

**FETAL OUTCOMES AMONG PREGNANT WOMEN PRESENTING
WITH REDUCED FETAL MOVEMENTS AT KENYATTA
NATIONAL HOSPITAL: A CROSS SECTIONAL STUDY**

A RESEARCH DISSERTATION IN PARTIAL FULFILMENT

OF

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SUBMITTED BY

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LIST OF ABBREVIATION

ACOG	American college of Obstetric and Gynaecology
AIDS	Acquired immunodeficiency syndrome
APH	antepartum hemorrhage
BPP	Biophysical profile
CNS	Central nervous system
CTG	Cardiotocography
DBP	Diastolic blood pressure
DFM	Decreased fetal movements
DM	Diabetes mellitus
GBD	Gestation by dates
GB U/S	gestation by ultrasound
HB	Haemoglobin
H.I.V	Human immunodeficiency syndrome
FKC	fetal kick chart
FM	Fetal movements
FHR	fetal heart rate
IUFD	Intrauterine fetal death
KMTC	Kenya Medical Training College
KNH	Kenyatta National Hospital
NBU	Newborn Unit
NICU	Newborn intensive care unit
NRFS	Non reassuring fetal status
P.I.H	Pregnancy induced hypertension
pO ₂	Partial pressure of oxygen
PTB	Pulmonary tuberculosis
PROM	Premature rupture of membranes
SVD	Spontaneous vaginal delivery
VDRL	Venereal Disease Research Laboratory

DEDICATION

This book is dedicated to my wife Jepkorir, my daughter Jepkosgei and my son Tali.

To my mother Jerop whom I consider my first teacher in life

To my late father Kikwai Tali for purchasing books for me early in life especially the encyclopedia in standard seven

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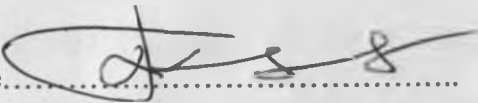
Special thanks to my supervisors, Dr. Guyo Jaldesa and Dr. Beatrice Anne Kihara for their support and guidance. It is through their dedication that I have come this far. All members of staff of the department of obstetrics and gynaecology including the chairman Prof. Koigi Kamau, all the consultants for their words of wisdom enriched with experience. To Dr. Kinuthia, your input was of much help.

I wish to appreciate the administration of Kenyatta National Hospital for allowing me to collect my Data in labour ward and antenatal wards. I also thank my research assistants, Jebet, Dome and Mwaniki for their good job. Special thanks to Francis Njiri for the data analysis.

Thanks to all my colleagues, fellow postgraduate students and all staff of Kenyatta National Hospital for the good interaction we had during my entire training period.

DECLARATION

This dissertation is my original work and has not been presented elsewhere. References to work done by others have been clearly indicated.

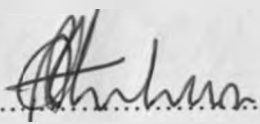
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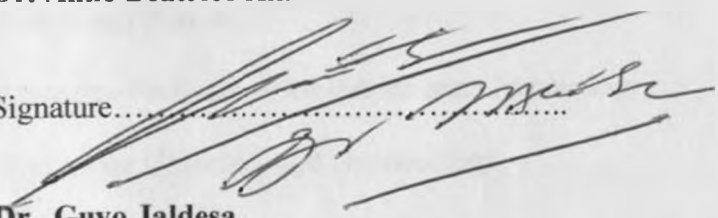
Approval:

This dissertation has been submitted with our approval as University of Nairobi supervisors:

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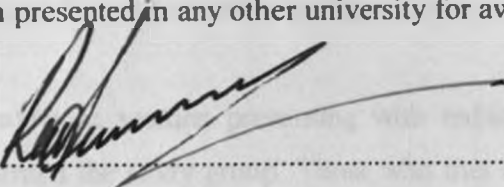
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CERTIFICATE OF AUTHENTICITY

This is to certify that this dissertation is the original work of Dr Kikwai Willey Kibet Master of Medicine student in Department of obstetrics and Gynaecology, Registration number H58/70975/2007 University of Nairobi (2007-2011). The research was carried out in the department of obstetrics and Gynaecology, School of Medicine, College of Health Sciences. It has not been presented in any other university for award of a degree.

Signature.....

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ABSTRACT

Background: Reduced fetal movement in pregnancy is a common cause of anxiety and admission of pregnant women. It is considered a high risk pregnancy with the fetus at risk of hypoxia and sudden death. Fetal surveillance is always indicated to assess the fetal wellbeing and to aid in opportune time of delivery.

Objectives: This study was undertaken to examine fetal outcome of mothers who presented with decreased fetal movements

Design: The study was hospital based descriptive cross-sectional study.

Study population: women presenting with reduced fetal movements at ≥ 34 weeks gestation formed the study group. Those who met eligibility criteria were consented and standardized structured questionnaire administered. The study subjects followed the standard operating procedure for Cardiotocography (CTG) and Biophysical Profile (BPP) as tools for fetal surveillance.

Setting: This study took place at Kenyatta National Hospital, the largest referral hospital in Kenya located in Nairobi.

Duration of the study: The study took 4 months to complete. The study was conducted between June-September 2010.

Data collection: Data was collected using a structured questionnaire. The questionnaire was administered by the principal researcher and three trained research assistants.

Data analysis: Data analysis was performed using Statistical Package for Social Scientists (SPSS Version 17.0). Proportions were estimated using simple frequencies. Multivariate analysis was performed using logistic regression to determine independent factors associated with poor obstetric outcome.

Main outcome measures: Apgar score at 5 minutes, resuscitation of the new born, admission to Newborn Unit (NBU), low birth weight, congenital anomaly and stillbirth.

Results

The newborns who had Apgar score of <4 at five minutes, congenital anomalies and fresh stillbirth were 1.3% each while 2% had macerated stillbirth and 3.3% had birth weight less than 2000. Newborns that had Apgar score of 4-7 at five minutes were 7.9% and similar proportion of the newborn were resuscitated, 8.6% were admitted to NBU and 14.5% had birth weight of > 3500.

Conclusion

Majority of pregnant women with reduced fetal outcome have good fetal outcome. Fetal surveillance improves fetal outcomes in women who present with decreased fetal movements

Recommendation

Fetal surveillance tools should be used routinely in all women with reduced fetal movements and they are best delivered by caesarian section if a risk is identified. Pregnant women with pregnancy induced hypertension and reduced fetal movements require close fetal surveillance because the risk to poor fetal outcome is significantly increased.

