EFFECT OF BODY MASS INDEX ON PREGNANCY OUTCOME AT KENYATTA NATIONAL HOSPITAL: COHORT STUDY

A dissertation submitted as partial fulfillment for the award of degree of Master of Medicine in Obstetrics and Gynecology of the University of Nairobi.

PRINCIPLE INVESTIGATOR:

DR. MILKA MUTHONI KIHARA RITHO,

SENIOR HOUSE OFFICER

DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

UNIVERSITY OF NAIROBI

DECLARATION

This is to declare that this research proposal is my original work and that it was done with the guidance of my supervisors. It has not been submitted to any other university for the award of a degree.

Signature... Muthoni Ritho

Date: 21/01/2012.

Dr. Milka Muthoni Kihara Ritho

Senior House Officer,

Department of Obstetrics and Gynecology,

University of Nairobi.

H58/71963/08

CERTIFICATE OF SUPERVISION

This is to certify that this dissertation was developed under my guidance

Dr. Omondi Ogutu

Senior Lecturer and

Consultant Obstetrician and Gynecologist

Department of Obstetrics and Gynecology

School of Medicine

University of Nairobi

Signature.....

Date 3rd January 2012

Dr. Lubano Kizito

Consultant Obstetrician and Gynecologist

HIV Specialist

Hon Lecturer

Department of Obstetrics and Gynecology

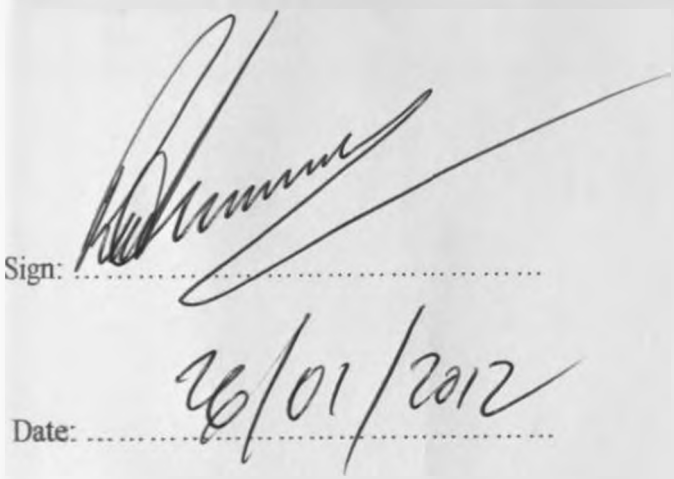
University of Nairobi

Signature.....

Date

DEPARTMENT CERTIFICATE OF AUTHENTICITY

This is to certify that this dissertation is the original work of Dr. Milka Muthoni Kihara Ritho, M.Med student registration number H58/71963/2008 in Obstetrics and Gynecology department, University of Nairobi (2008-2012). The research was carried out in the department of Obstetrics and Gynaecology, School of Medicine, College of Health Sciences under the guidance and supervision of Dr Omondi Ogutu and Dr Lubano Kizito. It has not been presented in any other university for award of a degree.



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Date: 26/01/2012

PROF. KOIGI KAMAU

ASSOCIATE PROFESSOR OF OBSTETRICS/GYNAECOLOGY,

CONSULTANT OBSTETRICIAN AND GYNAECOLOGIST'

CHAIRMAN

DEPARTMENT OF OBSTETRICS/GYNAECOLOGY

UNIVERSITY OF NAIROBI.

DEDICATION

To my beloved parents Dr. E. K. Ritho and Mrs. Mary Ritho

Your inspiration and encouragement has been invaluable to me.

ACKNOWLEDGEMENTS

Acknowledgements are few and well deserved. First to my supervisors, Dr Omondi Ogutu and Dr Kizito Lubano, for your patience, understanding and guidance without which this study would not have been accomplished.

To my research assistant Maureen and my statististician Michelle, your assistance was invaluable to me.

