Pregnant woman in labour
Intrapartum:	Ooccurring during delivery
Antepartum:	Occurring before delivery
Asphyxia:	Decreased delivery of oxygen
Hypoxia:	Decreased oxygenation in the tissues
Hypoxemia:	Decreased arterial oxygenation
Neonate:	Child under 28 days of life
Perinatal:	22 completed weeks of gestation up to seven completed days of life.
Perinatal Mortality:	Perinatal deaths per 1000 total births.

LIST OF TABLES

LIST OF FIGURES

TABLE OF CONTENTS

ABSTRACT

Background: Admission Cardiotocography (ACTG) is a record of the foetal heart rate for 20 minutes upon admission in labour ward. Assessment of foetal wellbeing throughout labour and delivery is vital for identifying and averting intrapartum foetal compromise. In Low to Middle Income Countries (LMIC) including Kenya there are unproportionate doctor and nurse to patient ratios, as a result labour wards are overcrowded and foetuses at risk of intrapartum hypoxia may be indentified late and interventions instituted late leading to unfavorable neonatal and maternal outcomes that have immense financial, emotional and physical impact. Locally, studies on ACTG and Intermittent Auscultation (IA) are limited despite known shortcomings of IA. To address these aspects of intrapartum foetal monitoring and provide data that could potentially improve the maternal and neonatal outcomes of pregnancy, we aim to fill this gap.

Study Objective: To compare obstetric and neonatal outcomes of parturients undergoing ACTG versus IA at the Kenyatta National Hospital (KNH), Kenya.

Methodology: This was an open label Randomised Control Trial (RCT) at the KNH labour ward. One hundred (100) Women admitted at KNH for delivery at 37 to 41 completed weeks of gestation were evaluated by taking obstetric and medical history, a general and obstetric exam done and those who matched our inclusion criteria were recruited using two stage randomization. Fifty (50) parturients allotted to the IA arm and 50 ACTG arm. Written consent was obtained from parturients and a structured questionnaire used to collect data on the sociodemographic and reproductive characteristics of participants. Parturients in the ACTG arm underwent ACTG for monitoring of foetal heart rate while those in the IA arm underwent IA. After either ACTG or IA, patients were allowed to proceed to delivery normally and birth outcomes reported after a 24-hour follow-up. The mode of delivery, need for intrapartum interventions and maternal and neonatal outcomes were evaluated. Data analysis was done using version 21 of the Statistical Package for Social Scientist (SPSS). The sociodemographic and reproductive characteristics of women were analysed using Chi square and t-test at 95% CI with a P value <0.05 considered significant.

Results

100 women (50 in ACTG arm and 50 IA) were studied. In IA arm, 98% (49/50) of patients had regular foetal heart rate, while 84% (42/50) in ACTG arm had normal findings. About 30% (15/50) and 10% (5/50) of women who underwent ACTG and IG exams delivered by caesarean section, with 1.7 times more women in CTG arm undergoing a CS (P=0.01). The incidence of adverse pregnancy outcomes such as prolonged labour and NRFS did not vary statistically by the type of examination. Apgar scores at five minutes and incidence of NBU and NICU admission of neonates did not vary statistically between the study arms ($P>0.05$).

Conclusions: Routine use of ACTG for low risk parturients does not improve maternal or neonatal outcomes.

Key Words: Admission Cardiotocography, Intermittent Auscultation, Labour, Obstetric outcomes, Neonatal outcomes

CHAPTER: ONE

1 INTRODUCTION

1.1 Background

It has been observed that intrapartum foetal heart auscultation during labour in the first half of the 20th century became the standard of care globally to monitor foetal health (1)(2). Freeman *et al.* first described foetal heart sounds in the 17th century in poetry (3). A Foetal Heart Rate (FHR) of 120 to 160 beats per minute (bpm) is within the normal range and many international guidelines define the ranges of 110 to 160 as safe in daily practice. Monitoring of FHR during pregnancy, labour and delivery is vital for monitoring foetal wellbeing so as to optimize foetal outcomes (4). Recording of FHR using CTG was performed as an important part of antepartum and intrapartum care routinely in hospitals all over the world.

Assessment of FHR using IA involves auscultating and enumerating the FHR for one minute or more unlike ACTG that records the FHR and uterine activity electronically for about 20 minutes (5). The justification of FHR assessment on admission in labour is to establish intrapartum foetal compromise and offer Continuous Cardiotocography (cCTG) or expedited delivery (6). In low risk gestations, evidence on benefits of using ACTG is lacking with some guidelines recommending the use of IA in parturients without risk factors for continuous monitoring (7),(8),9). Observations from past trials that guided these guidelines assessed effects of ACTG in the context of established labour, spontaneous onset of labour or induced labour (10–12). However, the studies also recommend further investigations on effects of ACTG on women in labour and utilization before a diagnosis of spontaneous or induced labour (13,5).

1.2 Statement of the Problem

Current practice at KNH is to perform IA on a need to need basis. This poses a significant challenge due to the high number of mothers in labour at a given time and the limited number of health care workers managing parturients at KNH labour ward. Although the use of ACTG remains widespread, some aspects remain controversial like routine use of ACTG on parturients at low risk of intrapartum hypoxia, efficacy of ACTG at predicting fetuses at risk of intrapartum hypoxia and the effect of ACTG on maternal and neonatal mortality and morbidity. A critical time gap exists where foetal compromise might occur before a CTG is done. Current perinatal mortality rate in Kenya is 29% (33) with birth asphyxia being the

commonest cause. Around 67% of neonatal admissions at KNH NBU yearly are attributable to birth asphyxia. This calls for an alternative remedy that is sensitive, safe, and acceptable in our regional settings.

Intermittent Auscultation (IA) is subjective despite being the current mode of intrapartum FHR monitoring at KNH. In developed countries Meta analyses have shown it to be as effective as ACTG however, in these countries, many factors favor such findings, which include the low number of patients delivering in hospitals at any given time, better patient to health care worker ratios, and constant training on optimal use of a pinard fetoscope. ACTG serves as a better screening tool for detecting foetal distress (present or likely to develop) and prevent unnecessary delay in intervention (14). ACTG has high specificity and might aid in 'triaging' foetuses in labour wards of developing countries with a heavy workload and limited resources (14). We assessed whether ACTG has beneficial effects on pregnancy outcomes in the African parturient. This has not been studied sufficiently in Africa and Kenya.

1.3 Justification

This was a pioneer study evaluating effectiveness of ACTG versus IA for intrapartum FHR monitoring in Kenya. This study yielded valuable information on the status of intrapartum FHR in monitoring in Kenya/Africa. We evaluated the effectiveness of IA protocols and whether ACTG offers better results in LMICs. We sought to address the contributors to the high perinatal mortality rates, high NBU admissions, poor maternal and neonatal outcomes that would be the result of inadequate intrapartum FHR monitoring guidelines and or modalities available. The data will guide public health planning and formulation of policies for improving intrapartum FHR monitoring and the maternal and neonatal outcomes of low risk parturients.

1.4 Research question

What are the obstetric and neonatal outcomes of parturients who undergo Intermittent Auscultation (IA) versus Admission Cardiotocography (ACTG) in Kenyatta National Hospital labour ward?

1.5 Hypothesis

The obstetric and neonatal outcomes of parturients who undergo ACTG versus IA for FHR monitoring at KNH are comparable.

1.6 Study Objectives

1.6.1 Broad Objective

To compare the obstetric and neonatal outcomes of women in labour undergoing ACTG versus IA for FHR monitoring at the KNH labour ward

1.6.2 Specific objectives

i. To compare the obstetric outcomes of parturients who undergo ACTG versus IA at KNH
ii. To compare the neonatal outcomes of parturients who undergo ACTG versus IA at KNH

CHAPTER: TWO

2 LITERATURE REVIEW

2.1 Description of Condition

Issue 2 of the Cochrane review of 2012 describes two common means of FHR monitoring. IA and Electronic Foetal Monitoring (EFM) through CTG (9). In Cochrane review, IA entails listening to the foetal heart at specific intervals with Pinard stethoscope or hand-held Doppler ultrasound device for 1 minute or more after a contraction. CTG machine produces a print depicting the foetal heart rate recorded externally with an ultrasound transducer or internally using a foetal scalp electrode, and uterine contractions recorded through a pressure transducer on the anterior abdominal wall or via an intrauterine pressure device within the uterine cavity.

2.2 Description of the Intervention

The importance of monitoring the heart rate of foetus during labour and delivery has been recognised for years now. It is one of the best techniques for detecting distress in labour. It can mitigate excessive use of interventions such as syntocinon that cause uterine hyperstimulation leading to uteroplacental insufficiency and foetal hypoxia. When such problems are detected early appropriate management of labour can be offered to parturients and thus change the outcomes of pregnancy (9, 11).

For decades, clinicians have evaluated the Foetal Heart Rate (FHR) during pregnancy, labour and or delivery as an indicator of foetal well-being. The procedure is done either by admission cardiotocography (ACTG) or Intermittent Auscultation and is one of the best techniques for identifying babies who are at risk of foetal compromise. (9). ACTG is a 20-minute record of FHR and uterine activity upon admission of parturients with spontaneous uncomplicated labour. IA, on the other hand, is periodic monitoring of the FHR at 15-minute intervals during the first stage of labour and 5-minute intervals during the second stage of labour using either a pinard stethoscope or a hand-held Doppler. Women with spontaneous uncomplicated labour undergo ACTG and others IA.

By analysing the uterine contraction patterns and foetal movements of high risk parturients, CTG can be used to investigate the risk of foetal hypoxia. As such, if interpreted accurately, it allows for timely intervention during labour, which lowers the risk of stillbirths and

mortality at infancy. However, the reports of other authors do not support the need for ACTG analysis when a parturient has a low-risk pregnancy. Instead, IA is recommended for monitoring whenever pregnancy is considered low risk (12, 14). However, whether IA confers better maternal and neonatal outcomes compared to ACTG has not been studied sufficiently in low-income settings such as Kenya. Such data is important for proper management of parturients in our region.

2.3 Working of the Intervention

In the 1970s, EFM was adopted into clinical practice where it gained extensive clinical utilization in aiding the diagnosis of hypoxia depicted by abnormal FHR patterns. EFM thus allowed prevention of neurological damage and or death of the foetus through early detection (15). Preexisting risk factors during pregnancy do not prelude to those that consequently will suffer neonatal morbidities and or mortality so as to gain from intense monitoring by cCTG, foetal scalp blood gas sampling or prompt interventions such as caesarean delivery (16,17). Currently it has been established that neonatal encephalopathy, cerebral palsy and perinatal mortality prevalence rates are lowered and only but a minimal proportion are presumptively directly attributable to intrapartum causes (17). It has, thus, been hypothesized that the FHR pattern changes are not specific or sensitive (18). Decreased FHR variability and multiple late decelerations are affiliated with an high risk of cerebral palsy (15). ACTG was utilized by about 79% of maternity units in the UK in 2000, 96% of units in Ireland in 2004, 76% of Canadian hospitals in 1998 and all (100%, n = 42) labour units in Sweden in 2008 (19,20,21).