CHAPTER 1

INTRODUCTION AND LITERATURE REVIEW

Reduced fetal movement is a common indication for assessment of fetal wellbeing. Reduced fetal movement is considered as high risk pregnancy with the fetus at high risk of hypoxia and sudden demise. The situation is even more significant when pregnancy is complicated by diseases like hypertension, diabetes mellitus and anemia. There's evidence that raising maternal awareness of fetal movements leads to a decrease in perinatal mortality. Maternal perception of decreased fetal movements affects 5-15% of pregnancies and is associated with poor fetal outcome which include; asphyxia, growth restriction, preterm birth or death in 10.6 % of cases.¹⁻⁵

In 5% of patients who reported decreased fetal activity, the incidence of stillbirth is 60 times higher, the risk of fetal distress in labour 2 to 3 times higher, the incidence of lower Apgar score at delivery 10 times greater, and the incidence of severe growth restriction 10 times higher¹. It has been observed that the normal pregnancy does not decrease activity in the week before delivery. Using the Cardiff count to ten charts, Liston et al found that 60% of patients who reported decreased fetal activity did exhibit evidence of fetal compromise². The number of false alarm was manageable. In a study done by Sinha et al to review the outcome of women who presented primarily with reduced fetal movements and to compare with women of similar age and gestation who did not have reduced fetal movements (controls), he found that some 19% of intrauterine growth restricted babies were found in the study group, compared with none in the control group. In the study group, 32% of women needed intervention solely due to fetal compromise compared with 21% in the control group.³

Other studies found that 54.7% of cases of stillbirth women presented with reduction or absence of fetal movements before the diagnosis of Intra uterine fetal death (IUFD). It is therefore recommended that reduced fetal activity should be investigated thoroughly with formal measurement of fetal growth as part of the assessment.⁴

Fetal movements

The movements of the fetus are detected by the mother from 20 weeks. In the last 10 weeks of pregnancy they may be used as a crude measure of fetal wellbeing. Many women feel individual movements distinctly; they record these on a "count to ten" kick chart, which estimates how long it takes for the fetus to make 10 movements. In most cases this happens within the first hour or two of the observation period, but fewer than ten movements in 12 hours maybe an early warning sign of problem. ^{5,6,7}

Maternal perception of normal fetal movements has long been recognized as a reliable indicator of fetal wellbeing⁸. Nelsdam S. assessed the value of maternal monitoring of fetal movements in 2250 pregnant women. Half of the women were taught to count fetal movements methodically and contact the hospital if they felt less than 3 fetal movements (FM) per hour. There were 8 IUFD in infant weighing more than 1500g without major malformation in the control group and no death in the group with maternal monitoring of FM. These results demonstrate maternal monitoring of FM can aid opportune delivery of infant who are at increased risk of intrauterine death. ^{9,10}

A low daily fetal movement count (minimum 10 counts in 12 hours) is associated with a high incidence of fetal asphyxia, and when fetal death occurs, fetal movements rapidly diminished and stopped 12 to 48 hours before death¹¹. There are wide variations in the practice of Obstetricians and midwives with regard to women presenting with decreased fetal movements (DFM). Many aspects of practice are not based on the available evidence¹². At present, there is no evidence that any absolute definition of reduced fetal movements is of greater value than maternal subjective perception of reduced fetal movements in the detection of intrauterine fetal death or fetal compromise. Further investigation is required to determine an effective method of identifying patients with reduced fetal movements and to determine the best subsequent management. ^{10,13}

Evaluation of fetal movements

Studies performed using real time ultrasonography have demonstrated that during third trimester, the human fetus spends 10 % of its time making gross fetal body movements and that 30 such movements are made each hour¹⁴. The mother appreciates about 70 to 80 % of gross fetal movements¹⁵. The fetus does make fine body movements such as limb flexion and extension, hand grasping, and sucking, which probably reflect more coordinated central nervous system (CNS) function. However, the mother is generally unable to perceive these fine movements. Fetal movements appear to peak between 9.00 pm and 1.00 a.m, a time when maternal glucose levels are falling.^{14, 16}

In a study in which maternal glucose levels were carefully controlled with an artificial pancreas, hypoglycemia was associated with increased fetal movements¹⁷. Fetal activity does not increase after meal or after maternal glucose administration^{18, 19}. Using a sheep model, Natale et al demonstrated that fetal activity is extremely sensitive to a decrease fetal oxygenation. A small fall in fetal pO_2 was associated with a cessation of limb movements in the fetal lamb. In general, the presence of fetal movements is a reassuring sign of fetal health. However, the absence of fetal activity requires further assessment before one concludes that fetal compromise exist.²⁰

Fetal and placental factors that influence maternal assessment of fetal activity include placental location, the length of fetal movements, the amniotic fluid volume, and fetal anomalies²¹. If the placenta is anterior, maternal perception of fetal movements may be decreased. Movements lasting for 20 to 60 seconds are most likely to be felt by the mother²². Hydramnios reduces the mothers' appreciation of fetal activity. Hydramnios may be associated with a fetal anomaly and should be further evaluated using ultrasonography. 26% of fetuses with major malformations show decreased fetal activity compared with only 4% of normal fetuses. Anomalies of the CNS are most commonly associated with decreased activity.²³

Maternal factors that influence the evaluation of fetal movements include maternal activity, obesity, and medication. Mothers appear to appreciate fetal movements best

when resting on the left lateral recumbent position. Obesity decreases maternal appreciation of fetal activity. Maternal medication such as narcotic or barbiturate may depress fetal movements.^{21, 22}

Pregnancy induced hypertension was associated with fetal activity which significantly lower than controls at the beginning of third trimester and significantly higher at term²⁴. Marked reduced fetal movements in hypertensive are highly suggestive of fetal distress and following verification by additional test, the appropriate clinical measures should be undertaken.

Fetal surveillance methods

The goal of antepartum fetal surveillance is to prevent fetal death. Ante partum fetal surveillance techniques based on assessment of fetal heart rate patterns have been in clinical use for almost three decades. Women at high risk for stillbirth should undergo ante partum fetal surveillance using the nonstress test, contraction stress test, biophysical profile or modified biophysical profile.²⁵

Techniques of Antepartum Fetal Surveillance

Several techniques for ante partum fetal surveillance currently in use are discussed in the American College of Obstetric and Gynecology (ACOG bulletin)²⁶. These include fetal movement assessment, nonstress test, contraction stress test, fetal biophysical profile, modified biophysical profile and umbilical artery Doppler velocimetry. In this study, CTG and BPP shall be used to evaluate pregnancies with reduced fetal movements

Nonstress test

In the nonstress test, the heart rate of the fetus that is not acidotic or neurologically depressed will temporarily accelerate with fetal movement. Heart rate reactivity is believed to be a good indicator of normal fetal autonomic function. Loss of reactivity is commonly associated with a fetal sleep cycle but may result from any cause of central

nervous system depression, including fetal acidosis. Results of nonstress tests are classified as reactive or nonreactive. Various definitions of reactivity have been used. Most commonly, the nonstress test is considered reactive, or normal, if there are two or more fetal heart rate accelerations within a 20-minute period, with or without fetal movement discernible by the woman, according to ACOG²⁶. The nonreactive stress test lacks sufficient fetal heart rate accelerations over a 40-minute period. The nonstress test of the neurologically healthy preterm fetus is frequently nonreactive. From 24 to 28 weeks of gestation, up to 50 percent of nonstress tests may not be reactive, and from 28 to 32 weeks of gestation, 15 percent of nonstress tests are not reactive.

Biophysical Profile

The biophysical profile discussed in the ACOG bulletin is a nonstress test plus four observations made by real-time ultrasonography. The five components of the biophysical profile are as follows: (1) nonstress test; (2) fetal breathing movements (one or more episodes of rhythmic fetal breathing movements of 30 seconds or more within 30 minutes); (3) fetal movement (three or more discrete body or limb movements within 30 minutes); (4) fetal tone (one or more episodes of extension of a fetal extremity with return to flexion, or opening or closing of a hand; and (5) determination of the amniotic fluid volume (a single vertical pocket of amniotic fluid exceeding 2 cm is considered evidence of adequate amniotic fluid).

Each of the components is given a score of 2 (normal or present as defined previously) or 0 (abnormal, absent or insufficient). A composite score of 8 or 10 is normal, a score of 6 is equivocal and a score of 4 or less is abnormal. In the presence of oligohydramnios, further evaluation is warranted regardless of the composite score. This fetal surveillance shows acute fetal compromise.

