# FACTORS ASSOCIATED WITH FETAL MACROSOMIA AT KENYATTA NATIONAL HOSPITAL

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**A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT FOR THE AWARD OF**

**DEGREE IN MASTER OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY**

## DECLARATION

This is to certify that the work presented herein is my original work, has not been presented for a degree course in any other university and was supervised by senior members of the Department of Obstetrics and Gynaecology, School of Medicine, College of Health Sciences, University of Nairobi, Kenyatta National Hospital Campus, Nairobi Kenya

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## CERTIFICATE OF SUPERVISION

This dissertation has been submitted for examination with our approval as the university supervisors.

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**CERTIFICATE OF AUTHENTICITY**

This is to certify that this is the original work of Dr. Arnold Bugah Bunyoli, Masters of medicine student department of obstetrics and gynaecology, registration number H58/67252/2013. 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.

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## DEDICATION

This book is dedicated to my parents, Mr. Edward Bugah Busolo and Mrs. Jane Bugah Busolo who have raised me to the person I am today. And to my dear fiancée and colleague Dr. Leonesa Njoroge, you are my inspiration.

**ACKNOWLEDGEMENTS**

I wish to offer my appreciation to Professor Ndavi and Professor Jaldesa for their guidance and mentorship during the course of this study.Special acknowledgement to Dr Njoroge P.L, my lead research assistant for her valuable input and members of staff of Kenyatta National Hospital for their cooperation during this study.

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## ABBREVIATIONS AND ACRONYMS

ACOG-American College of Obstetricians and Gynaecologists

ANC-Antenatal Care

BMI-Body Mass Index

CPD -Cephalopelvic Disproportion

EFW-Estimated Fetal Weight.

GDM-Gestational Diabetes Mellitus

KDHS- Kenya Demographic and Health Survey

KNH-Kenyatta National Hospital.

LBW-Low Birth Weight

LGA- Large for Gestational Age.

PPH-Post-Partum Hemorrhage

RCOG-Royal College of Obstetricians and Gynaecologists.

WHO- World Health Organization

## ABSTRACT

### Introduction

The World Health Organization defines macrosomia as absolute birth weight of 4000 grams and above. It occurs in 0.5%- 15% of pregnancies worldwide and is associated with adverse maternal and fetal outcomes that is mostly accounted for by the risk of labor and delivery. The aim of this study was to identify the risk factors associated with fetal macrosomia and to add new information that will help the health care providers to identify women at increased risk for fetal macrosomia and thus enabling effective and timely interventions.

### Broad Objective:

To determine the sociodemographic and maternal factors associated with fetal macrosomia among women who deliver at Kenyatta National Hospital.

### Study design:

This was a Case control study in which 101 women who delivered infants weighing 4000 grams and above were compared to 101 women who delivered infants of normal birth weight, from 2500 grams to 3999 grams.

### Study setting:

This study was conducted at the maternity units of Kenyatta National Hospital, Nairobi Kenya

### Study population:

This was drawn from women who delivered singleton infants and whose gestational age was 37 weeks and above at the maternity units Kenyatta National Hospital. Cases were 101 women with newborn infants weighing 4000 grams and above. The Controls were 101 women with new born infants of normal birth weight i.e. from 2500 grams to 3999 grams.

**Data collection:**

Recruitment took place at KNH labour ward. The sampling procedure was an unmatched consecutive sampling procedure of all infants with birth weights of 4000 grams and above as the cases and normal birth weight infants (2500 grams to 3999 grams) as the controls. A structured questionnaire was used to collect the data and the appropriate responses filled. Intrapartum patient records were also used as a reference and also to provide information on participants' height, weight, mode of delivery, gestational age at onset of labour, maternal and fetal complications. The data was collected by the principal researcher or a trained research assistant.

**Data Analysis:**

Statistical analysis was performed using SPSS version 21.0 software. Participants were described using sociodemographic, obstetric and medical factors. Characteristics of the cases were compared with the controls using means, percentages and odds ratio where appropriate. Multiple logistic regression analysis was also used to determine factors independently associated. All statistical test was interpreted at 5% level of significance (95%confidence interval).

**Results:**

Out of a total of 2027 deliveries, 101 were macrosomic giving a prevalence of 5.4%. Maternal age, Maternal BMI, weight gain during pregnancy, history of previous macrosomic delivery, diabetes /glycosuria, higher parity, late term pregnancy was associated with a higher risk of delivering a macrosomic infant.

Mothers who had delivered a macrosomic infant were more likely to have had prolonged labor, undergo caesarean delivery and sustain perineal injuries of a higher grade as compared to those

who delivered NBW infants. Macrosomic infants were more likely to be male, admitted to NBU. Still births and shoulder dystocia were only recorded among macrosomic deliveries.

**Conclusion:**

This study was able to capture significant factors associated with fetal macrosomia this is similar to international and regional studies earlier done, which includes higher maternal BMI, weight gain during pregnancy, history of diabetes, glycosuria during the antenatal period and hyperglycemia.

Although the study was not designed to estimate the prevalence of fetal macrosomia, with the total deliveries conducted at the maternity unit 2027 there were 101(5.4%) newborns that were born macrosomic.

**Recommendations:**

1. Counselling on excessive weight gain during pregnancy due to its association with development of fetal macrosomia
2. The study was not set to establish the prevalence, immediate and fetal maternal complications therefore a study with the appropriate design is recommended to capture this (case cohort or cross sectional study)

## INTRODUCTION

There is no international agreement on the definition of fetal macrosomia and hence it varies depending on the region being termed as an absolute birth weight of equal to or greater than 4000 grams or equal to or greater than 4500 grams irrespective of the fetal gestational age(1). The Royal College of Obstetricians and Gynecologists (RCOG) and the American College of Obstetrician and Gynecologists (ACOG) define fetal macrosomia as birth weight greater than 4500 grams irrespective of the gestational age(2,3),locally we define fetal macrosomia as birth weight equal to or greater than 4000 grams(4,5). Due to these varying definitions, it has a wide prevalence of 0.5% to 15% of all pregnancies worldwide(6). At Kenyatta National Hospital according to a review of birth weight done between 10$^{th}$ March 2014 to 1$^{st}$ May 2014 , out of a total of 1874 deliveries there were recorded, 75 (4.0%) deliveries with birth weight of equal to or more than 4000 grams(7).

The largest recorded birth weight worldwide is 10.78 kilograms in Ohio USA in 1894(8) while in Kenya the largest recorded birth weight was in 2014 a 7.0-kilogram infant in Busia County, western Kenya

Delivery of a macrosomic infant predisposes both the neonate and the mother to a number of complications that is mostly attributed to by the risk of labor and delivery(1). Shoulder dystocia, clavicle and humeral bones fractures, brachial plexus injuries, facial nerve injuries, fetal and infant death are some of the fetal complications that may occur. There is also evidence of a likelihood of the infants developing obesity in their childhood, adolescent and even early adulthood(1,2). Consequently, they may be at risk of developing cardiovascular and metabolic complications(1,2,9). Maternal complications of fetal macrosomia include prolonged labor, cesarean deliveries, postpartum hemorrhage (PPH), infection, and perineal injuries(1).

Some of the risk factors associated with fetal macrosomia include previous delivery of macrocosmic infants, parity, infant gender, pre gestational and gestational diabetes, gestational age, maternal age, and maternal weight at delivery, parental height and ethnicity(1,2,4,10).

## LITERATURE REVIEW

Macrosomia is defined as a birth weight that is two standard deviations above the weight for the gestation age or above the 90$^{th}$ percentile on the Lubencho growth curve growth chart(4).This definition allows preterm, term and postdates neonates to be designated as an LGA. Lawrence E. et al describes term LGA as macrosomia (8). The other common definitions used are infants of birth weight more than 4000 grams or 4500 grams depending on the region(2–4).