To my fellow residents, your encouragement and criticism was invaluable to me during the course of this study.

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LIST OF ABBREVIATIONS

i.	BMI……	Body Mass Index
ii.	IUFD……	Intrauterine Fetal Demise
iii.	IUGR……	Intrauterine Growth Restriction
iv.	IOM……	Institute of Medicine
v.	LBWT……	Low Birth Weight
vi.	LGA……	Large for Gestational Age
vii.	NRFS……	Non Reassuring Fetal Status
viii.	PET……	Pre-eclamptic Toxemia
ix.	PROM……	Pre-labor Rapture of Membranes
x.	RDS……	Respiratory Distress Syndrome
xi.	RTI……	Respiratory Tract Infection
xii.	SGA……	Small for Gestational Age
xiii.	UTI……	Urinary Tract Infection
xiv.	WHO……	World Health Organization

ABSTRACT

Introduction

The increasing population of overweight and obese women world-wide is a major public health concern now reaching epidemic proportions. Two thirds of these women are in the reproductive age which has critical consequences for fetal and maternal health.

Maternal obesity has been shown to be associated with adverse pregnancy outcomes such as hypertension, diabetes , infections such a urinary tract infections (UTI), preterm labor, increased cesarean delivery; and poor neonatal outcomes such RDS, macrosomia and prematurity . Obesity thus results in increased maternal and perinatal morbidity and mortality with increased costs of provision of healthcare.

Objective

This study was aimed at determining the effect of high maternal body mass index (BMI) i.e. ≥ 25 and gestational weight gain on pregnancy outcomes.

Study setting

The study was carried out at the K.N.H labour ward

Study design

This study was designed as a hospital based cohort study

Study population

This was comprised of mothers coming to K.N.H for delivery. A total of 400 women were recruited into the study, the exposed group were women with increased BMI i.e. >25 and the unexposed were women with normal BMI i.e. 18.5-24.9.The exposed were 226 in total and were further divided into overweight group (BMI 25-29.9) with 203 women and obese group (BMI 30-34.9) with 23 women. The unexposed were 174 in number.

Study Methodology

The women delivering at the KNH labor ward were randomly recruited in the first stage of labor after their booking BMI at or before 20 weeks gestation was calculated from the antenatal cards. BMI was established by use of measures of height and weight using the formula BMI= weight (kg) ÷height $(m)^2$. The maternal outcomes of interest were pregnancy induced hypertension, pre-eclampsia, eclampsia, gestational diabetes, PROM, preterm delivery, post term delivery, induction of labor and its indications, caesarian section and its indication, postpartum hemorrhage and duration of hospital stay. Fetal outcomes of interest include SGA, LGA, RDS and perinatal deaths. The frequency of these outcomes in each BMI group was recorded and compared using univariate and multivariate regression techniques which controlled for confounding factors.

Data Handling and analysis:

The extracted data was entered into Statistical Package of Social Science™ (SPSS) version 17.0 for Windows (SPSS, Chicago, IL, USA) statistical software to check for errors and perform the requisite statistical test. Frequency distribution was used for data cleaning. Data was analyzed using the same software. Descriptive analysis was performed to characterize the number and type of patient outcome. To obtain insight into the social demographics factors of the patients, frequency tables were used with accompanying percentages. Bivariate comparison of continuous symmetric characteristic was performed using t-test and using the Mann-Whitney test for non-symmetric characteristics. Fisher exact test and chi square test, as appropriate was used for comparison of categorical characteristics.

Correlation between variables was tested using the Pearson correlation co-efficient. Statistical significance was defined as a two tailed p-value of less than or equal to 0.05.