Management protocol of reduced fetal movements

There is no universally agreed management protocol for clients who present with reduced fetal movement because the term reduced fetal movements is controversial and a universal definition has not been agreed upon. In a study done in all delivery units in

Eastern Norway. Standard procedures varied extensively; ultrasonography was used in 39.0% to 98.6% and Doppler in 4.5% to 74.6% of cases. There was an association between outcomes and the procedures used. Women who waited 24 hours with reduced or absent movements before contacting healthcare had increased risk. Among those with absent movements, 47% (42-52%) had such risk behavior⁷. All delivery units used a non-stress test when available, but few included ultrasound and Doppler examinations routinely. Five of 55 units advised women that absence of fetal movements up to 24 hours may be normal.

National guidelines and university curricula in Norway recommend that distinct reduction of fetal movements require investigation. Formal kick counting was regarded as either useful, recommended or to be dissuaded. Information for pregnant women emphasizes the importance of vigilance towards fetal movements, but has contradictory limits for normal fetal movements. There is a significant variation in clinical routines, which do not correlate with information given to pregnant women, the literature, or guidelines. This can lead to uncertainty for both pregnant women and health care professionals and may put patient safety at risk. There is a need for evidence-based guidelines.²⁷

The question faced by all professionals in antenatal care is when to accept that fetal movements have been reduced for long enough to warrant intervention. No-one has suggested that reduced fetal movements over 1 hour gives any concern, but all would agree that no movements felt at all over several days would be a serious symptom.²⁸

Cardiotocography would normally be included in an assessment of a woman referred to a maternity unit because of a reduction in perceived fetal movement, but surprisingly little evidence exists to support this form of further assessment. The fetal heart rate (FHR) is analyzed with respect to (a) the baseline, (b) variability, and (c) periodic patterns, including FHR accelerations and decelerations.

Category I (reassuring): Tracings with all these findings present are strongly predictive of normal fetal acid-base status and the fetus can be followed in a standard manner:

- Baseline rate 110-160 bpm.
- Moderate variability,
- Absence of late, or variable decelerations,
- Early decelerations and accelerations may or may not be present.

Category II (suspicious): Tracing is not predictive of abnormal fetal acid-base status, but evaluation and continued surveillance and reevaluations are indicated:

Category III (nonreassuring): Either tracing predicts abnormal fetal acid-base status; this requires prompt evaluation and management:

- Absence of baseline variability with recurrent late or variable decelerations or bradycardia; or
- Sinusoidal fetal heart rate.

The 2003 Cochrane review by Pattison and McCowan only includes four studies, all in high or intermediate risk pregnancies, dating between 1982 and 1985. No significant effect on perinatal mortality or morbidity was found^{28, 29}. Better assessment may depend on more modern techniques such as Doppler velocimetry,³⁰ or vibroacoustic testing.³¹ ³²In a brief communication in 2001, Berbey *et al* reported a statistically significant association between decreased fetal movements and several other prenatal or postnatal assessments of fetal wellbeing including Apgar score, but details of the study were sparsely reported and no attempt was made to link the data to outcomes of pregnancy.³²

JUSTIFICATION

Maternal perception of fetal movement is widely used as a marker of fetal viability and well being. Pregnancies with decreased fetal activity comprise a very high risk group. The clinical significance of a history of reduced fetal movements remains unclear, and assessment and management of these pregnancies is controversial.

Perception of reduced fetal movement causes concern and anxiety to the pregnant mothers and it is one of the causes of unplanned hospital visit and admission. Formal counting of fetal movement by the pregnant mothers could possibly identify the fetuses which are at risk of compromise thus allowing appropriate action to be taken.

Cardiotocography, and ultrasonography have been used for ante partum fetal assessment in pregnancies with reduced fetal movement and these tools are available at Kenyatta National Hospital. However evidence of clinical benefit is limited. Women presenting with reduced fetal movement do have a high risk of still birth, fetal growth restriction, fetal distress and preterm birth. No study has been done on reduced fetal movements at Kenyatta National Hospital and in Kenya as a whole to identify optimal management and outcome of mothers who present with reduced fetal movement. Furthermore, reduced fetal movements is one of the danger signs checked for in focused antenatal care to identify optimal management and ensure good fetal outcome.

The antenatal ancillary test performed in addition to maternal subjective counting of fetal movement has not been determined whether it adds value to the management and outcome. In view of current rise in medico legal issues, it imperative that mothers with reduced fetal movements are evaluated properly and appropriate management instituted to reduce chances of perinatal mortality. I therefore intend to provide baseline information on the outcome of these pregnancies and correlate with the ancillary test performed.

RESEARCH QUESTION

What is the magnitude of poor pregnancy outcomes for women presenting with reduced fetal movements at Kenyatta National Hospital?

OBJECTIVES

Broad Objective

To determine the pregnancy outcome for women presenting with reduced fetal movements at Kenyatta National Hospital.

Specific Objective

1. To determine the prevalence of poor fetal outcomes among women presenting with reduced fetal movements.
2. To describe the correlation of fetal outcomes with concurrent obstetric and medical complications
3. To describe the correlation of fetal outcomes with the fetal surveillance methods
4. To describe the correlation of fetal outcomes with mode of delivery

CHAPTER 2: STUDY DESIGN AND METHODOLOGY

Study design

This was a hospital based descriptive cross-sectional study.

Study Site and Setting

This study was carried out at Kenyatta National Hospital (KNH) labour ward, labour ward theatre, antenatal/ postnatal wards (wards; 1A, GFA and GFB). KNH is the largest referral hospital in Kenya and it is situated at the capital city, Nairobi. KNH also serves as a training facility for postgraduate and undergraduate students of the University of Nairobi. It is also used by Kenya Medical Training College (KMTC) to train students undertaking various diploma courses in the medical field. The hospital attends to referral patients and also acts as a primary hospital serving many inhabitants of Nairobi mainly of poor socioeconomic background. It is one of the only two public institutions providing tertiary delivery services in the city.

The department of Obstetric and Gynecology is staffed by consultants, registrars and nurses as technical staff. Each year an average of 9000 deliveries are conducted. The routine standard of care for a patient who presents with reduced fetal movements is: history and physical examination. Depending on the gestation, those who are term are delivered immediately while those who have not attained a term gestation are evaluated and managed appropriately by use of fetal kick chart (FKC), CTG monitoring, BPP, Doppler studies (figure 1). This is the standard operating procedure that this study followed. The consultants decide on time of delivery of preterm pregnancies based on CTG and BPP results. The care of patients in labour ward is done by registrars in consultation with consultants and formulated care plan is implemented by nursing staff who are trained midwives. Consultants ward round is done twice daily in the morning and evening while the registrar are available round the clock. Labour process is monitored by a partograph. The delivery room has two delivery beds and delivery is conducted by midwives. Maternity theatre is adjacent to labour ward with two operating tables. Emergency and elective caesarian sections are performed there. Registrar is

available to do emergency caesarian section and elective caesarian section is usually performed by the consultant on call.

Monitoring of these patients has been enhanced because the KNH labour ward has CTG machines and back up of ultrasound machines. This study concentrated on CTG and biophysical profile as method of fetal surveillance employed to evaluate pregnancies with reduced fetal movements. Two CTG machine are available in the labour ward at all times. Printed documental evidence of CTG tracings was availed in patients file when done. Two ultrasound machines are available at KNH Radiology department and further two ultrasound machines are available at University of Nairobi Radiology department. The University Radiology department operates between 8a.m – 5p.m while the KNH department is operational for 24 hours. BPP and Doppler studies are performed by Consultant Radiologist and Registrars in the radiology department. In addition, trained diploma holders in radiology are allowed to conduct the investigation. Reporting was done by the registrar or the consultant who performed the procedure and results were available within one hour of the procedure.