The worldwide prevalence of macrosomia is wide, and ranges from 0.5% to15% depending on the regional cutoff birth weights to define macrosomia(10).The incidence of macrosomia in Kenya according to the national birth survey 4 in 1989 was 4.2% in the general population and 1.3% among the teenage mothers in Nairobi(11). Orero et al on a case control study on record files over a 24-month period between April 1988 and March 1990, reported that, out of 13818 deliveries that occurred during the two-year period, there were 113 infants (0.83%) that weighed 4000 grams and above at Kenyatta National Hospital(5). No other studies on fetal macrosomia have been done locally to determine the incidence or prevalence of macrosomia, although on a report by Mugambi et al during a review on maternal factors associated with low birth weights at KNH between 10$^{th}$ March 2014 and 1$^{st}$ May 2014, reported that out of 1874 deliveries that occurred during that period there were 75 (4.0%) infants with birth weight equal to or greater than 4000 grams(7).Elsewhere ACOG reports that in the United States the incidence of macrosomia is 1.5% of all neonates with birth weights of above 4500 grams and up to 10% with birth weights above 4000 grams(2). In China, the incidence was 7.6% in 2010 with birth weights 4000 grams and above. This was a longitudinal trend analysis on the birth weights on urban districts in Beijing between 1996 to 2010(12).In Nigeria an incidence of 8.1% was reported in a 3 year retrospective study where out of 5365 deliveries between 1$^{st}$ January 2005 to 31$^{st}$ December 2007 there were 434 cases of birth weights equal to or greater than 4000 grams(13).

Various factors have been reported to be associated with fetal macrosomia and can be broadly divided into maternal factors and fetal factors(1). Some of the maternal factors include maternal body size and glucose intolerance/diabetes(1,2,14,15).Maternal obesity can be defined as a body mass index (BMI) of equal to or greater than 30(16)and has been shown to play a significant role in fetal overgrowth. Maternal obesity likely contributes to fetal overgrowth through mechanism that may include insulin resistance (even in women without diabetes) resulting in an increase in fetal glucose and insulin levels. Triglycerides in maternal blood are metabolized by placental lipases with fatty acids being transported to the growing fetus(17). A systematic review and meta-analysis on the effect of maternal obesity and fetal overgrowth was undertaken by Guadet et al in 2014(18). It included 21 retrospective cohort studies, 8 prospective cohort study design and 1 retrospective case control study in upper and middle income countries. Sixteen of these studies that used the definition of macrosomia as birth weight of 4000 grams and above reported that there were 20693 obese women, 110696 underweight and normal weight women. There were 13612 macrosomic infants delivered and out of this 3275 were from obese women (15.8%) as compared to 10337 who were born of the underweight and normal weight women (9.3%) OR 2.17(1.92, 2.45). Eight studies that used 4500 grams as the definition of macrosomia reported there were 18909 obese women and 62712 underweight and normal weight women. There were 1739 macrosomic infants delivered and seven hundred and forty-six were from obese women (3.9%) as compared to 993 from underweight and normal weight women (1.6%) OR 2.77 (2.22-3.45)(18). This systematic review concluded that, there is a strong association between maternal obesity and fetal overgrowth with the odds of delivering a large infant more than 4000 grams increasing by 117% and odds of delivering a large infant more than 4500 grams increasing by 277% when one is obese(18). These findings are similar to what Muthoni. et al reported on a

cohort study on the effect of body mass index on pregnancy outcome at Kenyatta National Hospital in 2012(19).She reported that, of the 400 women recruited on her study, 23 were obese, 203 were overweight, and 176 were normal weight-women with regards to their body mass index. A total of 37 infants were born with birth weights equal to or above 4000 grams and of this 10 were from normal weight women(5.685%), 23 from overweight women (11.33%) and 4 from obese women (17.39%).She concluded that the incidence of macrosomia was higher in over weight and obese groups with an OR 2.385 (CI 0.97-5.85) And OR 4.32 (CI 1.12-16.67) respectively(19).

Other known risk factor is diabetes. It is defined as a state of impaired glucose homeostasis that is characterized by hyperglycemia, abnormalities in lipid and protein metabolism due to the defect of insulin secretion and its action(1). Diabetes can be broadly classified according to the pathophysiology leading to the development of hyperglycemia. Type 1 diabetes/ insulin dependent diabetes mellitus which is marked by insulin deficiency and ketosis, type 2 diabetes /non-insulin dependent diabetes mellitus marked by insulin resistance and ketosis, gestational diabetes occurs during pregnancy ,due to the changes that involve carbohydrate metabolism in pregnancy(1). Gestational diabetes is estimated to complicate 1% to 14% of pregnancies(14), and has been associated with maternal and neonatal morbidities, that are preventable when gestational diabetes is diagnosed early. A 5-year cohort study on the occurrence of fetal macrosomia rate and its maternal and neonatal complications at an Iranian hospital between 2007 and 2011(20), it was reported to have a higher incidence. Out of 20000 deliveries recorded during the 5 year period, 1800 (9%) infants had birth weights equal to and above 4000 grams and 712 (39.5%) versus 6.1% of the control group (normal weight infants) had diabetes(20).In contrast at Kenyatta National Hospital Orero et al in his case control study of record reviews

during the period of April 1988 and March 1990 reported that out of the 113 cases of macrosomia they reported that 2 who had a history of diabetes and 3 from the controls (with neonates less than 4000 grams) of 204 had a history of diabetes. (5).

Nutrition plays an important role in development of fetal macrosomia especially the type and content of carbohydrates being consumed(21). A glycemic index as a method to asses glycemic responses to different carbohydrates was developed by Jenkins et al in 1981(9,21). He categorized them as low glycemic index, mid and high glycemic index carbohydrates. Low glycemic diet has shown to blunt the increase in insulin resistance and the second and third trimesters. Eating primarily high glycemic index carbohydrates has been noted to result to feto-placental overgrowth and excessive maternal weight gain leading to an increased predisposition to fetal macrosomia(9).

Multiparity has been noted in various studies to be significantly associated with fetal macrosomia, with the average birth weight with successive pregnancy increasing by about 80 grams to 120 grams to every pregnancy up to the fifth pregnancy(4,22). Macrosomia has been noted to occur more frequently with increase in parity with up to 81% of macrosomic deliveries occurring in multiparous women in some studies. This has been attributed to the fact that most of the multiparous women who deliver are older as compared primiparous women. It is hypothesized that the reason for this risk of macrosomia with advanced age is that, with the metabolic changes that occur with advancing age, there are specific metabolic factors that stimulate higher fetal growth velocity ,resulting to higher risk of macrosomic births, although the said factors are yet to be known(22).

A case control study done in Iran between October 2006 and March 2007 on fetal macrosomia, risk factors, maternal and perinatal outcomes at both private and public hospitals(23), in which 32 macrosomic infants and their mothers were recruited (birth weight equal to or more than 4000 grams) with controls of 132 mothers of normal weight birth weights, it was noted that most of the macrosomic deliveries occurred in women who were multiparous as compared to primigravid women but after analysis this finding was reported as being statistically non-significant this may have been due to the low power that the study had in regards to the small sample size(23). This is in contrast to a similar case control study done in that region on evaluation of the prevalence of macrosomia and the maternal risk factors at a maternity hospital in a province in Iran(24). During a 3-month period in 2010 there were five hundred deliveries that occurred and 59 had macrosomia. Grandmultiparity (parity more than 5) was found to have a statistically significant association with macrosomia(24).Locally with the one retrospective study done in 1990 on fetal macrosomia out of the 132 macrosomic infant deliveries that occurred during the 3 year period of 1988 and 1991 only 11 were primigravid and Para 1 the rest were Para 2 and above with 26 out of 102 being Para5 and above. This was noted to be statistically significant(5).

Other studies have mentioned other various factors depending on the region and the study design used. In one prospective cohort study between July 1997 and September 1999 in San Francisco USA, to assess the risk factors for macrosomic infants birth among Latina women(15). Three hundred and fifty pregnant Latina women were recruited in the antenatal clinic at 20-week gestation or above and followed prospectively until delivery. Eleven percent delivered macrosomic infants (birth weight equal to or above 4000 grams). After cofounders were adjusted using multivariate analysis older mothers (10 year increments were used on the survey) had an elevated risk for macrosomia with an odds ratio of 3.09. (95%CI1.80-5.32). Four out of the ten

mothers aged between 40-49 years delivered a macrosomic infant. Other factors that were statistically significant in this study were previous history of macrosomic delivery in which with 29.8% having a previous history of macrosomia. The gestational age of 40 weeks and above was reported as nearing statistical significance as compared to infants who were 38 weeks – 40 weeks at the time of delivery.Pre pregnancy diabetes, maternal height, male infant sex were reported as statistically non-significant although this study was found to be of a low power and a larger sample size study was recommended(15).