2.4 Interventions for the Assessment of Foetal Heart Rate

Evaluation of foetal well-being is important in achieving optimum neonatal outcomes in antepartum and intrapartum period. Recognizing a foetus at risk of Hypoxic Ischaemic Encephalopathy (HIE) by identifying imminent asphyxia or the probability that such outcomes may result during labour or delivery is vital in enhancing neurological outcomes for all neonates and those at more risk with pre-existent IUGR (22).

Poor foetal prognosis can be identified by a Doppler ultrasound through abnormal blood flow pattern that result during intrapartum foetal compromise. A false positive Doppler ultrasound may lead to preterm delivery and other adverse outcomes due to unwarranted interventions (23). Majority of foetuses in high-income countries develop uneventfully in utero. However, in the eventuality of medical disorders in pregnancy or placental insufficiency it can lead to

growth restriction with intrauterine foetal demise as a sequela. Doppler ultrasound detects blood flow alterations in the foetal circulatory system thus pin pointing a foetus at risk. Results from a number of studies in a 2017 Cochrane review revealed that umbilical artery Doppler can reduce neonatal mortality and result in minimal caesarean sections and labour inductions (23). This implies that a Doppler ultrasound in high-risk gestations may minimize obstetric interventions and poor foetal outcomes.

Authors inferred that Doppler sonography of the umbilical artery improve perinatal outcomes in high-risk pregnancies at risk of placental insufficiency. An elaborate description of suspected placental insufficiency, frequency of Doppler studies and timing of delivery in the presence of abnormal Doppler studies of umbilical artery remains elusive (23). Umbilical artery Doppler is beneficial in hypertensive disorders of pregnancy and small for Gestational Age (SGA) foetuses while applicability in other high risk gestations including post-term, diabetes and uncomplicated dichorionic twin gestation is debatable. We intend to corroborate these results in Kenya. A comparison of the maternal and neonatal outcomes of pregnancy after ACTG and IA was done in a tertiary hospital in Nairobi, Kenya.

Existing clinical guidelines on intrapartum foetal heart rate monitoring as per Institute of Obstetricians and Gynaecologist Royal college of Physicians of Ireland recommend that with the current evidence base they do not support the use of the admission CTG in low risk pregnancies and is therefore not recommended as a routine (24). NICE guidelines recommend not to offer cardiotocography to women at low risk of complications in established labour rather to offer intermittent auscultation of the foetal heart rate to women at low risk of complications in established first stage of labour (25). On the other hand WHO GDG (Guidelines Development Group) does not recommend routine cardiotocography for the assessment of foetal well-being on labour admission in healthy pregnant women presenting in spontaneous labour(26). The evidence was derived from a Cochrane systematic review in High Income Countries (HIC) that included four RCTs conducted in Ireland (1 trial) and the United Kingdom (3 trials)(9). Despite this recommendation they had a priority question related to this recommendation: For women classified to be low risk in Low middle Income Countries (LMICs) and any setting with inadequate antenatal care provision, can routine CTG on labour admission improve birth outcomes?(26).

Impey et al 2003 reported less than 0.4% (17/4298) of infants in the ACTG and < 0.25% (11/4282) of infants in IA group had Apgar scores of 7 at 5 minute. The relative risk for

having an Apgar score of less than 7 at 5 minutes in ACTG group was 1.54 (95% CI 0.72–3.28). Primary outcome of neonatal morbidity or mortality, there was no difference in neonatal morbidity or mortality between ACTG and IA (RR 1·01; 95% CI 0·70–1·47) (11). Mires et al 2001 reported that 2.1% (25/1186) of infants in ACTG and similarly 1.5% (18/1181) of infants in IA group had an Apgar score of 7 at 5 min after delivery thus the RR was 1.39 (95% CI 0.72–2.66). Five (5) % (61/1186) of women in the ACTG arm and 3.6% (43/1181) of women in IA had a caesarean section thus the RR of having a caesarean section in ACTG (12).

Cheyne et al 2003 reported that 1.2% (2/164) of infants in IA arm and none in ACTG arm had Apgar score less than 7 at 5 minute after delivery, RR 0.2 (95% CI 0.01–4.6). It was also reported that 7% (11/148) of women in ACTG arm and 5% (9/164) in IA arm had a caesarean section. The RR of having a caesarean section in ACTG arm was 1.35 (95% CI 0.6–3.1)

2.5 Conceptual Framework

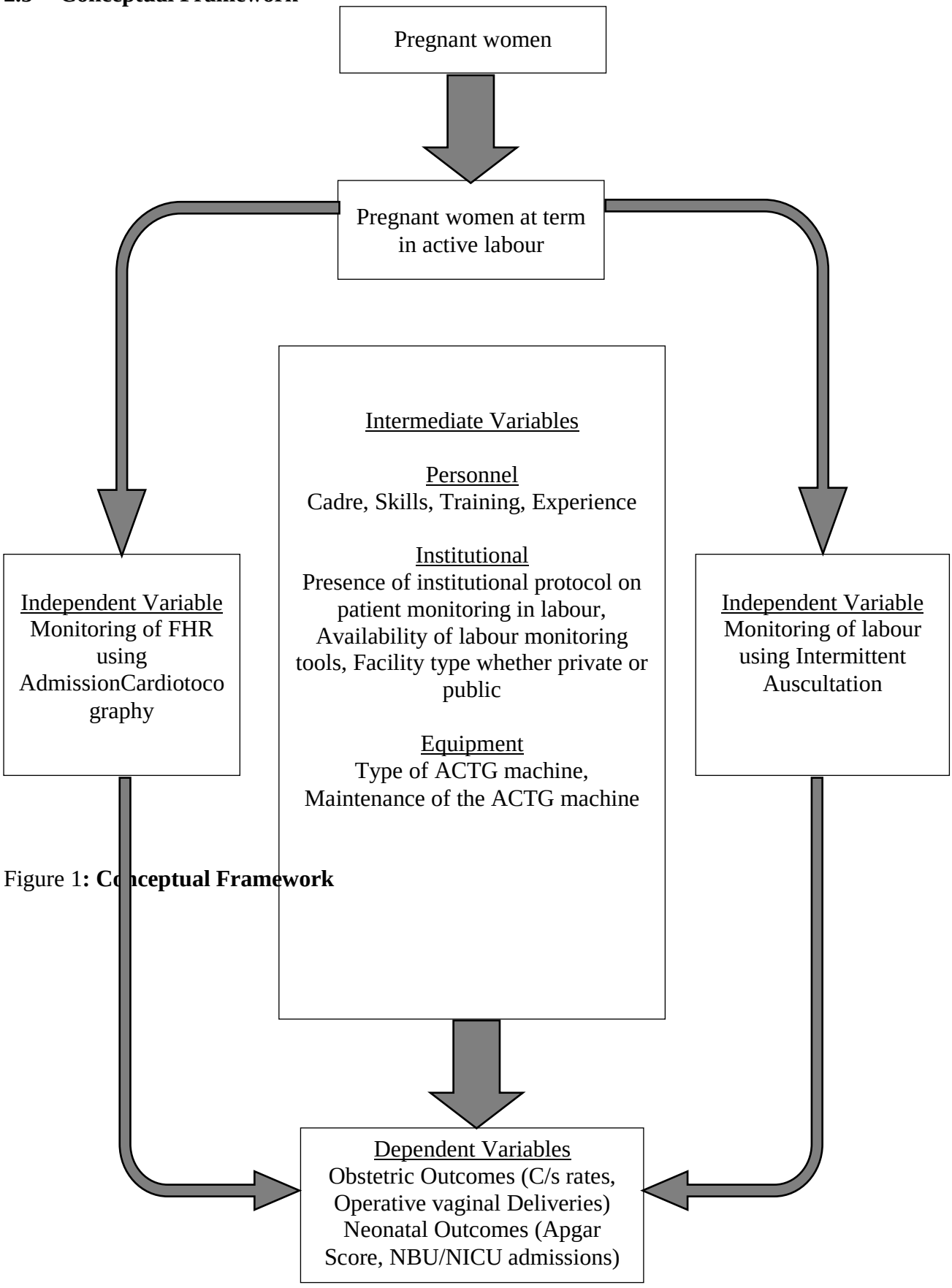


Figure 1**: Conceptual Framework**

CHAPTER: THREE

3 METHODOLOGY

3.1 Study Design

A Randomized Control Trial (RCT) was done at the Kenyatta National Hospital labour ward between March and September 2019. One hundred (100) women at term and in active labour had intrapartum FHR monitoring either by using CTG or IA and maternal/fetal outcomes were analyzed.

3.2 Study Site

This study was conducted at the KNH, labour ward. KNH was started in 1901 to undertake its mandate of the National referral and teaching hospital. In 1987 it became a state corporation. KNH is the largest referral health facility in Kenya as well as the training site for the school of Medicine for the University of Nairobi.

KNH has fifty wards, Twenty two outpatient clinics, Twenty four theatres and Accidents and Emergency unit. Total bed space is 1800 consisting of 209 beds in the private ward. KNH serves about 80,000 admitted patients and more than 500,000 outpatient visits yearly. The reproductive health department consists of ANC, maternity theatre, antenatal wards, and gynaecology/oncology wards, NBU, NICU, and adult ICU. The labour ward in KNH has 2 maternity theatres, 32 patient beds (including 7 delivery couches). The unit serves between 60-120 patients per day, with a monthly average of 1400 patients.

The unit handles an average of 17,000 deliveries a year and is managed by several specialists and registrars. The labour ward unit is ran by about 10 nurses trained in midwifery and emergency obstetric care, 2 residents (one monitoring the acute patients), 2 residents covering maternity theatre and 2 specialist consultants at any given 12 hour shift. The monitoring of women in labour largely depends on a doctor's choice with majority using intermittent auscultation. When a parturient arrives they are first seen at triage room where patient biodata is enumerated, obstetric and general exam conducted. Parturient is then allocated to either acute room handling high risk parturients or general rooms handling low risk parturients. The patient is then allocated to a midwife (each handling about 8 parturients). Mode of FHR monitoring is by using IA done every 30mins and filled in a

partograph patient is thus followed till delivery. If complications arise in the intrapartum phase the covering registrar reviews patient and takes appropriate action.

3.3 Study Population

The population comprised gravid Kenyan women at 37 to 41 completed weeks of gestation with low risk pregnancy that satisfied our criteria for inclusion into the study.