The newborn unit (NBU) at KNH is equipped with incubators and ventilators that are used in the management of newborn with respiratory problem. It also has several phototherapy machines. Patients admitted there are kept warm, put on oxygen, intravenous drugs and fluids as per needs. Neonatal intensive care unit (NICU) is available within the NBU and any newborn requiring intensive life support can be attended there. NBU has division to cubicles A, B, C, D and isolation. As neonate improves they are progressively moved from unit A to D. mothers are roomed in mothers' hostels and prenatal wards while awaiting their neonates and feed them 3 hourly in NBU. The pediatric registrar is always available at the time of delivery of high risk pregnancy in labour ward and labour ward theatre to receive the baby, evaluate and manage. The consultants perform daily rounds in NICU and twice weekly in other cubicles. There is a consultant daily on call to attend to difficulties that a registrar cannot handle.

Study participants' recruitment and enrolment

The study participants were recruited in labour ward at the time of admission. At KNH, all women with reduced fetal movements are admitted through labour ward for initial assessment before being transferred to antenatal ward. Pregnant women who presented with reduced fetal movements as a primary complaint and met the eligibility criteria were consented and routine standard care of management was followed.

Study Population

Pregnant mothers who presented with reduced fetal movements to KNH at ≥ 34 weeks gestation as a primary complaint formed the study population. At 34 weeks gestation, the lungs will have produced sufficient surfactant to maintain respiratory activity and active intervention will increase chances of fetal survival.

Inclusion criteria

1. singleton pregnancy
2. ≥ 34 weeks gestation
3. Mothers willing to give consent

Exclusion criteria

1. Intra-uterine fetal death

Sample size and Sampling Procedure

Sample Size

A search on journals could not yield any published study on reduced fetal movements in the region, and therefore it was difficult to know the true prevalence and outcome of reduced fetal movements. A study was done in Eastern Norway on reduced fetal movements estimated the prevalence of asphyxia, death, growth restriction or preterm birth to be 10.6% ⁵ It was assumed that the proportion of women with poor obstetric outcome will be ($p_1=10\%$) in the group with reduced fetal movements. At 95% ($z=1.96$) confidence interval using the Fisher's formula below for estimating proportions, the study need 138 participants. Adjusting for an estimated 10% loss to follow up the study recruited 152 women with reduced fetal movements.

$$n = z^2 p (1 - p) / e^2$$

$$e = 0.05$$

$$n = 1.96^2 \cdot 0.1(1-0.1)/0.05^2$$

$$n = 3.84 \times 0.1 \times 0.9 / 0.0025$$

$$n = 138$$

Sampling procedure

Convenient sampling was used in this study. All the 152 patients who met eligibility criteria and consented were enrolled consecutively. This sampling procedure was appropriate for this study because of the small proportion of the study group compared to general population. Furthermore selecting every patient who consented eliminated selection bias.

Data collection and Management

Recruitment of study participants and collection of data was done by three trained research assistants. The research assistants had been trained on how to do proper consenting, assess for eligibility criteria and proper filling of the questionnaire. All the registrars and nursing staff in labour ward and antenatal wards were appraised about the study before commencement.

Data was collected by use of a structured questionnaire which captured the objective of the study (Appendix 3). The structured questionnaire had relevant history on: social-demographics and current pregnancy. In addition it also had fetal surveillance results and fetal outcome. The outcome measures in this study were: Apgar score at 5 minutes, resuscitation of the newborn, congenital anomaly, low birth weight, admission to NBU and stillbirth. Data forms were kept in a secure lockable cabinet only accessible by the principal investigator. Data was entered daily into a password protected Ms Access data base. The Principal Investigator did data cleaning and validation after completion of data entry. The study procedure described below was followed.

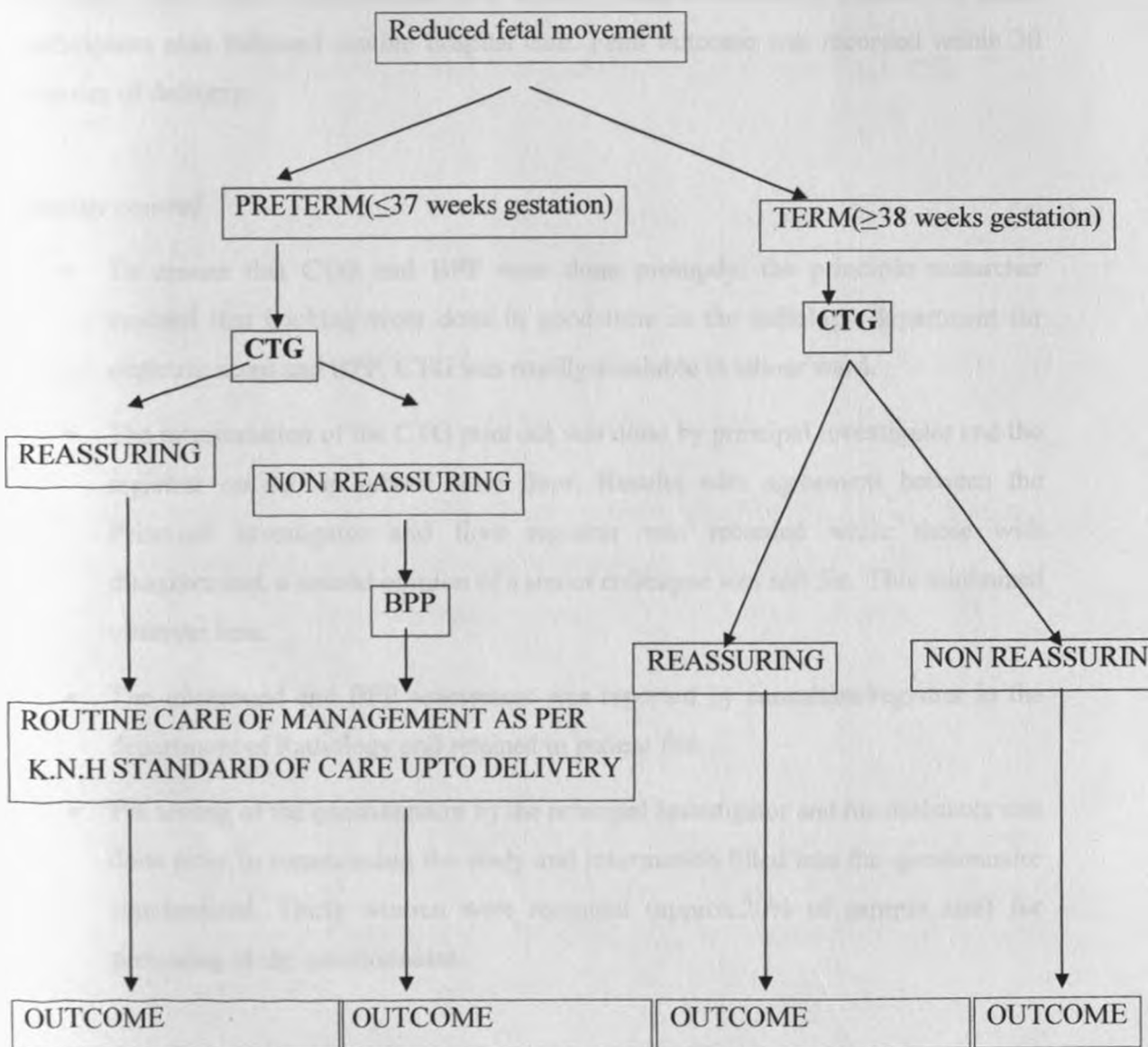
Study procedure (Standard Operating Procedure)

The principal researcher and the research assistants consented eligible study subjects and filled the questionnaire at 3 time points during the study: at recruitment, after fetal

surveillance and after the delivery of the baby. No new treatments or management was given to study participants by this study. All recruited patients were managed according to the routine standard of care at KNH as described under study site and setting section.