A 3year retrospective case control study done in Enugu, Nigeria on the obstetric outcomes of fetal macrosomia between 1st January 2005 and 31st December 2007(13),reported a total of 434 cases ( fetal weight more than or equal to 4000 grams) out of the 5365 deliveries during that period. Maternal age was a statistically significant factor with the mean maternal age of mothers with macrosomia was 30.6 years as compared to the mean maternal age of the control group as being 27 years. History of a previous macrosomic delivery was also found to be a statistically significant factor with a frequency of 39.5% among the cases compared to12.5% for the control group (normal weight babies 2500-3999 grams)(13).

Adverse maternal and neonatal complications increase with the birth weight of the infant. These adverse complications occur but not always during the process of labor and delivery(1,3,25).The perinatal complications associated with fetal macrosomia include shoulder dystocia, birth asphyxia and still births, skeletal fractures such as clavicle and humeral fractures, nerve injuries such as brachial plexus injuries and facial nerve injuries, meconium aspiration syndrome among others(1). In Kenyatta, National Hospital 27% and 9 % of macrosomic infants complicate with Hypoglycaemia and hypocalemia respectively(4).

One of the most dreaded complications is shoulder dystocia defined by ACOG as vaginal cephalic delivery that requires additional obstetric maneuvers for the delivery of the fetus after the head has delivered and gentle traction has failed(2). This usually occurs when either the anterior shoulder impacts on the maternal symphysis pubis or less commonly the posterior shoulder impacts on the sacral promontory. Maternal adverse outcomes associated with fetal macrosomia include perineal injuries, postpartum hemorrhage, increased risk of operative delivery among others(1,2,26).

A four-year record review case control study done by Florent et al between 2005 and 2008, on the adverse maternal outcomes associated with fetal macrosomia(26), it was reported that there were a total of 27630 deliveries that occurred during this period and out of this 1832 (6.6%) had birth weight 4000 grams and above. Two hundred and sixty-two (17%) had caesarean sections during labor, with the main indications being non-progressive labor and non-reassuring fetal status. Perineal tears occurred in 63% of the women who delivered macrosomic infants and 291(17%) experienced postpartum hemorrhage(26).A population based retrospective case control study done by Zhang et al, to examine the birth weight at which the risk of perinatal death, neonatal morbidity and caesarean section begin to rise(27), reported that with infants of birth weights 4000 grams to 4499 grams, there was no increase in risk of morbidity and mortality as compared birth weights between 3500 grams to 3999 grams. A significant risk of neonatal mortality, neonatal asphyxia, birth injury, meconium aspiration syndrome and caesarean section was noted with birth weight above 4500 grams. This risks increase significantly with birth weights above 5000 grams especially sudden infant death syndrome (27).

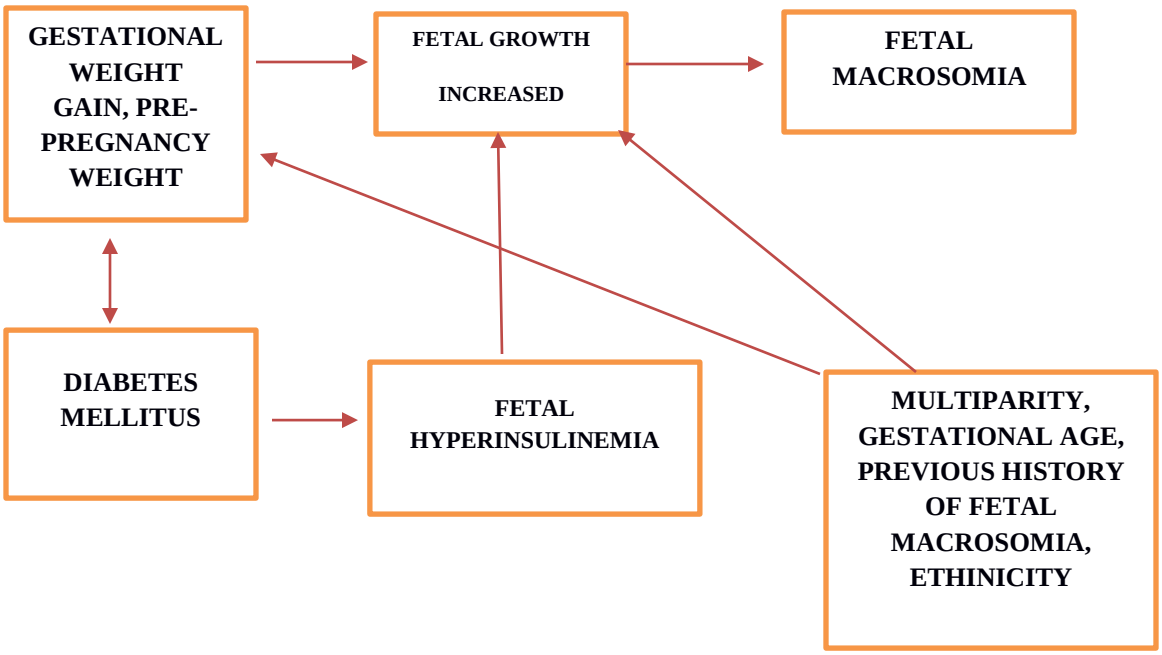
At KNH the only study done was in 1990 a case control study on 3 year record review reported that most of the complications associated with fetal macrosomia i.e. postdatism, Cephalopelvic

disproportion, ruptured uterus, fetal distress, Post-partum haemorrage,obstructed labor, prolonged labor when subjected to statistical analysis were found to have no association between then and macrosomia, but recommended a prospective case control study to carried out to determine this(5).

## CONCEPTUAL FRAMEWORK

Fetal macrosomia has been reported to be associated with undesirable outcomes both for the fetus and the mother. With the assessment of the factors that are associated with fetal macrosomia this can aid to reduce the feto maternal complications that are associated with macrosomia and also in predicting the occurrence.

Factors associated with macrosomia include diabetes, maternal weight and maternal weight gain during pregnancy, previous history of macrosomic delivery, gestational age, male infant sex, maternal age, and ethnicity.



## STUDY JUSTIFICATION

Fetal macrosomia has been linked to increased maternal and perinatal adverse outcomes. Macrosomic infants are prone to still births, birth asphyxia, meconium aspiration syndrome, skeletal injuries and shoulder dystocia. Maternal complications associated with macrosomic delivery include perineal injuries, post-partum hemorrhage, prolonged labor, assisted delivery and Caesarean sections.

There is need to assess the change that has occurred since he last study done on fetal macrosomia was 25 years ago, this was a 2-year record review case control study done at Kenyatta National hospital between April 1988 and March 1990. The incidence as reported was 0.83%, lower than what was reported by the national birth survey 4 of 1989 of 4.0% in the general population and 1.3% with the teenage mothers. In this study parity and maternal age were reported as significant factors. Distribution according to parity was 8.3% in primigravidas and para 1 with the rest being para 2 and above. Women who delivered macrosomia infants were noted to be older with the mean age being in their $3^{rd}$ and $4^{th}$ decades of life (55.9%) as opposed to the young teenage mothers (5.9%). Maternal weight and BMI has been documented in various study to be a significant factor associated with fetal macrosomia but these variables were not investigated. Other factors as, fetal sex, postdates, diabetes was found not to be statistically significant factors No other study has been done locally to identify the factors associated with fetal macrosomia.

This study was designed to identify the factors associated with fetal macrosomia and add new information as the most factors on the study done 20 years ago, were not in keeping with other regional and international risk factors identified. This may aid in stimulating the health care providers to identify women at increased risk for fetal macrosomia, help in developing standard

operating procedures and policy development on fetal macrosomia and thus enabling effective and timely interventions.