3.3.1 Inclusion Criteria

Parturients who met the following inclusion criteria were recruited:

- At term (37 weeks and 0 days to 41 weeks and 6 days of gestation)
- Had a low risk of intrapartum foetal hypoxia and lack of conditions (medical disorders) that predispose parturients to hypoxia such as Asthma, Cardiac disease, pulmonary embolism, Congenital anomalies pre eclampsia and eclampsia.
- Had a singleton pregnancy in the active phase of labour
- Able to provide informed written consent for inclusion in the study

3.3.2 Exclusion Criteria

Women with the following attributes were considered to have high risk of intrapartum foetal compromise and therefore were excluded from the study:

- Less than 37 and more than 41 completed weeks of gestation
- Previous uterine scars of caesarean section and myomectomy
- Hypertensive disorders in pregnancy
- Diabetes (insulin dependent or gestational)
- Suspected IUGR
- Antepartum Hemorrhage
- Multiple pregnancy
- Fetal malformation
- Breech presentation
- Rhesus isoimmunisation

3.4 Sample Size Determination

To calculate a sample size that reflects 80% power and a standard error of 5% (95% confidence level), we used published data from David *et al*. (2018) using the statistical formula cited by Donner (32).

$$n = \frac{2\left(z_{1-\alpha_{/2}}\sqrt{2\bar{p}(1-\bar{p})} + z_{1-\beta}\sqrt{p_c(1-p_c)+p_a(1-p_a)}\right)^2}{(p_c - p_a)^2}$$

We assumed that:

- The proportion of women who undergo CS after cardiotocography is 47%
- The proportion of women who undergo CS after intermittent auscultation is 18%.
- Statistical power of 80%
- Ratio of participants in IA versus ACTG arm of 1
- Risk ratio of 2.61

To get data with sufficient power (80%), we required a sample size of 80 parturients (40 in each arm). We assumed a response rate of 80% and the sample size was adjusted to 96 women (20% adjustment) to cover for attrition and loss to follow-up of participants and resulted in at least 48 women per arm.

3.5 Study Flow Chart

**Obstetric Outcomes – Maternal C/S rates and ICU Admissions*

***Neonatal Outcomes – APGAR score, Admission to NBU/NICU, Neonatal Death (within 48 hours, and HIE*

3.6 Sampling Procedure

Patients who were admitted at the KNH labour ward scheduled for a routine FHR examination were approached and the objectives of the study explained. The demographic and medical characteristics were evaluated, consent administered, and 100 patients selected randomly. Then recruitment into IA and ACTG study arms was done using a two-stage process. Random numbers from 1-100 were generated, coded as either CTG or IA arm. The assignment of each subject was swapped with the group assignment of a randomly selected participant and the step repeated twice to ensure optimal randomisation. Finally, the unique numbers (with the corresponding groups) was ordered sequentially from 1 to 100 in an Excel spreadsheet (year 2013) and patients allotted to the study groups sequentially by the PI.

3.7 Data Variables

3.7.1 Outcome Variable

The obstetric and neonatal characteristics of parturients after FHR assessment with ACTG or IA were the outcomes of our study. Under obstetric outcomes we evaluated the need for caesarean section deliveries by parturients in both study arms. Moreover, after a 24-hour follow up, we evaluated the occurrence of adverse maternal outcomes such as a need for ICU admission, mortality. The main neonatal outcomes that we evaluated were Apgar score of neonates at five minutes, the need for admission in NICU, NBU, and neonatal death. Finally, the incidence, severity and staging of HIE were interpreted as:

- **Mild:** hyper-alertness, hyper-reflexia, dilated pupil, tachycardia, absence of seizures
- **Moderate:** The presence of miosis, bradycardia, convulsions, lethargy, hyperreflexia, and hypotonia with weak reflexes
- **Severe:** Coma, flaccidity, small to mid-sized pupils poorly reacting to light, reduced stretch reflexes, hypothermia, and absent moro reflex (Sarnat, 1979)

3.7.2 Independent Variables

The main independent variable was the diagnostic procedure for FHR assessment that parturients are subjected to. Depending on their allotment, participant underwent either ACTG or IA for monitoring of FHR. Other independent variables were the age, gestation at birth, parity, gravidity, occupation, and level of education of parturient (Table 1).

Table 1: Summary of Outcome and Independent Variables

Outcome variables	Obstetric outcomes	Caesarean section
		Operative vaginal delivery
		Admission to ICU
		Maternal Mortality
	Neonatal outcomes	Apgar score at 5 minutes
		NBU admissions
		NICU admissions
		Neonatal Deaths
		HIE
Independent variables	Age	Age in years
	Weight	Weight in kilograms
	Gestation	Gestation in weeks
	Education level	Primary
		Secondary
		Tertiary
	Occupation	Employed
		Unemployed

3.8 Data Collection Procedures

3.8.1 Enrollment of Participants

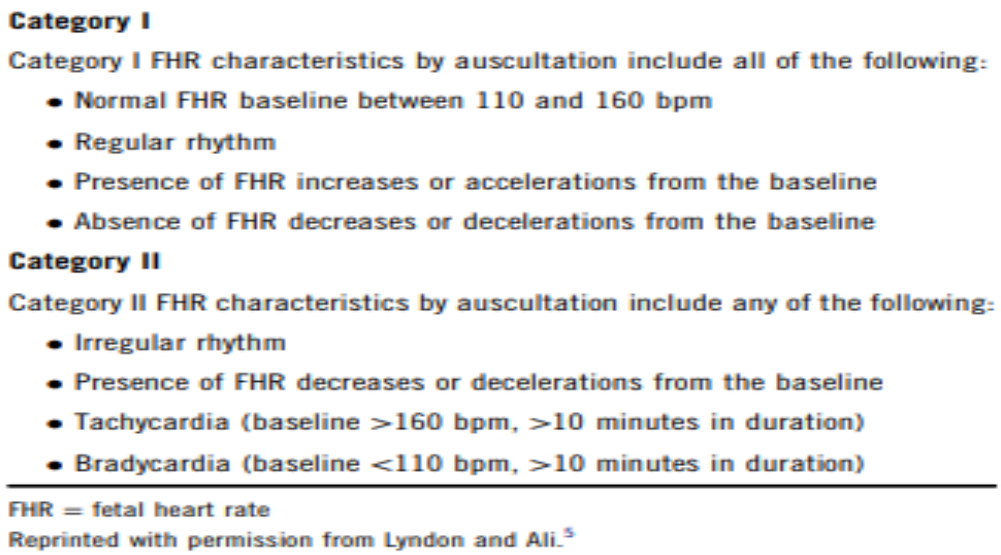
Parturients admitted at KNH labour ward for delivery at 37-41 completed weeks of gestation and willing to participate were enrolled in the study, by the research assistant who checked the health and reproductive information of parturients and consent was administered to all women who meet our criteria for inclusion. During consenting, the objective of the study was explained in English or Kiswahili and a question and answer session held between the parturients and research assistant. The concerns of all parturients were addressed, written consent for inclusion sought, and parturients enrolled in either ACTG or IA arms of the study after a two stage randomization process that resulted in random numbers representing different study arms into which parturients were allocated.

3.8.2 Data Collection

Trained research assistants collected quantitative data using a questionnaire. The tool was pretested and organized into four sections that capture unique sets of data. After inclusion, a research assistant recorded the sociodemographic characteristics of women (age, marital status, and occupation) in section one of the questionnaire and the health and reproductive attributes of parturients (weight, parity, and gravidity) in section two of questionnaires. Women allotted to the study arms underwent ACTG or IA during the assessment of FHR, following standard protocols.

3.8.2.1 Intermittent Auscultation (IA) Procedure

After performing Leopold maneuver to determine the foetal presentation and position, the parturient was positioned supine and uterine contractions assessed by palpation. A Pinard fetoscope was then placed on the anterior abdominal wall over the palpated position of foetal thorax or abdomen and baseline FHR determined by listening between contractions and when no foetal movements were palpable. In cases where the FHR was low or similar to maternal pulse, FHR was reassessed by counting while palpating the maternal pulse. Afterward, FHR was enumerated for one minute after a contraction and every 30 minutes during the first stage of labour and 5 minutes in the second stage of labour and recorded on a partograph and questionnaire. Women in IA arm underwent the normal admission procedure at KNH. However, if FHR was not within the normal range, the auscultation duration was increased to cover a minimum of three uterine contractions for at least 30 seconds after the contraction and IA interpreted according to Lyndon *et al.* (2009) (**Figure 2**).



Category I

Category I FHR characteristics by auscultation include all of the following:

- Normal FHR baseline between 110 and 160 bpm
- Regular rhythm
- Presence of FHR increases or accelerations from the baseline
- Absence of FHR decreases or decelerations from the baseline

Category II

Category II FHR characteristics by auscultation include any of the following:

- Irregular rhythm
- Presence of FHR decreases or decelerations from the baseline
- Tachycardia (baseline >160 bpm, >10 minutes in duration)
- Bradycardia (baseline <110 bpm, >10 minutes in duration)

FHR = fetal heart rate

Reprinted with permission from Lyndon and Ali.[5]

Figure 2: Interpretation of Intermittent Auscultation Findings

3.8.2.2 Admission Cardiotocography (ACTG)

After performing Leopold maneuver to determine the foetal presentation and position, the parturient was positioned supine and uterine contractions assessed by palpation. Patients were briefed on the procedure; the cardiotocogram switched on and the bio data of parturients fed in the CTG. The paper speed was set to 3 centimeters (cm) per minute. A thin layer of ultrasound gel was applied on the underside of the ultrasound transducer (records foetal heart rate) to ensure good contact and the transducer moved in a circular motion over the anterior abdominal wall at the palpated position of the foetal thorax or abdomen where foetal heart rate is best auscultated,. The transducer belt was positioned across the bed underneath the patients back and once a good audible signal was achieved, the transducer was fixed underneath the belt to minimize movement. FHR signals were compared to the maternal pulse periodically to ensure that only the FHR was being monitored. Toco-transducer (records uterine contractions) was also placed on the uterine fundus and immobilized by transducer belt to reduce movement. Finally, parturients were positioned to left lateral position and recording done for 20 minutes with simultaneous tracing on the cardiotocograph paper. Interpretation of the trace obtained was done according to RCOG/NICE 2017 guidelines (**Figure 3**).

Description	Feature		
	Baseline (beats/ minute)	Baseline variability (beats/ minute)	Decelerations
Reassuring	110 to 160	5 to 25	None or early Variable decelerations with no concerning characteristics* for less than 90 minutes
Non-reassuring	100 to 109† OR 161 to 180	Less than 5 for 30 to 50 minutes OR More than 25 for 15 to 25 minutes	Variable decelerations with no concerning characteristics* for 90 minutes or more OR Variable decelerations with any concerning characteristics* in up to 50% of contractions for 30 minutes or more OR Variable decelerations with any concerning characteristics* in over 50% of contractions for less than 30 minutes OR Late decelerations in over 50% of contractions for less than 30 minutes, with no maternal or fetal clinical risk factors such as vaginal bleeding or significant meconium
Abnormal	Below 100 OR Above 180	Less than 5 for more than 50 minutes OR More than 25 for more than 25 minutes OR Sinusoidal	Variable decelerations with any concerning characteristics* in over 50% of contractions for 30 minutes (or less if any maternal or fetal clinical risk factors [see above]) OR Late decelerations for 30 minutes (or less if any maternal or fetal clinical risk factors) OR Acute bradycardia, or a single prolonged deceleration lasting 3 minutes or more
Abbreviation: CTG, cardiotocography. * Regard the following as concerning characteristics of variable decelerations: lasting more than 60 seconds; reduced baseline variability within the deceleration; failure to return to baseline; biphasic (W) shape; no shouldering. † Although a baseline fetal heart rate between 100 and 109 beats/minute is a non-reassuring feature, continue usual care if there is normal baseline variability and no variable or late decelerations.			