A colored sticker with serial number was put on the eligible subjects' file to avoid double recruitment. The recruitment process was done by the principle researcher and trained research assistants. Recruited participants' followed the management practice in figure 1

Figure 1: Management practice for patients with reduced fetal movements at KNH



NOTE.

1. *Clients with normal CTG are managed actively at term gestation or if there is previous history of poor obstetric outcome.*
2. *Clients with abnormal BPP are delivered.*

As per routine care, all study subjects with reassuring CTG and if preterm were followed up conservatively until delivery and if term delivery was commenced. On the other hand those with a non-reassuring CTG underwent an obstetric scan with BPP if preterm and delivered if term. Those with normal BPP were conservatively followed up until delivery, while those with abnormal BPP delivery were immediately. Delivery of study participants also followed routine hospital care. Fetal outcome was recorded within 30 minutes of delivery.

Quality control

- To ensure that CTG and BPP were done promptly, the principle researcher ensured that booking were done in good time in the radiology department for obstetric scans and BPP. CTG was readily available in labour ward.
- The interpretation of the CTG print out was done by principal investigator and the registrar on call in labour ward floor. Results with agreement between the Principal Investigator and floor registrar was recorded while those with disagreement, a second opinion of a senior colleague was sort for. This minimized observer bias.
- The ultrasound and BPP assessment was reported by consultant/registrar in the department of Radiology and retained in patient file.
- Pre testing of the questionnaire by the principal investigator and his assistants was done prior to commencing the study and information filled into the questionnaire standardized. Thirty women were recruited (approx.20% of sample size) for pretesting of the questionnaire.

- Filling of questionnaire was done at the time of patient recruitment, after fetal surveillance and after delivery.
- The investigator double checked the questionnaire after filling for completeness of information and to made necessary inclusions/corrections from the patient's file record.
- Data was entered on a daily basis and missing data was followed up immediately before the patient left the hospital.

Data Analysis

Data analysis was performed using Statistical Package for Social Scientists (SPSS Version 17.0).

Descriptive Analysis: data analysis was begun with the summaries of socio-demographic characteristics, patient's medical and obstetric history, fetal surveillance and fetal outcomes. These were presented descriptively in form of means or medians for continuous variables and proportions for categorical variables.

The prevalence of poor fetal outcomes was determined and correlated to the fetal surveillance.

Association of poor obstetric outcomes with concurrent medical illness, social history and obstetric complication in women presenting with reduced fetal movements was determined. Statistical associations with p-values ≤ 0.05 were considered statistically significant.

RESEARCH ETHICS

The department of obstetric and gynaecology gave clearance to the study. The study proposal was reviewed and approved by the Kenyatta National Hospital/ University of Nairobi Ethics Research Committee (KNH/UON-ERC). Permission from the Hospital management was also granted to conduct the study.

CHAPTER 3: RESULTS

There were 4337 admissions in labour ward and 174 had reduced fetal movements giving a prevalence of 4%. 152 cases of reduced fetal movement met eligibility criteria and were recruited into the study and none was lost to follow up.

3.1 Sociodemographic

Table 1: Age Distribution

Age group	N (%)
15-20	10(6.8%)
21-25	49(33.3%)
26-30	46(31.3%)
31-35	28(19.0%)
36-40	13(8.8%)
41-45	1(0.7%)

Most of the study groups were between 21 and 30 years. 14 (9.5%) women were above 36 years. The mean age was 28years and median age 27 (table 1)

Table 2: Drug Habits /medications Use

Drug habits/use	N (%)
Currently smokes	2(1.3%)
Consumes alcohol	2(1.3%)
No drug use	148(97.4%)

Only two women (1.3%) smoked cigarettes and consumed alcohol (table 2).

Table 3: Gestational Age of the Study Participants

Gestation	N (%)
34-37 weeks	44(29.1)
37-40 weeks	99(65.6)
>40 weeks	8(5.3)

Table 3 above shows that 99(65.6%) of the study participants had gestation age of between 37-40 weeks. Both mean and median gestation was 38 weeks.

Table 4: Obstetric and Medical Condition

Obstetrics complication	N (%)	Medical condition	N (%)
PIH	23(15.1)	HIV INFECTION	7(4.6)
APH	4(2.6)	DM	4(2.6)
PROM	2(1.3)	ASTHMA	2(1.3)
Other complication	4(2.6)	PTB	1(0.7)
None	119(78.3)	None	138(90.8)

The most common obstetric complication is pregnancy induced hypertension representing 15.1%. There were 4 (2.6%) cases of diabetes and antepartum hemorrhage (APH) each. 7 (4.6%) women had HIV infection. Respiratory tract diseases; 2 cases of asthma and 1 case of PTB (table 4)

Table 5: Antenatal Profile

Parameter	Results	N (%)
HB	<6	1(0.7)
	6-8	3(2)
	9-10	17(11.2)
	>10	110(72.4)
	Not tested	21(13.8)
Diastolic BP	<90	121(79.6)
	90-100	17(11.2)
	>100	6(3.9)
	Not tested	8(5.3)
Rhesus factor	Positive:	122(80.3)
	Negative	8(5.3)
	Not tested	22(14.3)
HIV status	Positive:	8(5.3)
	Negative	138(90.8)
	Not tested	6(3.9)
VDRL	Positive:	2(1.3)
	Negative	132(86.8)
	Not tested	18(11.8)

Table 5 above shows that most women (72.4%) had HB >10 and 21(13.8%) had not been tested. A significant proportion (15.1%) had diastolic blood pressure (DBP) more than 100. Rhesus negative women were 5.3% while 8(5.3%) women were HIV positive. Only 2 (1.3%) women had positive VDRL.

3.2 fetal surveillance and mode of delivery

Table 6: Fetal Surveillance Method	
CTG	N (%)
Non-reassuring	22(14.5)
Reassuring	87(57.2)
Not Done	43(28.3)
BPP SCORE	N (%)
0-2	3(2)
4-6	19(12.5)
8-10	61(40.1)
Not Done	69(45.4)

Table 6 shows that for the women who had fetal surveillance method, 87(57.2%) had reassuring status in the CTG group while 61(40.1%) had BPP between 7-10. However 43(28.3%) never had CTG and 69(45.4%) had no BPP score.

Table 7: mode of delivery	
Mode of delivery	N (%)
Assisted vaginal delivery	1(0.6)
Caesarian section	98(64.5)
SVD	53(34.9)

Table 7 shows that 98(64.5%) of women delivered via emergency caesarian section

Table 8: Reasons for Emergency Caesarian

Reason for emergency C/S	N (%)
Dystocia	1(0.7)
NRFS	68(44.7)
Maternal condition	2(1.3)
Other reasons for CS	28(18.4)

Non reassuring fetal status was the most common reason for emergency caesarian section. Only 2(1.3%) women underwent emergency caesarian section due to maternal condition (table 8).