## RESEARCH QUESTION

What are the sociodemographic and maternal factors associated with fetal macrosomia among women who deliver at Kenyatta National Hospital?

## NULL HYPOTHESIS

There is no association between the sociodemographic and maternal factors and fetal macrosomia among women who deliver at Kenyatta National Hospital.

## BROAD OBJECTIVE

To determine the sociodemographic and maternal factors associated with fetal macrosomia among women who deliver at Kenyatta National Hospital.

## SPECIFIC OBJECTIVES

1) To determine the sociodemographic characteristics of women who deliver macrosomic infants
2) To determine the complications associated with delivery of a macrosomic infant.

## METHODOLOGY

## STUDY DESIGN

Case control study in which 101 women who delivered macrosomic infants were compared to 101 women who delivered infants weighing between 2500 grams and 3999 grams.

## STUDY SETTING

The study was conducted at Kenyatta National Hospital, which is the national referral and teaching hospital situated in Nairobi, 4 kilometers west of the central business district. It is also the main teaching hospital for the College of Health Sciences, University of Nairobi. KNH caters for patients from Nairobi and its environs as well as referrals from other hospitals in the country and the greater East African region. KNH has one public labor ward, three antenatal/postnatal wards, and a new born unit with a neonatal intensive care unit (NICU). The labor ward includes a triage room, first and second stage rooms, an acute room and two operating theatres. The hospital is manned by several service providers, including consultant obstetrician gynecologists, senior registrars, residents, nurses, midwives, medical and nursing students. There is also a multidisciplinary approach for complicated maternal medical conditions in pregnancy with physicians, surgeons, pediatricians and obstetrician Gynecologists, which helps in the management patients.

## STUDY POPULATION

The study participants were women who had singleton deliveries at 37 weeks' gestation and above between 27$^{th}$ August 2016 to 15$^{th}$ August 2016.They formed the population where the cases and controls were recruited.

## ELIGIBILITY CRITERIA

## INCLUSION CRITERIA

1) Women who delivered at Kenyatta National Hospital and birth weights recorded as equal as or greater than 4000 grams were considered as cases and 2500 grams to 3999 grams were considered as controls.

2) Participants who gave informed consent

**EXCLUSION CRITERIA**

1) Women who delivered infants at gestational age less than 37 weeks.

2) Multiple pregnancies

**SAMPLE SIZE DETERMINATION**

This study compared risk factors associated with fetal macrosomia in the cases and the controls. Previous studies have reported various factors associated with this condition and for the purpose of sample size estimation maternal obesity as a risk factor will be used. Sample size will be calculated using a formula for comparing 2 proportions as follows(28).

$$n = \frac{2(Z_{1-\alpha/2}+Z_{1-\beta})^2 P_{av}(1-P_{av})}{(P_0-P_1)^2}$$

N is the sample size required in each group

$Z_{1-\alpha/2}$refers to the normal standard deviate at 95% confidence interval = 1.

$Z_{1-\beta}$ refers to the power of obtaining difference between the two groups = 0.84 for 80% power

$P_0$ –Proportion of women with obesity in the control group = 26%(29).

This study has been designed to detect an estimated 2.5odds of fetal macrosomia associated with obesity. Therefore, the proportion of women with obesity among the cases ($P_1$) will be 47%

$P_{av}$ – Average proportion of obesity in the two groups = 36.5%

Substituting into the formula:

Sample size (n) is 84 in each group. The sample size population has increased approximately 10% to cater for incomplete documentation on record files. Therefore, the sample size is **92 in each group.** A **minimum of 184** women was required to determine the risk factors of fetal macrosomia.

**DEFINITION OF CASES AND CONTROLS**

Cases were defined as women who had delivered infants with birth weight of 4000 grams and above. Controls were defined as women who had delivered infants with normal birth weight (2500 grams to 3999 grams). Gestational age of equal to or above 37 weeks.

**DATA COLLECTION PROCEDURE**

Participants were identified from the delivery register, where the patient's delivery information including the birth weight has been recorded. They were selected through consecutive sampling procedure, whereby women who had delivered infants with birth weight of 4000 grams and above were approached to participate as the cases, and the next woman who delivered an infant with birth weight between 2500 grams and 3999 grams after the case has been identified was approached to participate as the control until the sample size was achieved. In a situation in which the case did not meet the inclusion criteria, the next woman who delivered an infant with birth weight of 4000 grams was recruited. In a case, whereby two consecutive women delivered infants with birth weight 4000 grams and above, the next two women who delivered infants with normal birth weights (2500 grams to 3999 grams) was recruited. After identification of the cases and controls, they were approached and explained for the purpose of the study and give consent to participate.

## DATA COLLECTION INSTRUMENTS

Data was collected using a structured questionnaire and was carried out by the principal investigator or the trained research assistant. The research assistant was comprised of a registered clinical officer or a registered nurse.

### Filling of the questionnaire

Once recruitment and consent had been obtained, a unique study number was allocated to the participant. The principal investigator or the research assistant administered the structured questionnaire to the participant and filled the appropriate response with regards to the participants age, marital status, parity, last menstrual period, history of previous macrosomic deliveries. Antepartum and Intrapartum records were also used as a reference and to obtain information on height, weight at time of delivery, antenatal visits, mode of delivery, gestational age at onset of labor, maternal and fetal complications during and after labor.

## QUALITY CONTROL OF THE DATA

Pre-test of the study instrument was carried out to be able to structure and modify the grammar to be used, so as to avoid bias, misinterpretations, ambiguity and improve content validity. The research assistant was trained on the study methodology and also on how to conduct the interview and information retrieval.

## DATA MANAGEMENT AND ANALYSIS

Questionnaires were coded and entered into a Microsoft Access 2013 database. Statistical analysis was performed using SPSS version 21.0 software. Mothers with fetal macrosomia (cases) were described using sociodemographic, obstetric and medical factors. Frequency tables were generated and chi square test used to ascertain the level of statistical significance. P-values

less than 0.05 were considered significant. Marital status, history of fetal macrosomia, parity, fetal sex and diabetes mellitus status were presented as percentages and associated with fetal macrosomia using Chi square test. Multiple logistic regression analysis was used to determine factors independently associated with fetal macrosomia.

## ETHICAL CONSIDERATIONS

Permission to conduct the research was sought from the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee. Informed consent was obtained from the study participants prior to recruitment, and they were accorded anonymity with the information treated with confidentiality. Data collected was kept under lock and key only accessible to the principal investigator and research assistant. Participants had a right to withdraw from the study and the standard of care was not compromised.

## RESULTS

The study period was from 27th June 2016 to 15th August 2016, and a total of 2027 deliveries (all deliveries) were recorded on the delivery register during this period in KNH. Of these 101 deliveries were macrosomic, giving a prevalence of 5.4%. Among the controls 20(1%) were excluded due to multiple gestation and 200(9.8%) excluded due to low birth weight (<2500 grams).