Results

In comparison with women of BMI 20 – 24.9, obese women faced the highest risk of pre-eclampsia OR 2.368 (95% CI 1.190, 4.700), pregnancy induced hypertension OR 4.320(95% C.I 1.200, 15.910, induced labour OR 4.300 (95% CI 1.390, 13.310), emergency Caesarean section rates OR 2.35 (95% CI 0.896, 6.817) and post term delivery OR1.346 (95% CI 0.499-3.633). Overweight women were more likely to have eclampsia OR 3.17 (95% CI 1.02, 9.80) and still births OR 3.170 (95% CI 1.020, 9.800) . The highest risk of birth weights > 4,000 g was in obese OR4.327 (95% CI 1.123, 16.672). Majority of the women in the normal BMI group had inadequate weight gain in pregnancy (81.6%) while majority of those in the overweight (84.72) and obese (73.91) groups had recommended weight gain. There was no positive linear association between excessive gestational weight gain and obstetric outcomes. Inadequate gestational weight gain was associated with increased risk of RDS OR 1.985 (p =0.016), SGA OR 1.1365 (p=0.017) and preterm labour OR 1.88 (p=0.051).

Conclusion

This study showed that increased maternal BMI is associated with increased risk of adverse obstetric outcomes and increased intervention rates .These include increased risk of PIH, pre-eclampsia, fetal macrosomia, post term pregnancy, induction of labour , ceaserian delivery and still births.

Excessive gestational weight gain did not result in increased risk of adverse outcomes; however, inadequate weight gain was associated with increased risk of preterm labour and SGA.

Recommendations

Preconception nutritional counseling is important for management of obesity before pregnancy.

Inappropriate weight gain in pregnancy (inadequate or excessive) should be recognized early enough and acted upon to reduce the attendant complications.

A nationwide community-based prospective study should be done to provide in-depth knowledge about the prevalence and impact of different categories of BMI on pregnancy outcomes among different socioeconomic and ethnic groups.

Policy makers need to recognize increased BMI as a health issue is prevalent in our population and formulate guidelines on management of these women to optimize maternal and fetal outcome

INTRODUCTION

The rising prevalence of overweight and obesity is a major public health concern and has currently reached epidemic proportions [1]. This has led to a World Health Organization declaration that obesity is a major killer disease of the millennium at par with HIV and malnutrition. This has resulted in a paradox in that the two extremes malnutrition and obesity can coexist. [2]

Obesity has been defined as a condition characterized by excessive body fat frequently resulting in impairment of health. [3]It is estimated that more than 300 million adults worldwide are obese, more than one billion overweight and a further 115 million suffer related problems. About 64% of the population in the USA is overweight or obese with morbid obesity affecting more than 9 million. In the UK, the prevalence of obesity is estimated at 23% in women and 22% in men [4].In addition it has been associated with 30,000 deaths and 18 million sick days off costing the economy about 3 billion pounds annually. [5]

It is estimated that in the developed countries about 28% of pregnant women are overweight and 11% obese. In the U.S.A, 18.5% to 38% of women are obese depending on the definition used and in the U.K, 56% of all women are above the recommended BMI with 33% overweight and 23% obese. Obesity was noted to be an important risk factor for maternal death with 35% of the mortalities being obese women in the UK [6]. In South Africa, 58% of women have been reported to be above the recommended BMI [7].In Kenya, it has been estimated that 43.3% of women are overweight or obese with risk factors of urbanisation and high income. [8, 9]

Pregnancy complications among the overweight women have been studied from as early as 1945. Since then several studies have reported a clear association between maternal overweight and

adverse fetomaternal outcomes. Effect of maternal underweight remains less clear. Some studies have reported increased incidence of preterm labor and LBWT babies while other studies have reported a protective effect on certain pregnancy complications and interventions including pre-eclampsia, gestational diabetes, caesarian sections and postpartum haemorhage. [10]

Definition of underweight, overweight and obesity differ in various reports. Body mass index (BMI) has become in recent times an accepted measure of weight. Other measures that have been used include waist hip ratio which has been shown to be a more accurate measure but such data is seldom available, waist circumference and absolute body weight (more than 90 kilos is overweight). BMI, also known as Quetelet index is a statistical measure that compares a person's weight for height and doesn't actually measure body fat. It is commonly used to diagnose weight problems in a population but is not appropriate for individual diagnosis [10] .The revised 2009 Institute of Medicine (IOM) guidelines classify the population into underweight, normal, overweight, obese and morbidly obese depending on the BMI. [2]Management of weight problems in pregnancy is three pronged. Primary prevention is aimed at optimizing preconception BMI to the ideal. Secondary interventions target mothers at risk of developing pregnancy related complications as a result of their BMI while tertiary interventions target women experiencing the pregnancy related complications.