3.3 obstetric outcomes

Table 9: Fetal Outcome

Fetal outcome		N (%)
Apgar 5 minutes	<4	2(1.3)
	4-7	12(7.9)
	>7	134(88.2)
	Unknown	4(2.6)
Resuscitation	Yes	12(7.9)
	No	140(92.2)
Admission to NBU	Yes	13(8.6)
	No	139(91.4)
Congenital anomalies noted	Yes	2(1.3)
	No	150(98.7)
Fresh still birth	Yes	2(1.3)
	No	150(98.7)
Macerated still birth	Yes	3(2)
	No	149(98)
Birth weight(in grams)	<1000	1(0.7)
	1000-1500	2(1.3)
	1501-2000	2(1.3)
	2001-2500	25(16.4)
	2501-3500	100(65.8)
	>3500	22(14.5)

Most newborn (88.2%) had good five minute Apgar score (>7) while 14(9.2%) had Apgar score <7 at 5 minutes. The newborns resuscitated were 12(7.9%) and 13(8.8%) were admitted to NBU. There were 2(1.3%) cases of fresh stillbirth and 3(2.0%) cases of macerated still birth. Most newborns (65.8%) had birth weight of between 2501-3500 grams. There was 1(0.7%) newborn with birth weight less than 1000grams and 22(14.5%) newborns had more than 3500grams (table 9).

3.4 correlations

Table 10: Correlating Gestational Age With Mode of Delivery and Fetal Outcome

PARAMETER		GESTATION			P value
		<37 weeks	37-40 weeks	>40 weeks	
		N (%)	N (%)	N (%)	
Mode of delivery	Assisted vaginal delivery	1(2.3)	0	0	.193
	Emergency c/s	26(59.1)	68(68.7)	3(37.5)	
	SVD	17(38.6)	31(31.8)	5(62.5)	
Apgar 5 minutes	<4	0	2(2.1)	0	.374
	4-7	3(7)	7(7.3)	2(25)	
	>7	40(93)	87(90.6)	6(75)	
Resuscitation	Yes	5(11.4)	6(6.1)	1(12.5)	.494
	No	39(88.6)	93(93.9)	7(87.5)	
Admission to NBU	Yes	7(15.9)	6(6.1)	0	.103
	No	37(84.1)	93(93.9)	8(100)	
Congenital anomalies noted	Yes	0	1(1)	1(12.5)	.016
	No	44(100)	98(99)	7(87.5)	
Fresh still birth	Yes	1(2.3)	1(1)	0	.785
	No	43(97.7)	98(99)	8(100)	
Macerated still birth	Yes	1(2.3)	2(2)	0	.913
	No	43(97.7)	97(98)	8(100)	
Birth weight(in grams)	<1000	1(2.3)	0	0	.086
	1000-1500	2(4.5)	0	0	
	1501-2000	1(2.3)	1(1)	0	
	2001-2500	12(27.3)	13(13.1)	0	
	2501-3500	25(56.8)	68(68.7)	6(75)	
	>3500	3(6.8)	17(17.2)	2(25)	

Table 10 shows that 26(59.1) with gestation <37 weeks delivered by caesarian section (p-value 0.193). 6(6.1%) with gestation age 37-40 weeks were resuscitated (p-value 0.494). 12(27.3%) with gestation <37 weeks had birth weight of between 2001-2500 (p-value 0.086). Gestation age is not significant for the fetal outcome.

Table 11: Correlates Pregnancy Induced Hypertension (PIH) With Fetal Outcome

FETAL OUTCOME		No hypertension N (%)	hypertension N (%)	P value
Apgar 5 minutes	<4	2(1.6)	0	.503
	4-7	9(7.1)	3(13.6)	
	>7	115(91.3)	19(86.4)	
Resuscitation	Yes	11(8.5)	1(4.3)	.494
	No	118(91.5)	22(95.7)	
Admission to NBU	Yes	8(6.2)	5(21.7)	.014
	No	121(93.8)	18(78.3)	
Congenital anomalies noted	Yes	2(1.6)	0	.548
	No	127(98.4)	23(100)	
Fresh still birth	Yes	1(0.8)	1(4.3)	.166
	No	128(99.2)	22(95.7)	
Macerated still birth	Yes	2(1.6)	1(4.3)	.374
	No	127(98.4)	22(95.7)	
Birth weight(in grams)	<1000	0	1(4.3)	.012
	1000-1500	1(0.8)	1(4.3)	
	1501-2000	1(0.8)	1(4.3)	
	2001-2500	18(14)	7(30.4)	
	2501-3500	89(69)	11(47.8)	
	>3500	20(15.5)	2(8.7)	

Table 11 shows that 5(21.7%) and 10(43.3%) with hypertension were admitted to NBU (p-value 0.014) and had low birth weight of ≤ 2500 (p-value 0.012) respectively.

Table 12: Correlating fetal outcome With CTG

FETAL OUTCOME		CTG RESULTS		P value
		Non-reassuring	Reassuring	
		N (%)	N (%)	
Apgar 5 minutes	<4	2(9.1)	0	0.011
	4-7	3(13.6)	6(7.1)	
	>7	17(77.3)	79(92.9)	
Resuscitation	yes	5(22.7)	3(3.4)	0.002
	No	17(77.3)	84(96.6)	
Admission to NBU	yes	5(22.7)	5(5.7)	0.014
	No	17(77.3)	82(94.3)	
Congenital anomalies noted	yes	1(4.5)	0	0.046
	No	21(95.5)	87(100)	
Fresh still birth	yes	1(4.5)	0	0.046
	No	21(95.5)	87(100)	
Macerated still birth	yes	0	1(1.1)	0.613
	No	22(100)	86(98.9)	
Birth weight(in grams)	<1000	1(4.5)	0	0.083
	1000-1500	1(4.5)	0	
	1501-2000	1(4.5)	1(1.1)	
	2001-2500	3(13.6)	16(18.4)	
	2501-3500	13(59.1)	61(70.1)	
	>3500	3(13.6)	9(10.3)	

As shown in table 12, women with reassuring CTG(92.9%) had good outcome with apgar score >7(p-value 0.011). likewise a small proportion with reassuring CTG 3.4% were resuscitate (p-value 0.002). The only still birth had a non reassuring CTG (p-value 0.046). As expected CTG results does not correspond with birth weight.

Table13: Correlation Between BPP SCORE and fetal outcome

Fetal outcome		BPP SCORE			P value
		0-2 N (%)	4-6 N (%)	8-10 N (%)	
Apgar 5 minutes	<4	0	1(5.3)	0	<0.001
	4-7	2(66.7)	0	4(6.8)	
	>7	1(33.3)	18(94.7)	55(93.2)	
Resuscitation	Yes	3(100)	1(5.3)	1(1.6)	<0.001
	No	0	18(94.7)	60(98.4)	
Admission to NBU	Yes	1(33.3)	1(5.3)	7(11.5)	0.332
	No	2(66.7)	18(94.7)	54(88.5)	
Congenital anomalies noted	No	3(100)	19(100)	61(100)	-
Fresh still birth	Yes	0	2(10.5)	0	0.032
	No	3(100)	17(89.5)	61(100)	
Macerated still birth	Yes	0	0	1(1.6)	0.833
	No	3(100)	19(100)	60(98.4)	
Birth weight	<1000	0	1(5.3)	0	0.038
	1000-1500	0	0	1(1.6)	
	1501-2000	1(100)	0	1(1.6)	
	2001-2500	0	5(26.3)	9(14.8)	
	2501-3500	2(66.7)	12(63.2)	42(68.9)	
	>3500	0	1(5.3)	8(13.1)	

As shown in table 13, 93.2% of women with a BPP SCORE of 8-10 had good Apgar score at 5minutes (p-value <0.001). All newborn to women who had a BPP SCORE of 0-2 were resuscitated (p-value <0.001). Biophysical profile and Birth weight were statistically significant but admission to NBU was not statistically significant for fetal outcomes.