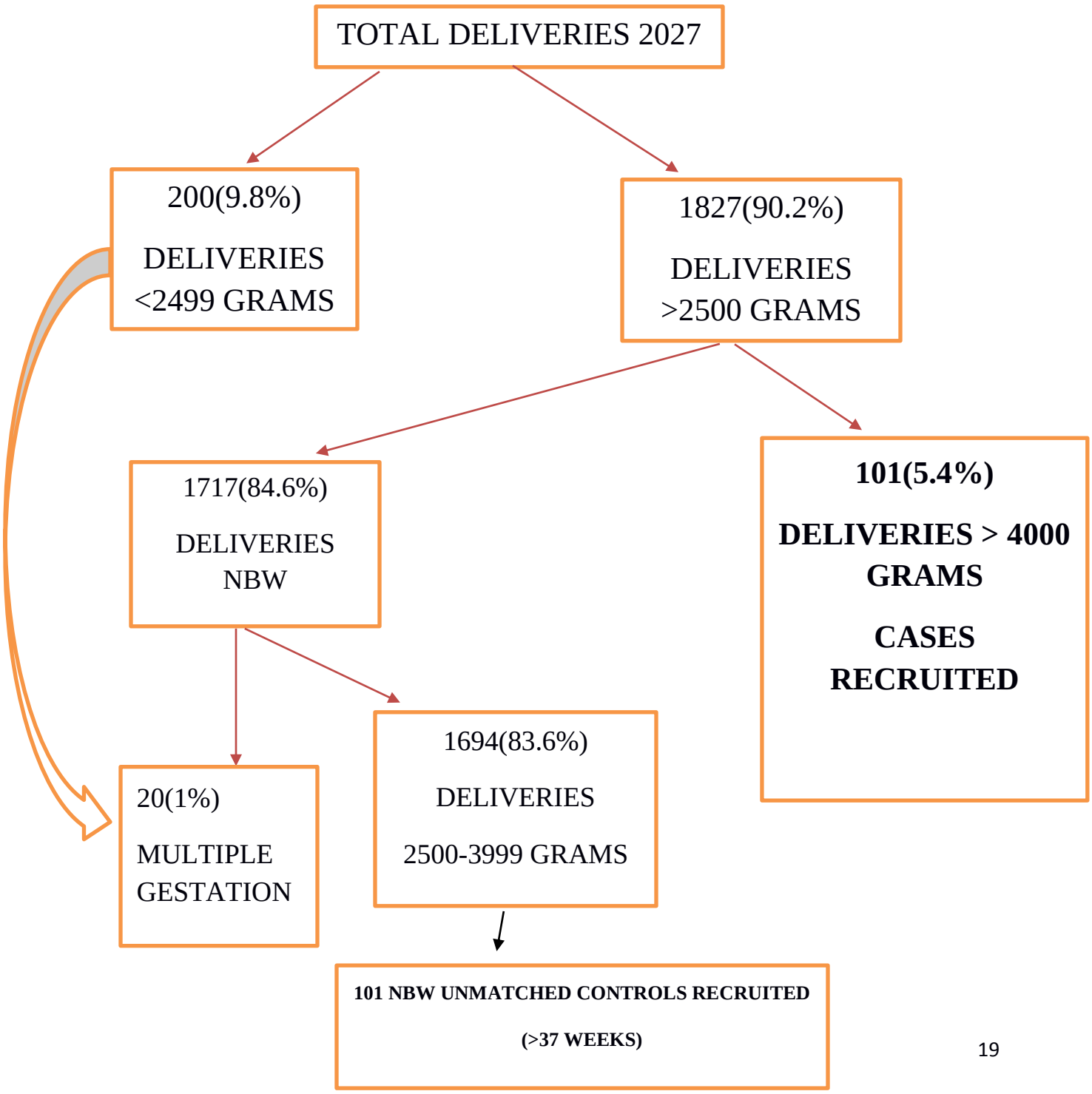


**Table 1: Sociodemographic and anthropometric characteristics of mothers of macrosomic and normal birth weight infants at KNH**

| | Cases n=101 (%) | Control n=101 (%) | OR | 95%CI | P value |
|---|---|---|---|---|---|
| **Age (mean in years)** | 29.8 | 27.0 | - | - | **0.001** |
| **Marital status** | | | | | |
| Single | 10(9.9) | 12(11.8) | 0.8 | 0.3-2.0 | 0.65 |
| Married | 91(90.1) | 89(88.1) | | | |
| **Maternal BMI** | | | | | |
| Normal (18-24.9) | 27(38.0) | 44(62) | 1.0 | NA | |
| Overweight (25-29.9) | 57(53.3) | 50(46.7) | 1.90 | 1.03-3.50 | **0.039** |
| Obese (≥30) | 17(70.8) | 7(29.2) | 4.04 | 1.48-11.01 | **0.006** |
| **Mean maternal weight change(kgs)** | | | | | |
| | 12.3 | 9.1 | | | **<0.001** |
| **Ethnic tribe** | | | | | |
| Kikuyu | 52(51.4) | 50(49.5) | 1.0 | NA | |
| Luhya | 21(20.8) | 19(18.8) | 1.06 | 0.51-2.20 | 0.870 |
| Luo | 14(13.8) | 11(10.9) | 1.22 | 0.50-2.95 | 0.65 |
| Kamba | 10(9.9) | 8(7.9) | 1.20 | 0.43-3.29 | 0.72 |
| Others | 4(3.96) | 12(12.87) | 0.32 | 0.09-1.06 | 0.06 |
| **Paternal BMI mean** | 23.6 (3.1) | 23.9 (1.5) | - | - | 0.297 |

Table 1, there was a significant association between macrosomia and maternal age, maternal BMI and maternal weight gain during pregnancy with the average age of mothers who delivered macrosomic infants being 29.8 yrs. and 27.0 yrs.' for mothers who delivered NBW infants (p value 0.001).70.8% of the mothers who were obese delivered macrosomic infants and 53.3% of the overweight mothers delivered macrosomic infants (OR 4.04 95% CI 1.48-11.01 P value =0.006) and (OR 1.90 95% CI 1.03-3.50 P value 0.039) respectively. The average maternal weight gain was 12.3kgs for the cases and 9.1 kgs for the NBW mothers (p value <0.001). Marital status, religion, ethnic group and paternal BMI showed no association with the delivery of a macrosomic infant

**Table 2: Antenatal, Medical and Nutritional Characteristics of mothers of macrosomic infants and NBW infants**

| | Case n (%) | Control n (%) | OR | 95%CI | P value |
|---|---|---|---|---|---|
| **Antenatal clinic attendance** | | | | | |
| Yes | 100 (99.1) | 101(100) | - | - | 0.316 |
| No | 1 (0.9) | 0(0) | | | |
| **Mean number of antenatal visits** | 4.6 | 4.7 | - | - | 0.580 |
| **Mean Hemoglobin levels(g/dl)** | 11.6 | 11.1 | - | - | 0.059 |
| **HIV** | | | | | |
| Positive | 0 | 2(2) | - | | 0.265 |
| Negative | 62(100) | 99(98) | - | | |
| **History of Diabetes/hyperglycemia Glycosuria** | | | | | |
| Yes | 33(86.8) | 5 (13.1) | 9.3 | 3.5-25.1 | **<0.001** |
| No | 68(41.4) | 96(58.5) | 1.0 | | |
| **Meal frequency** | | | | | |
| Less than 4/day | 9(8.9) | 18(18.2) | 1.0 | | |
| More than 4/day | 92(91.0) | 83(83.8) | 2.21 | 0.94-5.20 | 0.067 |

Table 2 shows that ANC attendance was reported in 99% of mothers with macrosomic neonates and all the mothers with normal birth weight neonates. The mean attendance of ANC with the cases was 4.6 as compared to the NBW, controls which was 4.7 *p=0.580.* There was significant association between history of diabetes, hyperglycemia or glycosuria and macrosomia with 32.7% of the cases having such a history as compared to 5% with the NBW, controls OR 9.3 95%CI 3.5-25.1 *p* value <0.001). Meal frequency did not show any association with fetal macrosomia.