Figure 3: Intrapartum NICE guidelines CG190 for CTG Interpretation of 2017

We generated generic tracings of different CTG anomalies and their interpretations that were then printed on a chart and the research assistants, admission nurses and clinicians were taken through to facilitate in interpretation of CTG. Standard Operating Procedures (SOPs) were developed and followed.

After examination, parturients in both arms were allowed to progress with labour and standard of care applied to both. Maternal outcomes (need for caesarean sections and or instrumental deliveries) and neonatal outcomes (APGAR scores at 5 minutes, NBU/NICU admission, and neonatal mortalities) 24 hours after the delivery were captured in sections five and six of the study questionnaire.

3.8.3 Data Analysis

Data analysis was done using version 21 of the Statistical Package for Social Scientists Software (SPSS). To establish the comparability of parturients who underwent ACTG and IA, sociodemographic and reproductive characteristics were compared at baseline using Chi square test for categorical variables and Independent sample t-test for continuous variables. Categorical data was visualised as proportions with odds ratios and continuous data

visualised as mean with standard deviations and confounders controlled using a logistic regression model during the definitive analysis. The mode of birth, the need for intrapartum interventions, and the maternal and neonatal outcomes were compared across study arms using Chi square test for categorical outcomes and independent sample t-test for continuous outcomes. The measures of association were the relative risk (RR) for categorical outcomes and t-static for continuous outcomes at a confidence level of 95%. $P<0.05$ were significant.

3.9 Ethical Considerations

3.9.1 Ethical Clearance

Permission to do this study was sort from the KNH/UON Ethics and Research Committee. We also obtained authorisation from KNH administration before the start of this study.

3.9.2 Informed consent

Every study participant voluntarily gave signed and informed consent for participating in the study. On determining eligibility, the consent form containing elaborate details of the research was shared with the parturients. If literate, and able to read she was allowed to do so herself or with assistance from a research assistant. If women were not been able to read, the research assistant or accompanying relative of their choice read the form for her in English or Kiswahili and made sure they understood the consenting process fully. Before appending their signatures or thumbprints, there was a question and answer session involving the research assistant and parturient. During the consent discussion, we:

- Explained the benefits and risk of the research
- Answered all queries and concerns of the research participant
- Deliberated on non-compulsory involvement
- Deliberated on the unconditional liberty to stop at any time
- Deliberated on the confidentiality of the parturient and their data

Women who accepted to be enrolled in the study signed two copies of consent forms (one for them and one for our record keeping). Signature and thumb impressions were allowed.

3.9.3 Confidentiality

In the course of the research and upon its completion the confidentiality of participants was upheld. When collecting data, identifiers were not featured on the collection tools. Dully-

signed consent form and questionnaires were stored securely using files in a case for future reference. Access to study tools was granted solely to the PI, statistician, and collaborators in the research study. Passwords were used to prevent unauthorized access to the database.

3.9.4 Adverse Events Reporting

Intermittent auscultation (IA) is a recommended procedure for monitoring the foetal heart rate (FHR) in low risk pregnancies. The procedure was safe, the standard of care and no adverse events were reported. According to Alfirevic *et al*. (2013), the methodology of IA has a limited ability to detect most late pathological FHR decelerations whenever decelerations fail to reach the nadir before a foetal contraction ends. When this happens, women have a high risk of delivering asphyxiated babies following a reassuring accelerative pattern during clinical diagnosis. To minimize the risk of unexpected asphyxia, FHR and contractions were recorded at baseline; auscultation was before and after contractions or from contraction to contraction; and interpreted after each contraction in reference to our baseline. The simple improvement in IA methodology has been reported to increase the ability of IA to detect late foetal decelerations, therefore ameliorate the risk of asphyxia, and increase the safety of both the parturients and neonates (Grivell *et al*. 2015).

Like the IA protocol for FHR analysis, cardiotocography (CTG) is a safe medical procedure and generally risk averse. However, its propensity to limit the movements of the parturients in labour has been reported. Prolonged monitoring of parturient in the supine position was avoided to lower the risk of aortocaval compression by the uterus that may lead to deprivation of foetal oxygenation and perfusion. Other adverse effects of this form of foetal assessment may include consequences of false negative results, inappropriate interpretation, and subsequent false reassurance of foetal well-being for the mother and the health practitioner. In addition, in the case of a false positive result, unnecessary procedures or interventions for mother or foetus and increased use of healthcare resources are common. This was mitigated by having study Sops on CTG monitoring and interpretation.

Research assistants with medical training were responsible for capturing and reporting all adverse events for patients recruited in the study. Before the start of the definitive study at the KNH labour ward, all research assistants attended a mandatory training on the study protocol and reporting of adverse events. They were also taught on how to make judgment about the severity of adverse events and how to fill the study-specific adverse event reporting form in

Appendix III. The form captured the date and site of occurrence of adverse events. It also captured the severity of the reaction, its probable causality, and the action taken to prevent it from worsening. Adverse events were to be reported to the PI immediately.

3.10 Limitations of the Study

There was minimal variability in the interpretation of CTG between different health care workers. To minimise bias, we followed the Standard operating procedures for CTG interpretation and charts available highlighting various CTG patterns and their interpretations. Interpretations were guided by IA and ACTG protocols highlighted in **Figure 2** and **Figure 3** above. Follow up ended 24 hours after delivery. Therefore, pregnancy outcomes (maternal and neonatal) occurring after the 24-hour follow-up time were not evaluated nor captured.

3.11 Study Results Dissemination Plan

Findings of this study would offer guidance in health policy formulation in maternal care and intrapartum foetal monitoring in Kenya. We will publish the research findings in peer-reviewed journals. Research data was presented at the Reproductive health department of the University of Nairobi and KNH, and will be shared in local or international research meeting and at Kenya Obstetrical and Gynecological Society (KOGS) conference.

CHAPTER FOUR

4 RESULTS

This study investigated obstetric and neonatal outcomes of 100 women in labour 50 of whom underwent ACTG and 50 Intermittent Auscultation of foetal heart sound at KNH labour ward

4.1 Study Flowchart

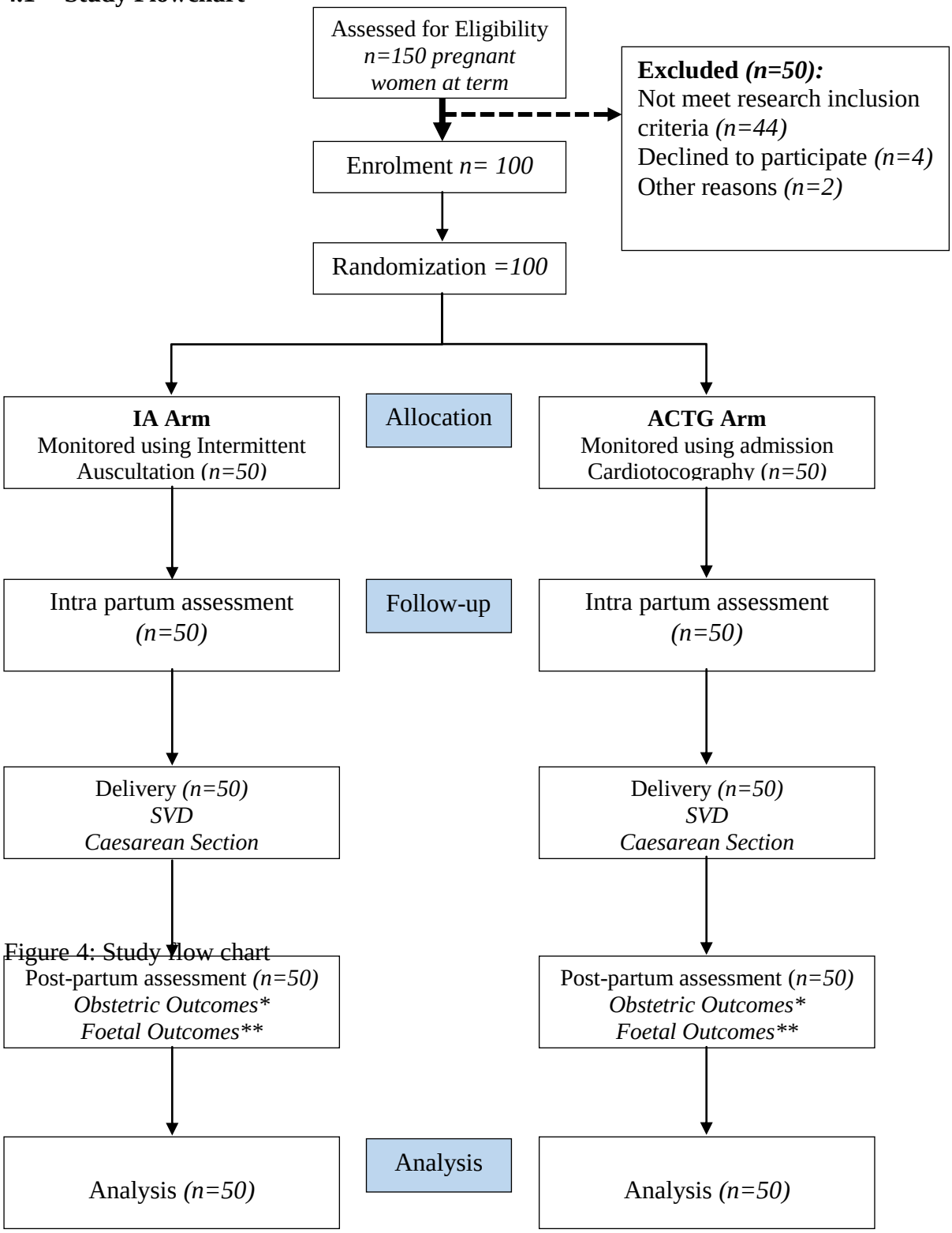


Figure 4: Study flow chart

4.2 Demographic, Reproductive, and Medical Characteristics

The mean age was 27.4 (SD=6.3), range 19 to 42 years, median 27.0 years, and an Inter Quartile Range (IQR) of 10. In auscultation arm the mean age was 26.8 (SD=5.8) years, range 19 to 40 years, and median 25. In the CTG arm, the mean age was 27.9 (SD=6.7), range 19 to 42 years, and median 27 years. Age did not vary statistically between women who underwent a CTG and IA p=0.385.

In Auscultation arm, 10 (20.4%) patients had a primary level education, while 19 (38.8%) and 20 (40.8%) had a secondary and tertiary education respectively. In the CTG arm, 5 (10.0%) had a primary level education, while 23 (46.0%) and 22 (44.0%) had secondary and tertiary level education respectively. The level of education of women who underwent a CTG versus IA did not very statistically (p=0.344).