Table 14: comparing fetal outcome with mode of delivery

		Mode of delivery			P value
		Assisted vaginal delivery	Caesarian section	SVD	
Fetal outcome		N (%)	N (%)	N (%)	
Apgar 5 minutes	<4	0	2(2.1)	0	0.004
	4-7	1(100)	10(10.3)	1(2)	
	>7	0	85(87.6)	49(98)	
Resuscitation	Yes	1(100)	11(11.2)	0	<0.001
	No	0	87(88.8)	53(100)	
Admission to NBU	Yes	0	12(12.2)	1(1.9)	0.09
	No	1(100)	86(87.8)	52(98.1)	
Congenital anomalies noted	Yes	0	2(2)	0	0.572
	No	1(100)	96(98)	53(100)	
Fresh still birth	Yes	0	2(2)	0	0.572
	No	1(100)	96(98)	53(100)	
Macerated still birth	Yes	0	1(1)	2(3.8)	0.505
	No	1(100)	97(99)	51(96.2)	
Birth weight(in grams)	<1000	0	1(1)	0	0.964
	1000-1500	0	2(2)	0	
	1501-2000	0	2(2)	0	
	2001-2500	0	17(17.3)	8(15.1)	
	2501-3500	1(100)	62(63.3)	37(69.8)	
	>3500	0	14(14.3)	8(15.1)	

Table 14 shows that delivery by caesarian section had higher rate of poor Apgar score at 5 minutes (p value 0.004) and resuscitation (p value <0.001)

CHAPTER 4: DISCUSSION

The prevalence of reduced fetal movements is 4% in this study. This prevalence is slightly lower with what has been described in other studies which ranges 5-15%¹⁻⁵. The study participants were between 21 and 30 years with a mean age of 28 years and median of 27 years. This group is representative of the peak reproductive age group and not different from the general population. The drug use by the study participants was negligible thus removing a confounder in the study as drugs are known to affect fetal movements, how it is perceived and the outcome of the pregnancy²¹⁻²². This shows that drug use in our setup by pregnant mothers is not a major cause of reduced fetal movements. In this study most mothers with reduced fetal movements were at term. It can be attributed to the fact that by this time most mothers will have attended antenatal clinic and emphasis on danger signs raise their awareness to reduced fetal movements. It can also be attributed to anxiety due to previous poor outcomes. However gestation could not influence the fetal outcome mainly because the gestation documented was at the time of recruitment and does not necessarily mirror the delivery time. A further study need to control for gestation and evaluate the outcome of the preterm deliveries with reduced fetal movements.

Patients with PIH are predisposed to reduced fetal movements. Fifteen percent of the study participants had pregnancy induced hypertension which was significant in this group. It is known that hypertension affect the placental perfusion and marked reduced movements in hypertensive are highly suggestive of fetal distress²⁴. Patients with PIH had significant association with admission to NBU. However because of significant proportion with low birth weight; it could not be determined whether admission to NBU was due to low birth weight or purely because of effect of hypertension on the fetus. Blood pressure should be assessed in all antenatal mothers and appropriate and prompt management be instituted.

In this study a significant proportion of women (10-20%) had no antenatal profile. This could possibly reflect mothers who had not attended antenatal clinic who miss the

importance of identifying the danger signs leading to late health seeking behavior. Lack of knowledge about complication of a particular symptom contributes to delay in recognizing the need for medical care and in this case, reduced fetal movements. Nelsdam S assessed the value of maternal monitoring of fetal movements in 2250 pregnant woman and demonstrated that maternal monitoring of fetal movements can identify infant with increased risk of intrauterine fetal ^{9, 10}. Pregnant women should be emphasized to monitor their fetal kicks and a chart be availed to those with increased risk like hypertension and diabetes. Women information can be improved by development of brochure of information that aims to increase maternal awareness and vigilance to significance of decrease in fetal activity, and to aid health promoting behavior. ³³

This study has shown that there is a role of CTG in monitoring pregnancies with reduced fetal movements. Patients with non reassuring CTG tracing had poor Apgar score at 5 minutes and therefore were resuscitated and admitted to NBU. This tool will identify fetus at risk thus allowing early interventional delivery as the fetus is no longer safe in the uterus. According to ACOG bulletin reassuring CTG is predictive of normal fetal acid base balance ²⁶. Similarly, ultrasonography has a role in management of these mothers. Patients with good BPP score had good Apgar score and unlikely to be resuscitated. In other studies, non stress test and ultrasound examination were found to be most useful tools for fetal surveillance in decreased fetal movement, while an umbilical artery Doppler examination failed to add significant information. ³³

A higher number of women (64.5%) with reduced fetal movements delivered by emergency caesarian section and the commonest reason were due to non reassuring fetal status. Despite the fact that some reason for emergency was due to other obstetric complication, this group had high index for caesarian because a risk factor already exist. This quick intervention could explain the low rate of poor fetal outcome in this study which was 1.3%-14% compared to results of a study in eastern Norway which showed that prevalence of asphyxia, death or growth restriction as 10.6- 15% ⁵. From the results of this study it can be inferred that Patients with evidence of fetal compromise or any other complication that is associated with decreased fetal activity are best delivered by

caesarian section. Patients delivered by caesarian had inherent risk and correlation with poor Apgar score at 5 minutes and resuscitation of the newborn was statistically significant. However the study was not able to tell whether the high caesarian rates were justified or not, a further study needs to evaluate caesarian section in this cohort.

These results shows that prudent use of CTG and BPP could identify fetus at risk and their active intervention can lead to good neonatal outcome. It also observed that pregnancy induced hypertension contribute significantly to admission to NBU and low birth weight as expected due to placental insufficiency. The study managed to recruit the required sample size and therefore the power was adequate. These baseline results will form benchmark for future comparison studies.

There were some limitations in this study. Not all women who presented with reduced fetal movements were subjected to fetal surveillance method because of machine breakdown and also some cases required emergency delivery due to other obstetric complications. In addition, there were few cases of associated obstetric and medical conditions thus the study was unable to correlate these conditions with fetal outcome. The study population is hospital based and therefore sample size might not be representative to give a generalization for the entire population. During the study period, it was observed that there were many women with confirmed IUFD but were excluded in the study because event has already occurred and majority of them had reduced fetal movements before diagnosis of IUFD. Most of these women with IUFD do not attend clinic.

Conclusion

Majority of women (90%) who present with reduced fetal movements and have fetal surveillance will have good fetal outcome though caesarian section rate seems to be higher in this cohort. Use of CTG and ultrasonography as tools for antenatal fetal surveillance can identify fetus at risks and therefore allow opportune time of delivery. These tools should be used routinely in all women with reduced fetal movements and they are best delivered by caesarian section if a risk is identified. Pregnant women with pregnancy induced hypertension and reduced fetal movements require close fetal surveillance because the risk to poor fetal outcome is significantly increased.