**Table 3: Obstetrics Characteristics of mothers of macrosomic infants and NBW infants**

| | Case n(%) | Control n(%) | OR | 95%CI | p value |
|---|---|---|---|---|---|
| **Parity** | | | | | |
| 1 | 22(21.7) | 47(46.5) | 1.00 | - | - |
| 2 | 35(34.6) | 28(27.7) | 2.67 | 1.31-5.4 | **0.006** |
| 3 | 26(25.7) | 11(10.9) | 5.04 | 2.11-12.0 | **<0.001** |
| ≥4 | 18(17.8) | 15(14.9) | 2.56 | 1.09-6.0 | **0.030** |
| **Gestational age at time Of delivery** | | | | | |
| Early Term | 19(18.8) | 33(32.7) | 1.00 | - | - |
| Term | 51(50.5) | 56(55.4) | 1.58 | 0.80-3.12 | 0.186 |
| Late term | 21(20.8) | 5(4.9) | 7.29 | 2.36-22.51 | **<0.001** |
| Post term | 10(9.9) | 7(6.9) | 2.48 | 0.81-7.5 | 0.110 |
| **History of Previous Macrosomia** | | | | | |
| Yes | 27(100) | 0 | - | | **<0.001** |
| No | 74(42.2) | 101(57.7) | | | |
| **Fetal Sex** | | | | | |
| Male | 72(63.7) | 41(36.3) | 3.6 | 2.0-6.5 | **<0.001** |
| Female | 29(32.5) | 60(67.4) | 1.0 | | |

Table 3 shows, higher parity, late term pregnancy and a history of previous macrosomia were significantly associated with delivery of a macrosomic neonate. The odds of having a macrosomic infant increased with increasing parity were with the highest odds being para 3(OR 5.04 95% CI 2.11-12.0) p value <0.001 . The odds of a macrosomic infant was 7.29 times more in late term gestations compared to NBW (OR 7.29,95% CI 2.36-22.51, *p=<0.001*). The odds of delivery of a macrosomic neonate was 2.48 in post term as compared to NBW but this was not statistically significant. (OR=2.48,95%CI 0.81-7.5, *p*=0.110). History of a previous macrosomic delivery was significantly associated. There were 27 cases with a previous history of macrosomia with none of the NBW, controls having such a history. P value <0.001. Male Fetus was also shown to be significantly associated with fetal macrosomia. Male infants were 3.6 times likely to be macrosomic than female infants (OR 3.6,95%CI 2.0-6.5 p value ≤0.001)

**Table 4: comparisons of complications during labor and delivery between macrosomic and NBW deliveries.**

| | Case | Control | OR | 95%CI | P Value |
|---|---|---|---|---|---|
| **Obstructed labor** | | | | | |
| Yes | 5(5.4) | 3(3.0) | 1.7 | 0.4-7.3 | 0.721 |
| no | 96(95.0) | 98(97.0) | 1.0 | | |
| **Prolonged labor** | | | | | |
| Yes | 32(31.7) | 9(8.9) | 4.7 | 2.1-10.6 | **<0.001** |
| No | 69(68.3) | 92(91.1) | 1.0 | | |
| **Fetal distress/NRFS** | | | | | |
| Yes | 11(11.1) | 17(16.8) | 0.6 | 0.3-1.4 | 0.222 |
| No | 90(89.1) | 84(83.2) | 1.0 | | |
| **Shoulder Dystocia** | | | | | |
| Yes | 1(1.0) | 0 | - | | 0.316 |
| No | 100(99.0) | 101(100) | | | |
| **Episiotomy done** | | | | | |
| Yes | 12(12.0) | 5(5.0) | 2.6 | 0.9-7.7 | 0.076 |
| No | 89(88.1) | 96(95.0) | 1.0 | | |
| **Perineal tears** | | | | | |
| Yes | 35(34.7) | 22(21.8) | 1.9 | 1.0-3.6 | **0.042** |
| No | 66(65.3) | 79(78.2) | 1.0 | | |
| **Perineal tear grade** | | | | | |
| 1 | 0 | 4(18.2) | - | | **0.015** |
| 2 | 32(91.4) | 18(81.8) | | | |
| 3 | 3(8.6) | 0 | | | |
| **Postpartum hemorrhage** | | | | | |
| Yes | 11(10.9) | 4(4.0) | 3.0 | 0.9-9.7 | 0.060 |
| no | 90(89.1) | 97(96.0) | 1.0 | | |
| **Delivery Mode** | | | | | |
| VD | 38(37.6) | 61(60) | 1.0 | | |
| C/Section | 63(62.4) | 40(40) | 2.5 | 1.4-4.4 | **0.002** |
| **NBU admission** | | | | | |
| Yes | 14(15.1) | 3(3.0) | 5.3 | 1.5-18.9 | **0.005** |
| No | 87(86.1) | 98(97) | | | |
| **Still Birth** | | | | | |
| Yes | 3(3.0) | 0 | - | - | 0.081 |
| No | 98(97.0) | 101(100) | | | |

As shown in table 4, the odds of prolonged labor were 4.7 times in the cases as compared to NBW, controls (OR 4.7,95%CI 2.1-10.6 *p=<0.001*), being statistically significant. There was one case of shoulder dystocia that occurred with the cases with none that complicated the NBW,

controls, *p*=0. 316.Episiotomies were performed in 12% of the cases as compared to 5% with the NBW controls. This was however not statistically significant. (OR 2.6,95%CI 0.9-7.7, *p* value =0.076). Perineal tears occurred in 34% of the cases as compared to 21.8% with the NBW, controls (OR 1.9 95% CI 1.0-3.6, *p* value =0.042). Perineal tears of a higher grades were noted with the cases as compared with the NBW controls with 8.6% of grade three perineal tears occurring with macrosomic deliveries. Post-partum hemorrhage occurred in 10.9% of the cases as compared to 4% with NBW, controls. This however was not statistically significant. (OR 3.0,95% CI 0.9-9.7. *p* value=0.060). Fetal distress/ NRFS during labor occurred in 11.1% of the cases as compared to 16.8% with the NBW, controls (OR 0.6 95%CI 0.3-1.4, *p* value = 0.222)

The odds of delivering a macrosomic infant via caesarean was 2.5 times compared to NBW and the odds of a macrosomic infant being admitted to the new born unit was 5.3 times compared to a NBW infant. (OR 2.5, 95%CI 1.4-4.4 *P=0.002)* and (OR 5.3, 95% CI 1.5-18.9*p=0.005).* All were statistically significant. There were 3 macrosomic infants delivered as still births and none in the NBW. (p value 0.081)

**Table 5: Multivariate logistic regression model analysis of independent maternal predictors of macrosomia at KNH**

| Variable | OR | 95%CI | P value |
|---|---|---|---|
| Maternal weight gain | 1.18 | 1.07-1.31 | 0.001 |
| History of diabetes, Glycosuria, hyperglycemia | 10.7 | 3.1-36.6 | <0.001 |
| Gestation at the time of delivery | 1.4 | 1.1-2.0 | 0.023 |
| **Sex:** | | | |
| Male | 4.5 | 1.9-10.6 | <0.001 |
| Female | 1.0 | | |
| History of previous macrosomia | 30.4 | 3.6-252.9 | 0.001 |

Findings in logistic regression analysis in table 5 showed that maternal weight gain, history of diabetes, hyperglycemia and glycosuria, gestational age, male sex and history of macrosomia to be significantly associated. The factors that showed higher odds of association were history of macrosomia 30.4 (3.6-252.9) p value =0.002, history of diabetes, glycosuria and hyperglycemia 10.7 (3.1-36.9) p value <0.001 and male sex 4.5 (1.9-10.6) p value <0.001

## DISCUSSION

This was a hospital based unmatched case control study conducted at Kenyatta National Hospital, with objective of determining the sociodemographic and maternal factors associated with fetal macrosomia among women who deliver at Kenyatta National Hospital. The study was conducted during the period of 27th June 2016 and 15th august 2016.There were a total of 2027 deliveries during this period and out of this 101 were macrosomic deliveries (5. 4%).This is higher when compared to the case control study done in 1990 by Orero et al where the prevalence was reported as 0.83%, and also higher as compared to the prevalence reported by the national birth survey 4 of 1989(5). The prevalence in this study lies within the worldwide estimated prevalence of between 0.5% - 15%(10).

In this study the odds of a male macrosomic neonate was 3.6 time more s as compared to a female neonate, that was statistically significant with a male female ratio of 72:29, showing that fetal sex influenced macrosomic potential. Compared to the only previous study done in KNH the odds were 1.16 with a male female ratio of 60:42, this was not a statistically significant factor according to his study(5).

There was a high caesarean section rate, of 62.4% in mothers of macrosomic neonates than those of non macrosomic neonates (40%), with the main indication being prolonged labor. This rate was much higher in comparison to earlier studies done at KNH in 1990 where the caesarean rate was reported as 25.4% in mothers with macrosomic neonates (5). In Nigeria, a study done in 2007 reported a caesarean rate of 27%(13).