In auscultation arms, 28.0% (14/50) were employed, while 56.0% (28/50) and 16.0% (8/50) were unemployed and self-employed respectively. In the CTG arm, 16.0% (8/50) were employed, while 54.0% (27/50) and 30% (15/50) were unemployed and self-employed respectively (Figure 7). Occupation was comparable in the two arms, p = 0.151.

In the auscultation arm, the mean gravidity was 1.9 (SD=1.1), range 1-5, and median 2. In the CTG arm, the mean gravidity was 1.9 (SD=1.1), range 1-5, median 1.5 (Figure 8). The gravidity of parturients in arms was comparable (p=0.92).

In auscultation arm, mean gestation (in weeks) was 39 (SD=1.9), range 37-41 weeks, and median 39 weeks. In CTG arm, mean gestation in weeks was 39.3 (SD=1.9), range 30-41 weeks, and median 40 weeks (Figure 9). Gestation was comparable (p=0.361).

In auscultation arm, mean cervical dilation on admission was 5.2 centimetres (SD=1.1), range 4-7 centimetres, and median 5 cm. In CTG arm, mean cervical dilation on admission was 4.6 cm (SD=0.8), range 4-7 centimetres, and median 5 centimetres. Cervical dilation on was significantly higher in the auscultation arm by 0.4 centimetres (p=0.037).

In IA arm, 34% (17/50) did not have membranes on admission while 28% (14/50) and 38% (19/50) had flat and bulging membranes. In CTG arm, 33.3% (16/48) lacked membrane on admission, while 39.6% (19/48) and 27.1% (13/48) has flat and bulging membranes (Figure 11). The state of the membrane on admission was comparable between arms (p=0.39).

Meconium staining was found in 20.4% (10/49) and 22.9% (11/48) of parturient in the IA and CTG arm respectively, p=0.764. In the auscultation arm, 50.0% (5/10) and 50.0% (5/10) of patient with meconium stained liquor had grade I and II staining respectively. In CTG arm, 54.5% (6/11), 36.4% (4/11), and 9.1% (1/11), had grade I, II, and III staining (Table 2).

Table 2. Demographic and reproductive characteristics of women who underwent IA and ACTG at KNH in 2019

		IA	CTG	P
Age	(median, range)	(25, 19-40)	(27.9, 19-42)	0.38
Education	Primary	10 (20.4)	5 (10.0)	
	Secondary	19 (38.8)	23 (46.0)	0.34
	Tertiary	20 (40.8)	22 (44.0)	
Employment status	Employed	14 (28.0)	8 (16.0)	
	Unemployed	28 (56.0)	27 (54.0)	0.15
	Self employed	8 (16.0)	15 (30.0)	
State of membrane	Absent	17 (34.0)	16 (33.3)	
	Flat	14 (28.0)	19 (39.6)	0.39
	Bulging	19 (38.0)	13 (27.1)	
Meconium staining		10 (20.4)	11 (22.9)	0.76
Grade	I	5 (50.0)	6 (54.5)	0.56
	II	5 (50.0)	4 (36.4)	
	III	0 (0.0)	1 (9.1)	
Gravidity	(median, range)	(2, 1-5)	(1.5, 1-5)	0.92
Gestation	(median, range)	(39, 37-41)	(27.9, 19-42)	0.36
Age	(median, range)	(5, 4-7)	(5, 4-7)	0.05

4.3 Fetal Heart Rate Monitoring

4.3.1 Auscultation

Of the 50 auscultated patients, 98% (49/50) had regular foetal heart rate. The Mean FHR was 136.7 bpm (SD=6.1); range 120-151 bpm, and median 137 bpm (Figure 5).

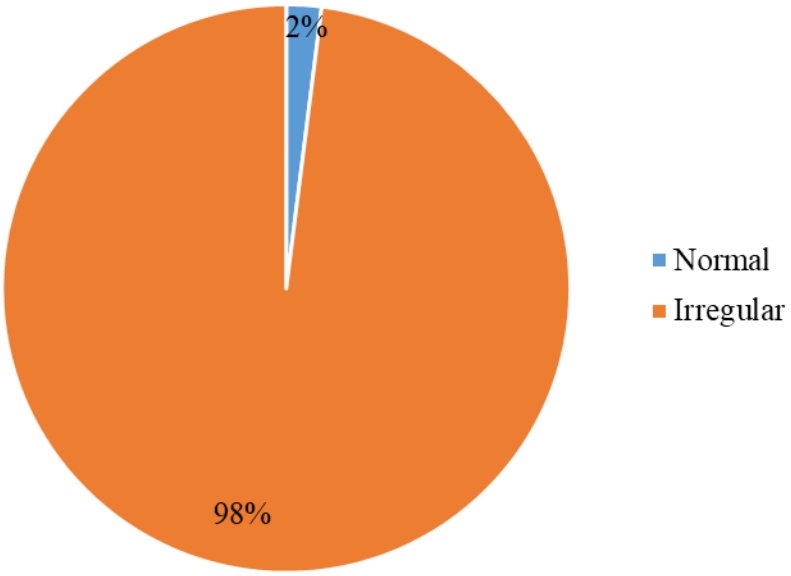


Figure 5: Outcome of Intermittent auscultation examination

A follow-up CTG was required for 10% (5/50) of women who underwent IA. Approximately 40% (2/5) were normal, while 40% (2/5) and 20% (1/5) were suspicious and pathological respectively (Table 3).

Table 3: Requirement for CTG after IA during delivery at KNH Labour

	N	%
Need CTG after IA	5	10.0
Normal	2	40
Suspicious	2	40
Pathological	1	20

4.3.2 Cardiotocography (CTG)

Fifty (50) parturients who were examined using ACTG, 80% (40/50) had normal CTG findings (Figure 6). Ten (10) had a suspicious CTG and repeat CTG was done for 40% (4/10) parturients of which 50% (2/4) were normal and 50% (2/4) suspicious. Overall, 84% (42/50) had normal CTG findings.

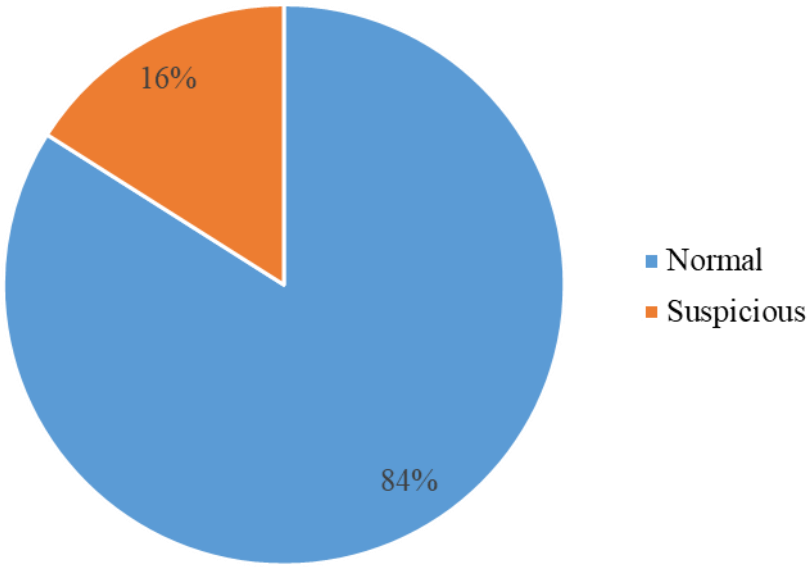


Figure 6: CTG findings of women in labour at KNH

4.4 Intrapartum interventions

ARM was required for 54% (27/50) of women who underwent IA and 46.9% (23/49) ACTG. Even though patients who underwent a CTG had a 10% more risk of ARM, this was not statistically significant (RR=1.1 (0.7-1.7), p=0.48). Of the 44 auscultated women who had a spontaneous vertex delivery, 1.6 times more patients who underwent IA required a vacuum assisted delivery but the difference was not statically significant (RR=1.6 (0.7-3.8), p=0.379). Fewer patients in the IA group 14.0% (6/43) than CTG 15.6% (5/32) needed episiotomy, but not statistically significantly (RR=1.0 (0.5-2.1), p=0.84) (Table 4).

Table 4. Intrapartum interventions of women who underwent IA and CTG at KNH labour ward

	Study Arm			
Intervention	IA	CTG	RR (95% CI)	P
Artificial Rupture of Membranes	27 (54.0)	23 (46.9)	1.1 (0.7-1.7)	0.48
Vacuum spontaneous delivery	1 (2.3)	2 (6.3)	1.6 (0.7-3.8)	0.37
Episiotomy	6 (14.0)	5 (15.6)	1.0 (0.5-2.1)	0.84
Caesarean section	5 (10.0)	15 (30.0)	0.4 (0.2-0.9)	0.01

4.5 Maternal Outcomes

Incidence of perineal tears was 30.0% (15/50) in IA arm and slightly higher in the ACTG arm at 34.0% (17/50), but the 4% difference was not statistically significant (P=0.66). Of the 15 patients in IA arm who developed perineal tears, 80% (12/15) had grade I perineal tears. Two

(13.3%) grade II and one (6.7%) grade III perineal tears. Of the 17 patients in the ACTG arm who had perineal tears, 76.5% (13/17) had grade I tears, while 17.6% (3/17) grade II and 5.9% (1/17) grade III perineal tears. Even though the RR of having a grade II (0.80 (0.13-4.62)) and I (0.96 (0.22-4.07)) perineal tear was lower in the IA arm. IA or CTG did not influence the grade of perineal tears statistically (P>0.05).

The incidence of PPH was 35% higher among patients who had IA that CTG but not statistically significantly (RR=1.35 (0.59-3.07)), p=0.55 (Table5).

Table 5. Maternal outcomes of women who underwent CTG and IA for FHR monitoring

	Study Arm			
	IA	CTG	RR (95% CI)	P
Caesarean section	5 (10.0)	15 (30.0)	0.4 (0.2-0.9)	0.01
Indications				
Prolonged labour	4 (80.0)	7 (46.7)	3.2 (0.4-24)	0.19
NRFS	2 (40.0)	2 (13.3)	2.6 (0.6-11)	0.19
Obstructed labour	0 (0.0)	2 (13.0)	-	-
CPD	0 (0.0)	3 (29.0)	-	-
MSLI/II	0 (0.0)	5 (33.3)	-	-
Perineal tears	15 (30.0)	17 (34.0)	0.91 (0.58-1.41)	0.66
Grade I	12 (80.0)	13 (76.5)	0.96 (0.22-4.07)	0.95
Grade II	2 (13.3)	3 (17.6)	0.80 (0.13-4.62)	0.80
Grade III	1 (6.7)	1 (5.9)	-	Ref
Cervical tear	0 (0.0)	2 (4.0)	-	-
PPH	2 (4.0)	1 (2.0)	1.35 (0.59-3.07)	0.55
Vaginal wall hematoma	1 (2.0)	0 (0.0)	-	-

Caesarean deliveries were required for 30% (15/50) of patients who underwent ACTG and 10% (5/50) IA. The risk of undergoing a caesarean delivery was 1.7 times higher when patients had a CTG examination (p=0.012).