Recommendations

1. Reduced fetal movements must be sought for in all antenatal mothers and mothers counseled on the same to reduce anxiety and identify those at risk by use of non stress test as a routine. A brochure with information regarding reduced fetal movements should be availed to all antenatal mothers.
2. Health care providers at all levels of service delivery should be trained on the use of CTG machine in fetal surveillance. These fetal surveillance tools should not only be available in tertiary institutions, but the Ministry of medical services should roll out this equipments to the health center level and build the capacity of the staff to use these tools.
3. Health institutions should have guidelines on evaluation and management of women who present with reduced fetal movements.

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Appendix 1: PATIENT INFORMATION AND CONSENT FORM.

The study is on the poor obstetric outcomes among pregnant women with reduced fetal movements at KNH.

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Chairperson KNH-ERC: Professor K. M Bhatt, 0202726300.

Introduction

The purpose of this consent form is to give you information about the study on reduced fetal movements. This information will help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer and anything else about the research or this form that is not clear. When we have answered all questions, you can decide if you want to be on the study or not. This process is called informed consent. If you wish, we will give you a copy of this form for your records.

Reasons for research

The purpose of this study is to analyze the outcome of pregnancies of mothers who present with a primary complaint of reduced fetal activity/ movements. We do know that a reduced fetal movement poses danger to the fetus and efforts must be made to evaluate the mother and the fetus. Reduced fetal movements causes anxiety and it's a frequent cause of admission. I therefore intend to lay baseline information that will be used in future to optimize the management of reduced fetal movements in our facilities and improve pregnancy outcomes, for indeed that is an effort that requires cooperation of a health care giver and recipient.

Benefits

The results will be useful in determining the prevalence of pregnancies with reduced fetal movements and circumstances surrounding it. You will also be able to understand

circumstances that causes reduced fetal movements. With increase in knowledge, future pregnancies with reduced fetal movements will be managed better.

Possible risks

There are no risks associated with the study because there is no invasive procedure to be performed on you as part of the study.

Confidentiality

The information given to researchers will be kept in strict confidence. This information will be part of your clinical records. However no information by which your identity can be revealed will be released or published.

Participant's agreement

I voluntarily agree to participate in the study on the poor obstetric outcome among pregnant who present with reduced fetal movements at KNH Antenatal wards (GFA, GFB), labour ward and labour ward theatre. I understand that participation in the study does not entail financial benefit. I have been informed that the information obtained will be treated with utmost confidentiality and my treatment will not be compromised if I decline participation or withdraw from the study.

I have had a chance to ask questions, if I have questions later about the research I can ask the researcher.

Signature of subject.....

Date.....

Witness

Date.....

I certify that the nature and purpose, potential benefits, possible risks associated with participating in this study have been explained to the above participant.

.....

.....

Signature of principal investigator

Date

Appendix 2: DATA COLLECTION SHEET

Note: Section A will be verbal from the patients

Section A: SOCIOL-DEMOGRAPHIC HISTORY

1. Serial Number

2. Clinic Number

3. Age in Years

4. Parity +

5. Do you currently Smoke cigarettes or use traditional tobacco?

1. Yes

2. No

6. If yes for how long have you smoked? Years

7. Do you consume alcohol? Yes

No

If yes, how many years _____

8. Are you on any of the following drugs?

1. Antidepressant

2. Antipsychotic

- 3. Sedative
- 4. Narcotic drugs
- 5. Opioid analgesics
- 6. Others

Note: Section B to F will be from the patients file

Section B: CURRENT OBSTETRIC HISTORY

9. GBD GB U/S

10. How long has the patient had reduced fetal movements?

- 1. <6 hours
- 2. 6-12 hours.
- 3. 12-24 hours
- 4. 24-48 hours
- 5. > 48 hours

11. Antenatal profile

1. HB <6 6-8 9-10 >10 Not tested

2. DBP <90 90-100 >100 Not tested

3. Rhesus factor. Positive Negative Not tested

4. HIV

1. Positive

2. Negative

3. not tested

5. VDRL.

1. Positive

2. Negative

3. Not tested

6. Urinalysis 1. Protein 2. sugar 3 ketones 4 not tested

Nil

Section C: OBSTETRIC COMPLICATION IN CURRENT PREGNANCY

12. Does the patient suffer from the following?

1. D.M

2. P.I.H

4. APH

5. PROM

6. Others

Specify _____

Section D: CONCURRENT MEDICAL ILLNESS

13. Does the patient suffer from the following illness?

1. PTB

2. AIDS

3. ASTHMA

4. CARDIAC DISEASE

5. OTHERS. (*Specify*) _____

Section E: FETAL SURVEILLANCE METHODS AND MODE OF DELIVERY

14. Method of surveillance employed.

1. CTG. Reassuring Non-reassuring

2. BPP. SCORE— 0-3 4-6 7-10

15. Management on the current pregnancy.

1. Active

2. Expectant

16. If expectant management, how long did she wait before being delivered? Specify the duration. < 1 week 1-2 weeks 3-4 weeks > 4 weeks

17. Mode of delivery. 1. SVD

2. Caesarian section

3. Assisted vaginal delivery

18. If caesarian section. 1. Emergency 2. Elective

19. Reason for emergency caesarian section.

- 1. Dystocia
- 2. NRFS
- 3. maternal condition
- 4. others (specify) _____

Section F: FETAL OUTCOME

20. Apgar score at 5 minutes.

1. <4

2. 4-7

3. >7

21. Resuscitation?

1. Yes

2. No

22. Admission to NBU?

1. YES.

2. NO.

23. Congenital anomalies noted.

1. yes

2. No

24. Fresh stillbirth.

1. YES

2. NO

25. Macerated stillbirth

1. Yes

2. No

26. Birth weight (grams)

1. <1000

2. 1000-1500

3. 1501-2000

4. 2001-2500

5. 2501-3500

6. > 3500

Appendix 3: TIME FRAME AND BUDGET

TIME FRAME						
Activity	Jan – December 2009	Jan- May 2010	May 2010	June- Sept. 2010	October 2010	November 2010
Proposal development						
Ethical approval						
Testing the questionnaire						
Data collection and entry						
Data analysis and write up						
Submission to department						

Budget	
ITEM DESCRIPTION	AMOUNT (Ksh)
1. principal researcher	15000
2. research assistant per diem	15000
3. stationary	5000
4. typing, printing, photocopying	5000
5. airtime for communication	10000
6. BPP for 40 patients @ Ksh 1500 per patient	60000
7. data entry	2000
8. data analysis/ management	20000
TOTAL	132000



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Ref: KNH-ERC/ A/460

15th April 2010

Dr. Kikwai W. Kibet
Dept. of Obstetrics & Gynaecology
School of Medicine
University of Nairobi

Dear Dr. Kibet

RESEARCH PROPOSAL: "CORRELATION OF PREGNANCY OUTCOMES OF MOTHERS PRESENTING WITH REDUCED FETAL MOVEMENTS AT KENYATTA N. HOSPITAL"
(P300/10/2009)

This is to inform you that the KNH/UON-Ethics & Research Committee has reviewed and **approved** your above revised research proposal for the period 15th April 2010 to 14th April 2011.

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given. Clearance for export of biological specimens must also be obtained from KNH/UON-Ethics & Research Committee for each batch.

On behalf of the Committee, I wish you a fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of the data base that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely

PROF A N GUANTAI
SECRETARY, KNH/UON-ERC

c.c. Prof. K. M. Bhatt, Chairperson, KNH/UON-ERC
The Deputy Director CS, KNH
The Dean, School of Medicine, UON
The HOD, Records, KNH
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