Despite the many studies done in the Europe and the USA on effect of maternal BMI on pregnancy outcomes, very few have been published in the continent and more so in Kenya. This study aimed to examine the effect of increased maternal BMI on pregnancy and neonatal outcomes, weight gain patterns among pregnant women and the effect of excessive weight gain in pregnancy among women delivering at the KNH labor ward.

LITERATURE REVIEW

BMI has been defined as weight in kilograms per square metre. It is calculated by division of a person's weight in kilograms by the square of their height in metres to give units in kilograms per square metre. It categorizes women into 4 groups i.e. underweight (<18.5kg/m^2), normal (18.5-24.9 kg/m^2), overweight (25-29.9kg/m^2) and obese (>30kg/m^2) [2]. It is a good statistical tool for diagnosis of weight problems in a population.

The prevalence of the overweight and obese population worldwide has been on the increase. This has posed a major public health concern as this population been associated with increased morbidity and mortality. In reproductive health, overweight and obesity has been associated with infertility and adverse pregnancy and neonatal outcomes.

Fetal risks associated with maternal obesity include recurrent first trimester abortions despite normal endometrial receptivity, [11] increased birth defects including neural tube defects, cardiac anomalies, omphalocele, cleft lip and palate [12].This has been hypothesized to result from undetected type 2 diabetes in early pregnancy. In addition, high BMI is associated with fetal macrosomia resulting in adverse maternal outcomes from interventions such as induction of labor, caesarian deliveries and adverse neonatal outcomes from shoulder dystocia such as nerve palsies. [13]. High BMI has also been associated with fetal distress with resultant increase risk of fetal meconeum aspiration, still birth and early neonatal death [13][14]

Maternal risks of increased BMI have been observed in the antepaturm, intrapaturm and postpartum period. Antenatal risks include increased risk of hypertensive disorders including pre-eclampsia, eclampsia and gestational diabetes. [18] .It has also been associated with difficulties in abdominal palpation in assessment of fetal growth and sonographic prenatal diagnosis especially if the BMI is above the 90th centile [16]. In addition, larger cuffs are required to measure blood pressure resulting in technical difficulties especially when the

upper arm circumference is greater than 35 cm. [17]. High BMI is also a risk factor for deep venous thrombosis and cholecystitis, preterm labor and PROM [18]

Intrapaturm risks include increased risk induction of labor, caesarian section, failed instrumental delivery, increased perineal tears and postpartum hemorrhage. [19] [20].There is also a reduced likelihood of vaginal birth after caesarian delivery (VBAC) and vaginal delivery if weight gain in pregnancy is greater than 18kg [21,25]. Success of VBAC was found to be less than 68.2% among the overweight compared to 79.9% in the normal population in a Chicago study. All these result in higher hospital stay and increased cost of health services. The high BMI is associated with co morbidities which increase the likelihood of anesthetic interventions. Failed regional blocks and failed inductions are more common in this group. PET and GDM increase this risk further [22] [23]. With the use of spinal anesthesia, high blocks are more common with resultant slower recovery. Hypoxic complications are also commoner due to upward shift of the diaphragm. [22] [24]

In the postpartum period, high BMI has been associated with increased post caesarian infection and morbidity despite use of prophylactic antibiotics. This has also been seen in elective caesarian section. Wound dehiscence's and sepsis requiring open debridement wound s significantly higher in obese women with vertical abdominal incisions and is unrelated to type of suture and use of drains. [24] [25] [26] Lesser rates of wound dehiscence were seen in closure of subcutaneous layer as opposed to non closure in a met-analysis. In addition, these women are at increased risk of postpartum UTI, anemia [18] hemorrhage, delayed lactation and lactation failure [28].