Of the five parturients who has IA and Caesarean section was done 80% (4/5) had prolonged labour while 40% (2/5) had NRFS. No parturient who underwent IA had obstructed labour, foetal bradycardia or CPD. Of the 15 women who underwent an ACTG and Caesarean section was done, 46.7% (7/15) had a prolonged labour while 40% (2/5) had NFRS. CPD, MSLI/II, and obstructed labour were indications for 29.0% (3/15), 33.3% (5/15), and 13.0%

(2/15) respectively. Risk of prolonged labour, and NRFS did not vary statistically between women who underwent IA and CTG (p>0.05).

Among the 10 parturients who had a suspicious CTG, caesarean deliveries were required for 5 (50%) while 5 (50%) had a spontaneous vertex delivery. Even though women with normal CTG results were 0.77 times less likely to undergo a caesarean section, it was not statistically significant RR=0.77(0.53-1.14), p=0.12. In IA arm, one parturient had an irregular foetal heart rate pattern but had a spontaneous vertex delivery (Table 6).

Table 6. Caesarean section rates among parturients done IA and ACTG

	Auscultation		CTG			
	Regular	Irregular	Normal	Suspicious	RR (95% CI	P
Caesarean	5 (10.2)	0 (0.0)	10 (25.0)	5 (50.0)	0.77 (0.53-1.14)	0.12
Spontaneous	44 (89.8)	1 (100)	30 (75.0)	5 (50.0)		Ref

4.6 Neonatal Outcomes

In auscultation arm, 100% (50/50) of women had a live birth, while admission to NBU was required for 4.0% (2/50) of neonates. In CTG arm, 98% (49/50) women had a live birth, while NBU admission and NICU admission were higher at 10.0% (5/50) and 2.0% (1/50). Even though the risk of NBU admission and neonatal deaths were 0.55 and 0.66 time lower in the IA group, neonatal outcomes did not differ statistically (P>0.05) (Table 7).

Table 7: Adverse Neonatal Outcomes among Women Who Underwent CTG and IA

		Study Arm			
		IA (n=50)	CTG (n=50)	RR (95% CI)	P
Birth outcomes	Live	50 (100)	49 (98.0)	-	-
	Still	0 (0.0)	1 (2.0)	-	-
Admission to NBU		2 (4.0)	5 (10.0)	0.55 (0.16-1.8)	0.240
Admission to NICU		0 (0.0)	1 (2.0)	-	-
HIE		1 (2.0)	0 (0.0)	-	-
Neonatal death		1 (2.0)	2 (4.0)	0.66 (0.13-3.3)	0.558

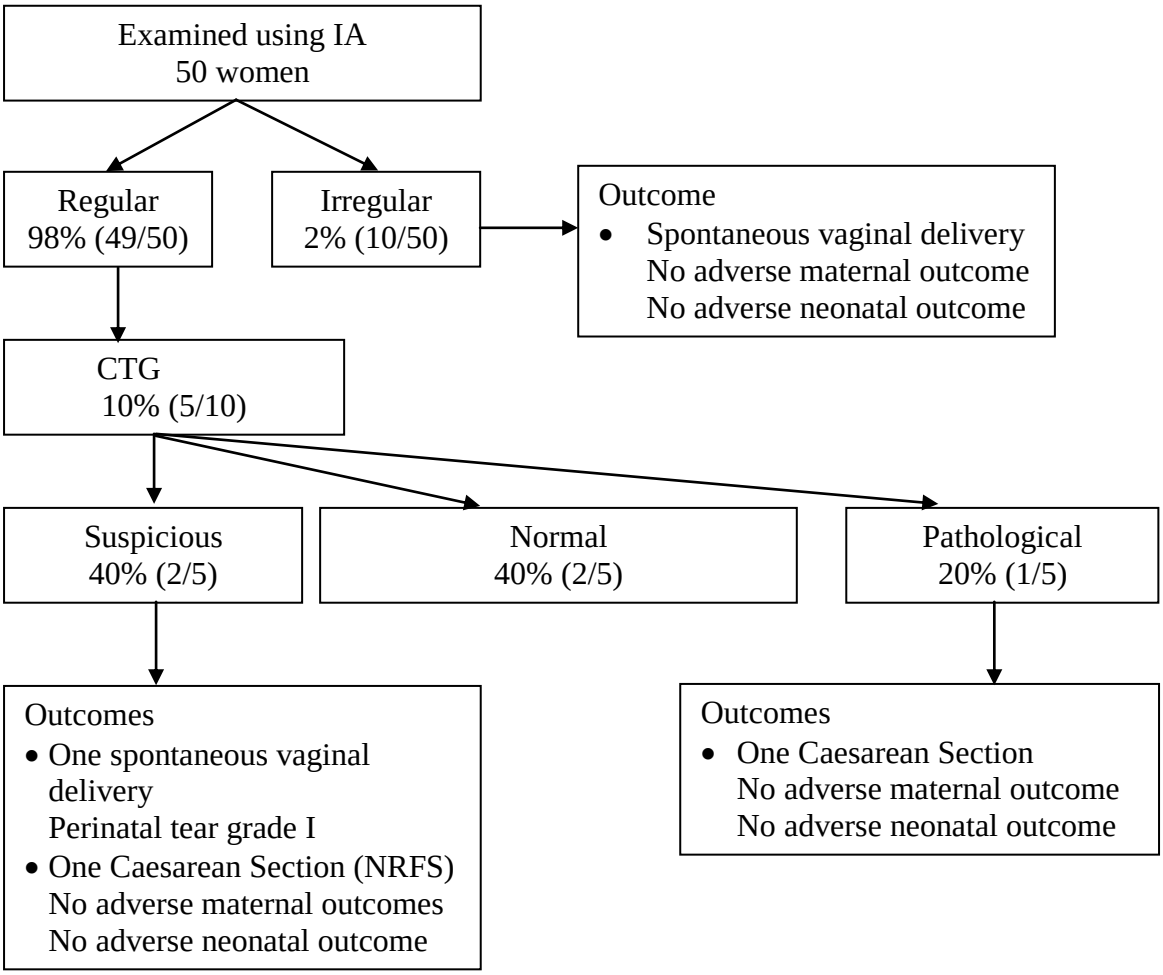
In the auscultation arm, the mean birth weight (in grams) was 31.95.8 (SD=427.4), range 2300-4100, and median 3200. In CTG arm, the mean birth weight was 3220.6 (SD=420.4), range 2310-4000, and median 3200. Birth weight was comparable in arms, t=-0.29, p=0.77. The mean Apgar score at 5 minutes was 9.2 (SD=0.82), range 6-10, and median 9 in the

auscultation arm. In CTG arm, the mean Apgar at 5 minutes was 9.1 (SD=1.5), range 0-10, and median 9. Apgar at 5 minutes was comparable in arms, t=0.65, p=0.52 (Table 8).

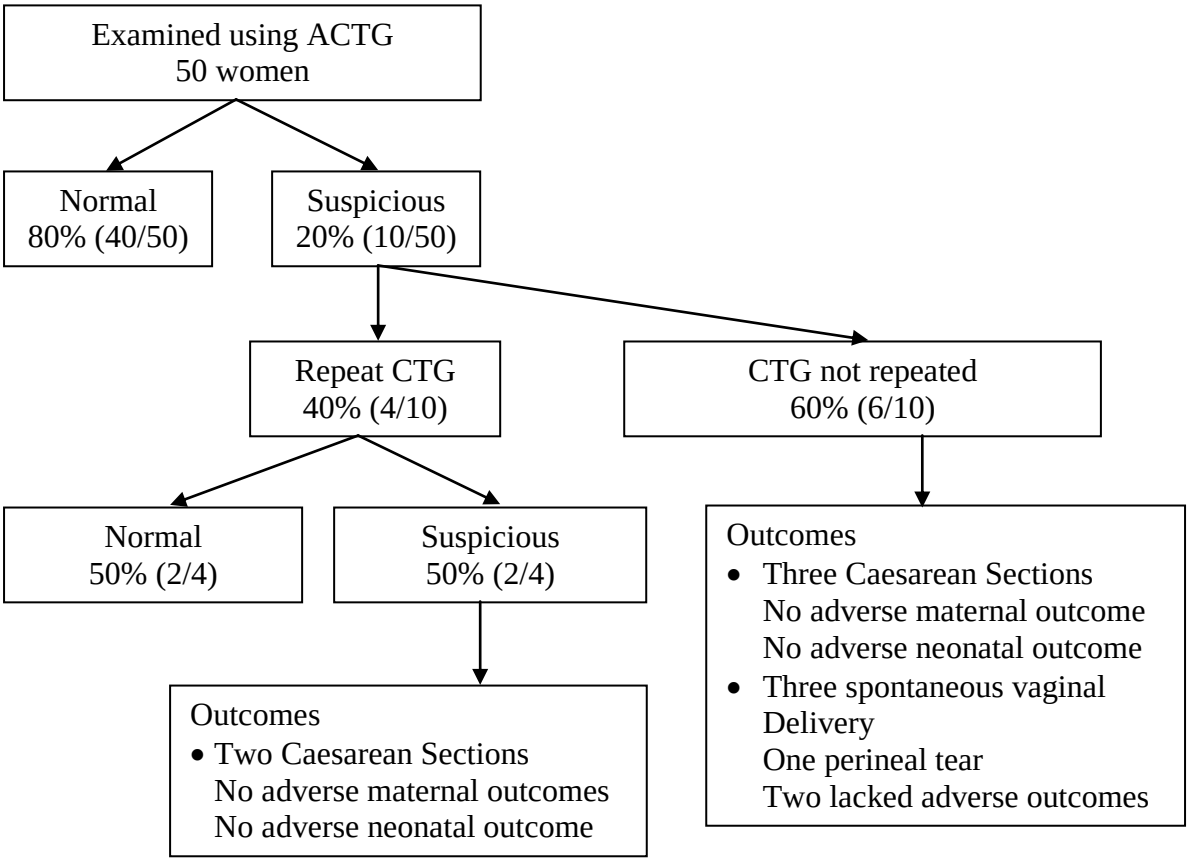
Table 8: Birth weight and Apgar scores of neonates of women who underwent CTG and IA

			t-test for Equality of Means				95% CI	
	F	P	t	df	P	Diff.	Lower	Upper
Birth weight	0.06	0.81	-0.29	98.00	0.77	-24.80	-193.05	143.45
			-0.29	97.97	0.77	-24.80	-193.05	143.45
Apgar at 1	0.43	0.51	-0.76	81.00	0.45	-0.15	-0.53	0.24
			-0.75	69.70	0.46	-0.15	-0.54	0.24
Apgar at 5	1.08	0.30	0.65	98.00	0.52	0.16	-0.33	0.65
			0.65	75.11	0.52	0.16	-0.33	0.65
Apgar at 10	0.04	0.85	0.11	81.00	0.91	0.01	-0.21	0.24
			0.11	78.76	0.91	0.01	-0.21	0.24

4.7 Summary of Intermittent Auscultation



4.8 Summary of ACTG Findings



CHAPTER FIVE

5 DISCUSSION

The sociodemographic and reproductive characters between the two study arms that is age, educational level, occupation, parity, gravidity, gestation, and cervical dilatation were comparable indicating effective randomization

The key findings of our study comparing IA and ACTG in 100 low-risk women presenting in active labour, did not provide significant differences in our measured outcomes both maternal and neonatal. However, among those examined using ACTG 20% (10/50) had suspicious CTGs and 40% (4/10) among them warranted a repeat CTGs resulting in 50% (2/4) with normal CTGs and 50% (2/4) with suspicious. Expedited delivery through caesarean section was done for the 100 % (2/2) of parturients with 2 consecutive suspicious CTG findings though neonatal outcomes among them were favourable with Apgar scores of ≥ 7 and no recorded maternal adverse outcomes. Among the parturients that were subjected to IA 2% (10/50) had irregular FHR while 98% (49/50) had regular FHR. Those with irregular FHR delivered vaginally with good maternal and neonatal outcomes, amongst those with regular FHR 10% (5/10) were subjected to a CTG and outcomes were suspicious CTGs 40% (2/5), Normal 40% (2/5), Pathological 20% (1/5). The parturient with pathological CTG had caesarean delivery with good maternal outcome and neonatal outcomes.