Maternal Age was noted to be a significant factor in macrosomic deliveries, with the mean age being 29.8 years with the cases versus 27.0 with the controls. This is similar to most other studies that have shown association between macrosomia and advancing maternal age(5,13,15,23).

Maternal BMI was also noted to be a significant risk factor to fetal macrosomia. There were 107 mothers who were overweight and 57 of these overweight mothers delivered macrosomic infants (53.3%). Twenty-four mothers were obese and 17 delivered macrosomic infants (70.8%). In comparison to the mothers with normal BMI, 27 out of 98 mothers delivered macrosomic infants (38.0%) This is similar to what was reported in 2012 in a study done in KNH on effects on BMI and pregnancy outcomes in which the incidence of macrosomia was noted to be higher in the overweight and obese groups of women(19). This is also similar and comparable to other regional and international studies done.

Paternal BMI was assessed in this study with only 54 fathers for the cases and 68 fathers for the controls being assessed. The fathers weight and height were recorded during their visits at the hospital or via a phone call so as to provide their height and weight. Mothers refusal for the partners' involvement, their unavailability or unreachable and refusal to give their measurements, attributed to the low numbers being interviewed. The acquired data did not show any association with macrosomic deliveries. The mean paternal BMI on cases was 23.6 as compared to 23.9 for the controls.

Ethnic tribe was also assessed in this study as other studies and literature have shown an association between ethnicity and macrosomia (1,2,16). In this study, no association was noted between ethnic tribe and macrosomic neonates, 52(51.4%) of all mothers who delivered macrosomic were kikuyu, and 50(49.5%) delivered normal weight neonates. 21(20.8%) of cases and 19(18.8%) of controls were from the Luhyia community.14(13.8%) of the cases and 11(10.9%) were from the Luo community. 10(9.9%) of the cases and 8(7.9%) of the controls were from the Kamba community. This distribution was noted to be similar to the ethnic distribution in the country according to the Kenya demographic and health survey 2014 in which

the largest ethnic group were reported as Kikuyu 22%, Luhya 15%, Luo, Kamba, Kalenjin 11-13% and 6% others for women (30).

A WHO report of 2015 reported the incidence of fetal macrosomia with diabetes as 20 % worldwide (14,31) and according to Mutungi et al the prevalence of glucose intolerance in antenatal mothers between 24-36 weeks gestation at KNH was reported as 18%(14) In view of this information, our study assed macrosomia in relation to having a history of diabetes, any episode of glycosuria during the antenatal period or an episode of elevated random blood sugars taken during the antenatal, intrapartum and immediate postpartum period as routine glucose intolerance screening or random blood sugar are not done at KNH at any gestation. There were 38 mothers with such a history and out of this 33 (86.8%) delivered infants with macrosomia and 5 (13.1%) delivered NBW infants (9.1%) We found no study with similar categorization but this study showed a significant association.

This study showed that mothers with a previous history of delivering a macrosomic infant was strongly associated with fetal macrosomia 27(26.7%) of the cases had a previous history of macrosomia as compared to none of the NBW, controls had such a history. Higher parity and gestational age at time of delivery was also noted to be significantly associated with fetal macrosomia. Mothers who just had their first delivery at the time of interview 21.7% delivered macrosomic neonates and 46.5% delivered NBW neonates. Compared to the higher parities 25.7% and 17.8% of the mothers were para 3 and 4 respectively had delivered macrosomic infants versus 10.9% and 14.9% who had delivered normal weighted neonates.

Post term has been noted in some studies to be significantly associated with fetal macrosomia. In this study 10 out of the 17 mothers (58.8%)who were postdates delivered macrosomic infants but

this was not found to be statistically significant. However, during the late term period (41 weeks to 41 weeks and 6 days) there were 26 mothers who delivered during this period and 21 delivered macrosomic infants (80.7%) and this was found to be statistically significant. Other studies done have shown an association between postdates and macrosomia and the findings in our study could have been brought about by the interventions undertaken prior to reaching postdates in order to avoid the morbidity and mortality that comes with postdates hence having the small number of 17 out of 202 women being postdates in our study.

Prolonged labor in this study was noted to be strongly associated with fetal macrosomia 32(31.7%) of the macrosomic infants were reported to have prolonged labor as compared to 9(8.9%) of the normal weight neonates. Perineal tears and lacerations occurred in 34.7% of mothers who had macrosomic deliveries as compared to 21.8% on mothers who delivered normal birth weight infants. This was found not to be statistically significant however perineal tears of a higher grade were not to be more on mothers who have delivered macrosomic neonates. Post-partum hemorrhage occurred in 10.9 percent of the cases as compared to 4% on the control. But this was not found to be statistically significant. Shoulder dystocia is a rare complication to fetal macrosomia and on our study there was one case of shoulder dystocia that was delivered. Fetal distress was also found to have no association with macrosomia. In the previous studies done at KNH similarities as seen as postdates, fetal distress, postpartum hemorrhage was also not found to be significantly associated with fetal macrosomia.

## STUDY LIMITATIONS

There were incomplete recordings on the antenatal booklet as some clinicians did not fill in all the sections.

This was a hospital based (tertiary facility) study and the results may not be inferred to the general population.

## CONCLUSION

This study was able to capture significant factors associated with fetal macrosomia that are similar to international and regional studies earlier done, which includes higher maternal BMI, weight gain during pregnancy, history of diabetes, glycosuria during the antenatal period and hyperglycemia.

Although the study was not designed to estimate the prevalence of fetal macrosomia, with the total deliveries conducted at the maternity unit 2027 there were 101(5.4%) newborns that were born macrosomic.

## RECOMMENDATIONS

1. Counselling and education on excessive weight gain during pregnancy due to its association with development of fetal macrosomia
2. The study was not set to establish the prevalence, immediate and fetal maternal complications therefore a study with the appropriate design is recommended to capture this (case cohort or cross sectional study)

**TIMELINES**

The research plan was as follows:

1. Proposal writing: November 2015-April 2016
2. Ethical committee revision: April 2016-June 2016
3. Data collection: June 2016-August 2016
4. Data analysis: August 2016-October 2016
5. Departmental Presentation-October 2016
6. Corrections and writing of Thesis: November 2016

## BUDGET

| components | Unit of measure | Duration/Number | Cost (kshs) | Total (kshs) |
|---|---|---|---|---|
| **personnel** | | | | |
| Research assistant | | 2 | 20000 | 40000 |
| statistician | | 1 | 35000 | 35000 |
| **printing** | | | | |
| Consent form | | 576 | 10 | 5760 |
| Questionnaires | | 768 | 10 | 7680 |
| Final report | | 124 | 10 | 1240 |
| **Misc** | | | | |
| Transport/travel expense/ airtime | | NA | NA | 20000 |
| Digital weighing scale (infant) | | 1 | 15000 | 15000 |
| Final report | | | | 10000 |
| **Total** | | | | **Ksh 134680** |

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## APPENDICES

## APPENDIX 1

## CONSENT FORM

## PART 1: INFORMATION SHEET

### Introduction

Dr. Bugah Arnold Bunyoli is a post graduate student in the department of Obstetrics and Gynecology, University of Nairobi., currently carrying out a study: Factors associated with fetal Macrosomia at Kenyatta National Hospital. You are invited to participate in this study and can take all the time needed to decide if you want to participate or not. Please take time to read through the information provided. If there are any questions, comments or clarifications, please feel free to ask the principle investigator or the research assistants.

### Purpose of the study

The aim of this study is to collect information on the factors that are associated with the delivery of a large baby (equal to or more than 4000 grams) at Kenyatta National Hospital, this is in order as to better manage our patients and reduce the adverse outcomes for both the mother and the baby.

### Procedure

If you decide to participate in this study you will have to sign and also date the consent form. A copy of the completed form will be made and given to you to keep. You will then complete a questionnaire that will be provided to you. A member of the research team will be present for any questions or clarifications you may have.

### Potential Risks

There are no anticipated risks associated with this study.