Long term risks include retention of the weight gained during pregnancy resulting in increased morbidity and mortality from coronary heart disease, diabetes, hypertension stroke

and a number of cancers [29] .In addition, negative self and body image may predispose these women to poor mental health.

Neonatal outcomes include LGA, SGA, RDS and prematurity. Low BMI and underweight on the other hand is less common. It has been associated with outcomes such as preterm led with labor, IUGR, prematurity and SGA

The determinants of BMI include genetics, ethnicity, lifestyle and diet. Socioeconomic factors have been shown to determine the same with women in lower income groups having a tendency to high BMI in the west. On the contrary, in the developing countries, higher economic status is associated with higher BMI.

It has been hypothesized that obesity is associated with a chronic inflammatory response with an associated increase in measurable inflammatory markers in the serum. This has been shown to interfere with normal function of the cells resulting in the final pathway for development of pregnancy complications such as hypertension, diabetes, PROM and Preterm labor [30].

Weight gain in pregnancy has also been established as an important determinant of pregnancy outcomes [20, 32, 40]. Initial recommendations for weight gain in pregnancy were controversial. Currently the 2009 Institute of Medicine (IOM) Guidelines are used which ranges depending on pre-pregnant weight .A systematic review of these recommendations by the California School of Public Health showed that pregnancy weight gain within the IOMs ranges is associated with the best fetal and maternal outcome[2]. High Pregnancy weight gain despite normal pre-pregnancy BMI is associated with poorer maternal and fetal outcomes. [32]

Table 1

Revised IOM recommendations for weight gain in pregnancy(2009)

Pre-pregnancy BMI	Recommended weight gain(kg)	Rate of weight gain in 2nd and 3rd trimesters(kg)/wk
Underweight <18.5	12.7-18.1	1 (1-1.3)
Normal 18.5-24.9	11.3-15.8	1 (0.8-1)
Overweight 25-29.9	6.8-11.3	0.6(0.5-0.7)
Obese >29.9	4.9-9kg	0.5(0.4-0.6)

(Calculations assume 0.5-2kg weight gain in first trimester)

Bhattacharya et al examined the effect of BMI on pregnancy outcomes among nulliparous women delivering singleton babies in Aberdeen in a retrospective cohort study. They found that in comparison with women with normal BMI, obese and women were at increased risk of developing PET, having IOL, PPH preterm labor and caesarian delivery. Underweight women were found to have LBWT babies and decreased risk of hypertension and DM.[17]

Naeye R.L et al evaluated the effect of maternal BMI on perinatal mortality rate and found that it was increased from 37 in 1000 in lean subjects to 121 in 1000 among obese mothers. More than half of these resulted from premature labor triggered most commonly by chorioamnionitis[31]. In another multicentre WHO study on perinatal mortality by Kramer et al [34] high maternal BMI was noted as a risk factor for increased perinatal mortality as a result of labor related complications and prematurity.

In a prospective cohort study done by D.A Doherty et al [35], women were recruited at 16 weeks gestation, BMI established and they were followed up until delivery. This study found

that pre-pregnancy obesity was associated with increased risk of gestational diabetes, PET, IOL, PPH, neonatal hypoglycemia, need for neonatal resuscitation and LBWT.

Usher Kiran et al [18] examined the incidence of adverse labor outcomes and feto-maternal morbidity in the obese primigravid women with singleton pregnancies at a hospital in Wales. This study found that there was increased risk of IOL, caesarian delivery, macrosomia, instrumental delivery, PPH, neonatal admissions in the obese population. Induction of labor was noted to be the starting point in the cascade of events.