The caesarean rate amongst parturients done ACTG was 30% (15/50) compared to 10% (5/50) in IA arm RR 1.7 (1.2 – 2.4) p=0.012. Some caesarean sections were attributable indirectly to obstetric causes and as a result the high incidence among ACTG group is a result of both CTG findings and obstetric causes. Previous RCTs comparing ACTG vs. IA reported higher rates of caesarean sections in ACTG arm. Mires et al. 2001 reported caesarean rates of 3.6% and 5.1% (12) and Cheyne et al.2003 reported rates of 6.2% and 8.9% (10).

Impey et al 2003 had varied results whereby caesarean rate was equally at 4% across both IA and ACTG RR 1·13 (0·92–1·40) they concluded ACTG does not cause a large increase in the frequency of caesarean section or instrumental delivery in this population (10). The good maternal and neonatal outcomes in our study would be attributable to early interventions after either suspicious repeat CTG or pathological CTGs.

. Parturients who undergo ACTG have a likelihood of undergoing caesarean delivery 1.7 (1.2-2.4) p=0.012 a similarity to Gary Mires et al 2001 study that focused on low risk obstetric population findings been use of ACTG resulted in increased obstetric

intervention(12). This was the same picture in the study by Devane et al whereby women allocated to ACTG were 20% probably more likely to have a caesarean section than women allocated to intermittent Auscultation(9). Alfirevic et al in 2017 Cochrane review had similar conclusions that incidence of caesarean section was increased among those who underwent CTG (28).

Neonatal outcomes in our study did not portray statistically significant differences though there were 3 neonatal deaths in total across both study arms attributable to multiple congenital anomalies, severe birth Asphyxia with HIE and an undocumented cause. Mean apgar score at 5 minutes was 9.2 (SD=0.82) in the IA compared to 9.1 in ACTG arm. Admissions to NBU were slightly higher in the ACTG arm 10% Vis a Vis 4% in IA arm though not significant. Admission to NBU were 5 in ACTG arm and 2 in IA 5 after spontaneous vaginal delivery and 2 post caesarean section indications for admission been birth asphyxia. Outcomes between the two arms did not differ significantly indicating outcomes observed would be due to labour processes rather than mode of intrapartum foetal heart rate monitoring. Smith et al 2018 in a multicenter RCT found that there is no significant difference in neonatal outcomes(27). Our findings support current guidelines that advocate for use of IA for low risk parturients.

Rahman et al 2012 reported that ACTG may be helpful among low risk parturients in identifying a foetus at risk of intrapartum foetal hypoxia as a result of uteroplacental insufficiency they noted a low risk of foetal compromise in parturients with normal ACTG compared with equivocal and ominous ACTGs 6.9%, 39.9% and 84.6% respectively p=<0.001 (14). The benefits presumed in these studies did not reflect in our study since the neonatal outcomes were comparable between the 2 study arms.

The current clinical guidelines (ACOG, NICE, WHO) recommend use of Intermittent Auscultation among parturients at low risk of intrapartum hypoxia(12,29). ACOG in 2019 concluded that many obstetric practices including EFM are of limited or uncertain benefit for low risk women in spontaneous labour. Therefore obstetric care providers should practise low interventional approaches for the intrapartum management of low risk parturients (30).

Mean cervical dilatation in the IA arm was 5.2cm and in the ACTG arm 4.6cm, noted to be higher in the IA arm p=0.037 with no significant differences in the maternal and neonatal

outcomes. Meconium stained liquor (MSL) was 20.4% in the IA arm and 22.9% in the ACTG arm, among those with MSL in ACTG arm 36.4% had grade II and 50% grade II in IA arm. Despite been a significant number of parturients with MSL, Apgar Scores at 5 minutes averaged 9.2 IA and 9.1 ACTG. This findings concur with a study done by Kumari et al 2012 that revealed neonates exposed to meconium stained liquor, 62 (82.7%) were delivered with Apgar scores >7 and only 13(17.3%) babies were delivered with Apgar score <7 in one minute (31).

Operative vaginal delivery (vacuum) was needed for 2.3% of parturients in IA arm and 6.3% ACTG arm there was however no significant difference between the 2 arms. Our research findings are similar to findings from a Meta analysis that included 3 studies. Cheyne et al.2003that reported 8% (12/148) of women in the ACTG arm and 13% (21/164) women in the IA arm had vaginal instrumental delivery RR 0.63 (95% CI 0.32–1.22) with no statistically difference(10). Similarities were observed too in Impey et al. 2003 who reported that 11.5% (493/4298) of women in the ACTG arm and 11.1% (476/4282) of women in the IA arm had vaginal instrumental delivery, RR 1.03 (95% CI 0.92–1.16) with no statistically significant difference between the two arms(11). Mires et al 2001 had contradicting results that reported 21.2% (252/1186) of women in the ACTG arm and 17.2% (204/1181) of women in the IA arm had vaginal instrumental delivery thus the RR was 1.23 (95% CI 1.04–1.45) with statistically significant difference(12).

CONCLUSIONS

- Routine use of CTG amongst low risk parturients for FHR monitoring does not improve maternal or neonatal outcomes. This is in keeping with NICE, ACOG, WHO guidelines.
- Intermittent auscultation when appropriately used with adherence to recommendations for intrapartum care improves the accuracy of intermittent auscultation and is a good option in intrapartum fetal heart rate monitoring in LMICs.
- Among parturients who underwent ACTG there was increased likelihood of caesarean section with some attributable to obstetric causes.

5.1 RECOMMENDATIONS

1. To update and train health care workers involved in management of parturients on the standardized use of Pinard fetoscope and the benefits of use among low risk parturients.
2. To develop National protocols for intrapartum Fetal Heart Rate monitoring that will guide maternity units countrywide on indications of cardiotocography and intermittent auscultation.
3. Improve CTG equipment use and interpretation significantly reducing interobserver and intraobserver variability that may contribute to unnecessary interventions.

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APPENDICES

Appendix I: Consent Form

English version

OBSTETRIC AND NEONATAL OUTCOMES OF WOMEN IN LABOUR UNDERGOING ADMISSIONCARDIOTOCOGRAPHY VERSUS INTERMITTENT AUSCULTATION AT KENYATTA NATIONAL HOSPITAL

Introduction

Assessment of foetal wellbeing throughout labour and delivery is paramount to optimizing foetal outcomes. This study intends to evaluate obstetric and neonatal outcomes in the native African woman who undergoes either Admission Cardiotocography or Intermittent Auscultation at the Kenyatta National Hospital.

What is the purpose of this study

You are invited to participate in this study to assist us formulate guidelines for monitoring of foetal heart during labour. Your participation is important because you will help us to get valuable information on the delivery of health services to mothers.

Who can participate in this research?

All pregnant mothers who are admitted for delivery at the KNH labour ward and qualify for this study. However, to be considered your pregnancy should have a gestation of 37-42 weeks. You should also be of good health and agree to be a participant in the study.

Research Intervention

The intervention for our study will be an Admission Cardiotocograph used to electronically detect and chart the foetal heart rate in labour. Before examinations, we will brief you on the procedure and position you in supine orientation. We will then use a machine called a cardiotocogram with 2 transducers(one that will be coated with a thin layer of gel) that will be placed on your abdomen to check the heart rate of your baby and the intensity and duration of contractions. The procedure takes approximately 20 minutes.

Alternative Intervention

The alternative intervention will be Intermittent Auscultation, which doctors at KNH perform on women like you regularly. During this procedure, you will be positioned supine and a Pinard fetoscope used to detect the heart rate of your baby by placing on your abdomen. This will be done every 30 minuted during the first stage of labour and every five minutes once you are in the second stage of labour.

Is my participation mandatory?

Do not feel obliged to be a participant in this study – participation in strictly voluntary. It is your choice to be a participant or not.

Can I change my mind after agreeing to participate?

Yes, you are allowed to change your mind at any time even after you have agreed to participate in the study. However, even if you decide to withdraw from this study, you will receive all the services you are entitled to in the hospital.

What happens if I agree to enrol in study?

A trained nurse will help you to lie comfortably in the admission bed at KNH labour ward. The heart rate of your unborn child will then be monitored using ACTG or IA depending on the arm you have been allocated. You will then be allowed to progress with labour naturally and pregnancy outcomes such as caesarean rate, ICU, NBU, and NICU admission evaluated 24 hours after you deliver.

Risk and benefits

There are no risks. We will not draw blood or cause you pain in any way throughout the examination. However, the information you offer use will help up to develop strategies for safe monitoring of foetal heart rate in Kenya, which is beneficial to women like you.

Right not to participate and withdraw

Your participation in this study is completely voluntary, and you have the sole authority to decide for or against your participation in this interview.

Principle of compensation

We will not pay you to help us or will not pay for agreeing to participate in this study.

Whom may I contact for further information or to report my concerns?

You are free to ask questions or discuss your concerns with the research assistants, hospital staff of KNH and the principal investigator, Dr. Samuel Mumira, at 0721371160. You should also feel free to contact the chairperson of KNH/UON Research and Ethics committee through P.O.Box 20723-00202 or via telephone, (254-020)2726300-9 Ext44355, 44102.Email: uonknh_erc@uonbi.ac.ke

Consent:
If you agree to our proposal of enrolling you in our study, please indicate that by putting your signature or your left thumb impression at the specified space below
Thank you for your cooperation

_____	_____	_____
Name of Participant	Signature of the Participant	Date

	If the participant is illiterate/unable to write in that case please take her left thumb impression

_____	_____	_____
Name of the Interviewer	Signature of the Interviewer	Date

Kiswahili version

Formu ya Idhini: Kichwa: OBSTETRIC AND NEONATAL OUTCOMES OF WOMEN IN LABOUR UNDERGOING ADMISSION CARDIOTOCOGRAPHY VS INTERMITTENT AUSCLTATION AT KENYATTA NATIONAL HOSPITAL LABOUR WARD

Utangulizi
Tathmini ya ustawi wa foetusi wakati wa uchungu wa uzazi ni muhimu kwa kuboresha matokeo ya foetusi. Utafiti huu unatarajia kuchunguza matokeo ya ujaa uzito na foetusi katika mwanamke wa Kiafrika ambaye anafanyiwa Admission Cardiotocography au Intermittent Auscultation katika Hospitali ya Kitaifa ya Kenyatta.