**Potential Benefits**

The information given to the research team by you is aimed to better manage patients who deliver large infants. You will also be able to better understand your condition, so as to be better prepared in future pregnancies**.**

**Confidentiality**

The information collected in this study will be confidential. No names will be used and instead each participant will be assigned an identification number. Only the research team will have access to the information provided, which will be kept under lock and key. Upon completion of the study, results will be shared only to the relevant parties.

**Right to refuse/withdraw**

Participation in the study is voluntary, therefore, you do not have to take part if you do not desire to. You may decide to withdraw from the study at any time you wish. Declining from participating or withdrawing will not in any way influence your current or future treatments/interventions and all your rights will be respected.

**Who to contact**

For any questions or clarifications about the study, feel free to contact:

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Email: uonknh_erc@uonbi.ac.ke

**PART 11: CONSENT**

I have read and understood the information provided above. I have been fully explained to about the study and have had the opportunity to ask questions which have been answered to my satisfaction. I have agreed to participate in this study voluntarily and have not been coerced/manipulated or bribed in any way.

Participant's Name: ---------- OR Thumb Print of Participant

Participant's Signature: ----------

Date: ----------

Witness's Signature: ---------- Date: ----------

**Statement by Researcher**

I have explained to the participant about the study. I have given the participant an opportunity to ask questions relevant to the study, and I have answered correctly to the best of my abilities. I have confirmed the participant has given consent voluntarily.

Name of Researcher: ----------

Signature: ----------

Date: ----------

**RIDHAA YA MAFUNZO**

**FOMU  YA MAELEZO**

**SEHEMU YA KWANZA: MAELEZO**

**Utangulizi**

Daktari Arnold Bugah Bunyoli ni mwanafunzi wa Chuo Kikuu cha Nairobi anaangazia maswala ya uzazi na afya ya wanawake kwa jumla. Ninafanya uchunguzi wa: Chanzo cha kujifungua mwana aliye na uzito ukubwa kuliko la kawaida.Unakaribishwa kushiriki katika uchunguzi huu na uamuzi wa kushiriki ni hiari yako. Kama kuna maswali yoyote au ufafanuzi utakao hitajika, kuwa huru kuwasiliana na mdadisi mkuu au manaibu wake.

**Lengo la utafiti**

Uchunguzi huu una nia ya kutambua chanzo kinachohusika na kujifungua mtoto aliye na uzito mkubwa kwa nia ya kuboresha matibabu, kupunguza madhara yanayotokana na ugonjwa huu, ili kuimarisha afya ya mama na mtoto.

**Namna**

Ukiamua kushiriki katika uchunguzi huu, utatia sahihi na tarehe katika fomu ya makubaliano. Utahitajika kujibu maswali utakayopatiwa, na kutakuwa na msaidizi atakapo hitajika.

**Hasara inayotarajiwa**

Hakuna hasara inayotarajiwa katika uchunguzi huu.

**Faida inayotarajiwa**

Matokeo ya uchunguzi huu yana lengo la kutoa matibabu bora kwa waadhiriwa wanaojifungua wana walio na kilo kupita iliyo ya kawaida na kuboresha afya kwa vizazi vijavyo.

**Usiri**

Matokeo ya uchunguzi huu yatawekwa siri. Hakuna majina yatatumika, kila muhusika atapewa nambari. Matokeo ya uchunguzi yatakabidhiwa kwa wanaohusika.

**Haki ya kukataa**

Kushiriki katika uchunguzi huu, ni kwa kujitolea. Una haki ya kujitoa kwa uchunguzi wakati wowote bila ya madhara yoyote.

**Kuwasiliana**

Kwa maswali yoyote au ufafanuzi wasiliana na:

Daktari Bugah Arnold Bunyoli

Mtafiti mkuu

Sanduku la Posta: 73897-00200

Nairobi

Nambari la simu: 0725004481

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Professor Muia Ndavi

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Secretary, KNH-UoN ERC

Sanduku la Posta: 19676-00202

Nairobi

Nambari ya simu: (254-020)2726300-9

Barua Pepe: uonknh_erc@uonbi.ac.ke

**SEHEMU YA PILI: MAKUBALIANO**

Nimesoma na nikaelewa ujumbe ulioko hapa juu. Nimeelezewa kwa makini kuhusu uchunguzi huu na nilipata nafasi ya kuuliza maswali yaliyojibiwa kamili. Nimekubali kushiriki katika uchunguzi huu bila kulazimishwa ama kupewa hongo.

Jina la Muhusika: …… AU Alama ya Kidole

Saini ya Muhusika: …….

Tarehe: ……

Saini ya Shahidi: ……. Tarehe: ……..,

**Taarifa ya Mdadisi**

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

Jina la mdadisi: ……

Saini: ……

Tarehe: …….

**APPENDIX 2: QUESTIONAIRRE**

Date: _____ Case: [ ] Control: [ ]

**SECTION A: Sociodemographic characteristics**

1. Age in complete years……
2. Marital Status: Single [ ], Married [ ], Separated [ ], Divorced [ ] , Widowed [ ].
3. Religion: Christian [ ], Muslim [ ], Others (specify)……..
4. Nationality……
5. Ethnic tribe……
6. Weight (in kilograms):
    a. Last weight recorded after 37 weeks of gestation and before delivery……
    b. Weight in the 1st trimester or preconception period…….
    c. Weight Change…….
7. Height (in meters) …….
8. Body mass index:

$$\frac{\text{Weight (6a)}}{(\text{Height (7)})^2}$$

BMI……

**Paternal**

1. Weight (kgs)…….
2. Height (in meters) ……
3. Body Mass Index……

**SECTION B: Antenatal Care**

1. Antenatal clinic attendance: Yes [ ] No [ ]
2. Number of visits…….
3. 

a) Antenatal profile done: Yes [ ] No [ ]

b) if 3a is yes, Hemoglobin levels……...g/dl

Blood Group(ABO)……(Rhesus)……

VDRL…….

HIV…….

4. 

a) Screening of diabetes in latest pregnancy, Yes [ ] , No [ ] if yes method of screening……..

b) History of Diabetes, Yes [ ] , No [ ]

c) If 4a is yes on medication [ ] Diet Control [ ]

**SECTION C: Latest Pregnancy**

**1.** Parity……...

**2.** Gestation at time of delivery……. (weeks)……. (days).

3. Mode of Delivery:

   a) Vaginal delivery. [ ]

   b) Caesarean section [ ]

4. Presentation:

   a) Cephalic [ ]

   b) Breech [ ]

   c) Transverse [ ]

   d) Compound [ ]

**5.** Duration of labour:

   a) Delivery within 12 hours [ ]

   b) Delivery within 13-19 hours [ ]

   c) Delivery within 20-24 hours [ ]

   d) Delivery after 24 hours [ ]

**6.** Complications during labour:

   a) Obstructed Labour, Yes [ ], No [ ]

   b) Prolonged labour, Yes [ ], No [ ]

   c) Fetal distress, Yes [ ], No [ ]

   d) Uterine rupture, Yes [ ], No [ ]

   e) Haemorrhage due to placenta praevia, Yes [ ], No [ ]

   f) Haemorrhage due to abruptio placenta, Yes [ ], No [ ]

g) Shoulder Dystocia, Yes [ ], No [ ]

7. Complications after delivery:
   a) perineal injury, Yes [ ] No [ ]
   b) post-partum haemorrhage, Yes [ ] No [ ]
   c) if 6b is Yes cause: Uterine Atony, Yes [ ] No [ ]

      Genital tract laceration, Yes [ ], No [ ]

8. Fetal Outcome
   a) Gender: Male [ ] Female [ ]
   b) Live Infant, [ ]
   c) Still Birth, [ ]
   d) NBU admission, [ ]

**SECTION D: Previous Obstetric history**

1. Previous history of macrosomia Yes [ ] No [ ]
2. Period between previous pregnancy and the latest……yrs.
3. a) History of family planning Yes [ ], No [ ]

   b) if 3a is yes, method of family planning…….

**SECTION E: Nutrition**

1. Approximate number of meals per day……
2. Nutrional taboos associated with pregnancy Yes [ ] No [ ] if yes which ones……

   ……

## APPENDIX 3:ADULT AND INFANT WEIGHING SCALE