Kusudi la utafiti huu ni nini?
Unaalikwa kushiriki katika utafiti huu ili kutusaidia kuunda miongozo ya ufuatiliaji wa moyo wa foetusi wakati wa kuzaa. Ushiriki wako ni muhimu kwasababu utatusaidia kupata maelezo muhimu juu ya utoaji wa huduma za afya kwa kina mama wajawazito.

Nani anaweza kushiriki katika utafiti huu?
Wanawake wajawazito ambao wanakubaliwa kwa ajili ya kujifungua kwa kata ya KNH ya ajira wanahitimu kwa ajili ya utafiti huu. Hata hivyo, kuchukuliwa yastahili mimba yako kuwa na ujauzito wa wiki 37-42. Unapaswa kuwa na afya njema na kukubali kuwa mshiriki katika utafiti huu.

Uingizaji wa Utafiti
Kuingilia kati kwa ajili ya utafiti wetu wa ACTG kutumika kuchunguza moyo wa foetusi. Kabla ya kipimo, tutakuelezea juu ya utaratibu na utakavyo lala wakati wa kipimo. Tutawaweka mashine inayoitwa cardiotocogram kwenye tumbo na kutumia vifaa viitwavyo transducer ili kusikiza na kujumuisha moyo wa foetusi na maumivu kwenye uterasi. Utaratibu huchukua dakika 20.

Uingizaji Mbadala
Uingizaji mbadala utakuwa uchunguzi wa moyo wa foetusi kutuimia kifaa kinachotumiwa na madaktari kwote ulimwenguni na KNH hutumiwa kwa wanawake kama wewe mara kwa mara. Wakati wa utaratibu huu, utalala chali na kifaa hicho(Pinard fetoscope) kitawekelewa tumboni na kutumika kuchunguza moyo wa foetusi. Shughuli hii itafanywa kila baada ya dakika 30 utakapokuwa na maumivu ya kuzaa kabla ya njia ya uzazi kufunguka centimetre kumi na baada ya dakika tano utapokuwa umehitimu kufunguka centimetre kumi.

Je! Kushiriki kwangu ni lazima?
Usihisi kwamba wajibu wa kuwa mshiriki katika utafiti huu ni lazima - kushiriki ni hiari yako na uchaguzi wako kuwa mshiriki au la.

Ninaweza kubadilisha mawazo yangu baada ya kukubali kushiriki?
Ndiyo, unaruhusiwa kubadilisha mawazo yako wakati wowote hata baada ya kukubali kushiriki katika utafiti. Hata hivyo, ukiamua kujiondoa kwenye utafiti huu, utapokea huduma zote unazostahili katika hospitali.

Nini kinatokea nitakapo kubali kujiandikisha katika utafiti?

Muuguzi mwenye ujuzi atakusaidia kulala chali kwa kitanda kilicho chumbani mwa kuzaa KNH kisha kiwango cha moyo wa foetusi kitahesabiwa kwa kutumia ACTG au IA kulingana na kikundi ulichopewa. Utaruhusiwa kuendelea na shughuli ya uzazi kama kawaida na matokeo ya uzazi kama vile upasuaji, kulazwa ICU, NBUau NICU itaorodheshwa masaa 24 baada ya kuzaa.

Hatari na faida

Hakuna hatari. Hatuta kuteka damu wala kusababisha maumivu yoyote katika utafiti huu. Habari utayochangia kwa utafiti huu utasaidia kuendeleza mikakati ya ufuatiliaji salama wa moyo wa foetusi nchini Kenya wakati wa ujaauzito na maumivu ya uzazi, ambacho kina manufaa kwa wajaawazito kama wewe.

Haki ya kushiriki na kujiondoa

Ushiriki wako katika utafiti huu ni kwa hiari, na una mamlaka ya kipekee ya kuamua dhidi ya ushiriki wako katika mahojiano haya.

Kanuni ya fidia

Hatutakulipa ili utusaidie au hatutalipa kwa kukubali kushiriki katika utafiti huu.

Ninaweza kuwasiliana na nani kwa maelezo zaidi au kutoa ripoti yangu?

Uko huru kuzungumza,kuuliza maswali na kujadili wasiwasi wako na wasaidizi wa utafiti, wafanyakazi wa hospitali ya KNH na mchunguzi mkuu, Dr. Samuel Mumira, katika 0721371160. Unapaswa pia kujisikia huru kuwasiliana na mwenyekiti wa kamati ya Utafiti na Maadili KNH / UON kupitia P.O. Box 20723-00202 au simu (254-020)2726300-9 Ext 44355, 44102 au barua pepe uonknh_erc@uonbi.ac.ke

Kibali:

Ikiwa unakubaliana na pendekezo lako la kujiandikisha katika utafiti wetu, tafadhali onyesha hivyo kwa kuweka saini yako au alama ya kidole gumba cha kushoto katika nafasi iliyochapishwa chini

_____ _____ _____

Jina la Mshiriki Sahihi ya Mshiriki Tarehe

☐ ikiwa mshiriki hajui kusoma ila kuandika, tafadhali ambatisha alama ya kidole gumba ya kushoto.

_____ _____ _____

Jina la Mhojiwaji Sahihi ya Mhojiwaji Tarehe

Appendix II: Study Questionnaire

OBSTETRIC AND NEONATAL OUTCOMES OF WOMEN IN LABOUR UNDERGOING ADMISSION CARDIOTOCOGRAPHY VS INTERMITTENT AUSCULTATION AT KENYATTA NATIONAL HOSPITAL

Questionnaire

Consent provided by participant

☐ **Yes** ☐ **No**

Study number**……. ……** Date of admission**……**

SECTION 1: SOCIODEMOGRAPHIC CHARACTERISTICS

1. Age in years: **……..**

2. Educational Level

☐ Primary ☐ Secondary ☐ Tertiary

3. Occupation

☐ Employed ☐ Unemployed

SECTION 2: REPRODUCTIVE CHARACTERISTRICS

4. Parity**……+…….**

5. Gestation**…….**weeks**…….**days ……

6. Cervical dilatation on Admission:

……cm Time…….

7. State of amniotic membrane on Admission

☐ **Absent**

☐ **Flat**

☐ **Bulging**

8. Spontaneous rapture of membrane

☐ **Yes**

☐ **No**

9. Artificial rapture of membrane

☐ **Yes** ☐ **No**

10. Meconium stained liquor Grade of Meconium

☐ **Yes** ☐ 1 ☐ 3

☐ .**No** ☐ 2 ☐ 4

SECTION 3: INTERVENTION

11. Study Arm:

☐ **A** ☐ **B**

12. Type of Intervention:

a) ☐ **Foetal Heart Rate by Intermittent Auscultation on Admission**

If yes rhythm

☐ Regular ☐ Irregular

Rate (Bpm)**…….**

Need for Cardiotocography during labour after Intermittent Auscultation

☐ **Yes** ☐ **No**

If yes, Cardiotocography findings

☐ Reassuring ☐ Non-Reassuring ☐ Abnormal

☐

b) ☐ **Admission Cardiotocography**

If Yes, status

☐ Reassuring ☐ Non-Reassuring ☐ Abnormal

Need for Cardiotocography during labour after admission cardiotocography

☐ **Yes** ☐ **No**

If yes, Cardiotocography findings

☐ Reassuring ☐ Non-Reassuring ☐ Abnormal

SECTION 4: MODE OF DELIVERY

13. Need for Caesarean Section

☐ Yes ☐ No

If yes indication of caesarean section**……**

14. Spontaneous Vertex Delivery Assisted Episiotomy

☐ Yes ☐ **Yes** ☐ **Yes**

☐ No ☐ **No** ☐ **No**

15. Operative vaginal/vacuum delivery

☐ Yes ☐ No

SECTION 5: NEONATAL OUTCOMES

16. Birth Outcome

☐ Live Male Infant ☐ Live Female Infant ☐ Fresh Still Birth ☐ Macerated Still Birth

17. Birth weight in grams **……...**

18. Apgar score at 5 minutes**……**

19. Need for Admission to New Born Unit

☐ **Yes** ☐ **No**

If yes Indication**……**

20. Admission to Neonatal Intensive Care Unit

☐ **Yes** ☐ **No**

If yes Indication**……..**

21. Hypoxic Ischemic Encephalopathy

☐ Yes

☐ No

If yes Sarnat Staging

☐ 1(mild)

☐ 2(moderate)

☐ 3 (Severe)

22. Neonatal Death

☐ **Yes**

☐ **No**

23. Cause of Death ……..

24. Other outcomes (specify) …….

SECTION 6: OBSTETRIC OUTCOMES

25. Admission to Intensive Care Unit

☐ **Yes** ☐ **No**

If Yes indication**…….**

26. Maternal Mortality

☐ **Yes** ☐ **No**

27. Other complications (specify) …….

Appendix III: Adverse Events Reporting Form

OBSTETRIC AND NEONATAL OUTCOMES OF WOMEN IN LABOUR UNDERGOING ADMISSION CARDIOTOCOGRAPHY VERSUS INTERMITTENT AUSCULTATION AT KENYATTA NATIONAL HOSPITAL

Adverse Event Reporting Form

Study ID ……. Date: ……

DIAGNOSIS……
…….....
.....

DESCRIPTION OF REACTION
……
……
……
…….....

PROCEDURE PRIOR TO THE EVENT

.....
.....
.....

Severity	*Action*	*Outcome*	*Causality of reaction*
☐Mild	☐Withdrawal	☐Recovering	☐Certain
☐Moderate	☐Increased	☐Recovered	☐Probable
☐Severe	☐Reduced	☐Hospitalised	☐Possible
☐Fatal	☐Unknown	☐Need intervention	☐Unlikely

Comments……
…….
…….
…….……

Reporting officer……. Date……
Email address…….. Phone……..
Title……. Signature…….

Appendix IV: ERC Approval

KENYATTA NATIONAL HOSPITAL APPROVED 14 AUG 2019 KNH/UoN-ERC P. O. BOX 20723 - 00202 NAIROBI

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Ref: KNH-ERC/A/309

14th August, 2019

Dr. Njihia Samuel Mumira
Reg. No.H58/ 80998/2015
Dept. of Obstetrics and Gynecology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Njihia

RESEARCH PROPOSAL: OBSTETRIC AND NEONATAL OUTCOMES OF WOMEN IN LABOUR UNDERGOING ADMISSION CARDIOTOCOGRAPHY VERSUS INTERMITTENT AUSCULTATION AT KENYATTA NATIONAL HOSPITAL (P376/05/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 14th August 2019 - 13th August 2020.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Protect to discover

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M.L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine,UoN
The Chair, Dept. of Obstetrics & Gynecology, UON
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