In a cohort study done by Wanjiku Kabiru [32] aimed at investigating the increase in body mass category on obstetric outcomes in Atlanta, primigravid women with singleton pregnancies were recruited. The increase in BMI was calculated as difference between initial BMI and that at delivery. The study showed that, 49% of the women had no change in BMI category, 43% increased 1 BMI category and 6.3% by >1 category. Increase in BMI category was associated with higher rates of gestational diabetes, failed induction, lacerations, caesarian deliveries and postpartum infection in normal weight women, overweight and obese were at increased risk of PET , operative vaginal deliveries, chorioamnionitis, failed induction and caesarian deliveries.

Denison et al [33] investigated the effect of maternal BMI on minor associated with additional medication use and consequent cost complication a retrospective cohort study in 42.2 % of women were found to be overweight or obese. Higher BMI in the first trimester was associated with increased minor complications in pregnancy such as pubic symphisis dysfunction, heartburn, and respiratory tract infections associated increased cost of hospital treatments

Very few studies have been published on this area in Africa. A study done in South Africa on women attending ANC at a downtown clinic [6] established that about 56% of the women attending clinic had BMI above recommended and these women were at increased risk of developing hypertension ,diabetes and preterm labor. In addition, the study evaluated the weight gained during pregnancy and found that women with rapid weight gain were at risk of developing adverse pregnancy outcomes despite having normal pre-pregnancy BMIs. There was no correlation found between BMI and birth weight of the babies. In a related study in the same country, outcome of pregnancy in obese women was evaluated [37], increased risk of hypertension, diabetes, UTI, IOL and perineal damage was established. There were also increased caesarian delivery rates with associated poorer wound healing and postoperative pain management. Another retrospective cohort study in Ghana by Addo et al found that the incidence of macrosomia, still birth, perineal trauma and PPH was significantly higher in the obese women. [44]

Weight continues to be an important determinant of health worldwide and even more so in reproductive health where both extremes of the spectrum are associated with adverse maternal and neonatal outcomes. The prevalence of the overweight and obese population in Europe and USA has been on the increase as a result of changing dietary patterns and sedentary lifestyles. This pattern has been noted to be reflected in the African population as well.

Most of the studies quoted above have been done in the developed world where maternal and neonatal healthcare is optimum This study aimed to establish the effect of increased BMI on pregnancy outcomes and come up with recommendations for local guidelines on management of such mothers in KNH. This would decrease both perinatal and maternal

morbidity and mortality in keeping with the millennium development goals 4 and 5 respectively.

JUSTIFICATION AND UTILITY

The population of women with extremes of BMI during pregnancy and delivery give obstetricians a new and unique challenge of management as a result of their vulnerability to the risks discussed previously .Currently, these challenges have not been comprehensively addressed in our set up partly due to lack of data on the prevalence of both the weight problem as well as the frequency of the complications. In addition, there are no guidelines on the management of women with weight as a health issue in pregnancy and delivery. These would include prepregnancy nutritional counseling and weight management, pregnancy weight gain management and interventions policies

Despite having numerous studies done in the developed world on weight gain during pregnancy and the effect of BMI on fetomaternal outcomes, there have been very few done on the African population and even so in Kenya. There is still no consensus on the ideal weight for optimum pregnancy outcomes as well as optimum weight gain in pregnancy in the black population.

CONCEPTUAL FRAMEWORK

Narrative

Women are grouped as exposed (increased BMI) and non exposed (normal BMI). Increased prepregnancy maternal BMI has been shown to have increased risk of adverse fetomaternal outcomes. In addition, inadequate weight gain in pregnancy has also been shown to increase the risk of these outcomes. This study was aimed at establishing the effect of increased maternal BMI and inappropriate gestational weight gain on pregnancy outcomes.

Women were recruited into the study in the labour wards and followed up until discharge. The exposed were women with increased BMI while the unexposed were women with normal BMI. The frequency of outcomes in the exposed and unexposed was then compared to establish risk.

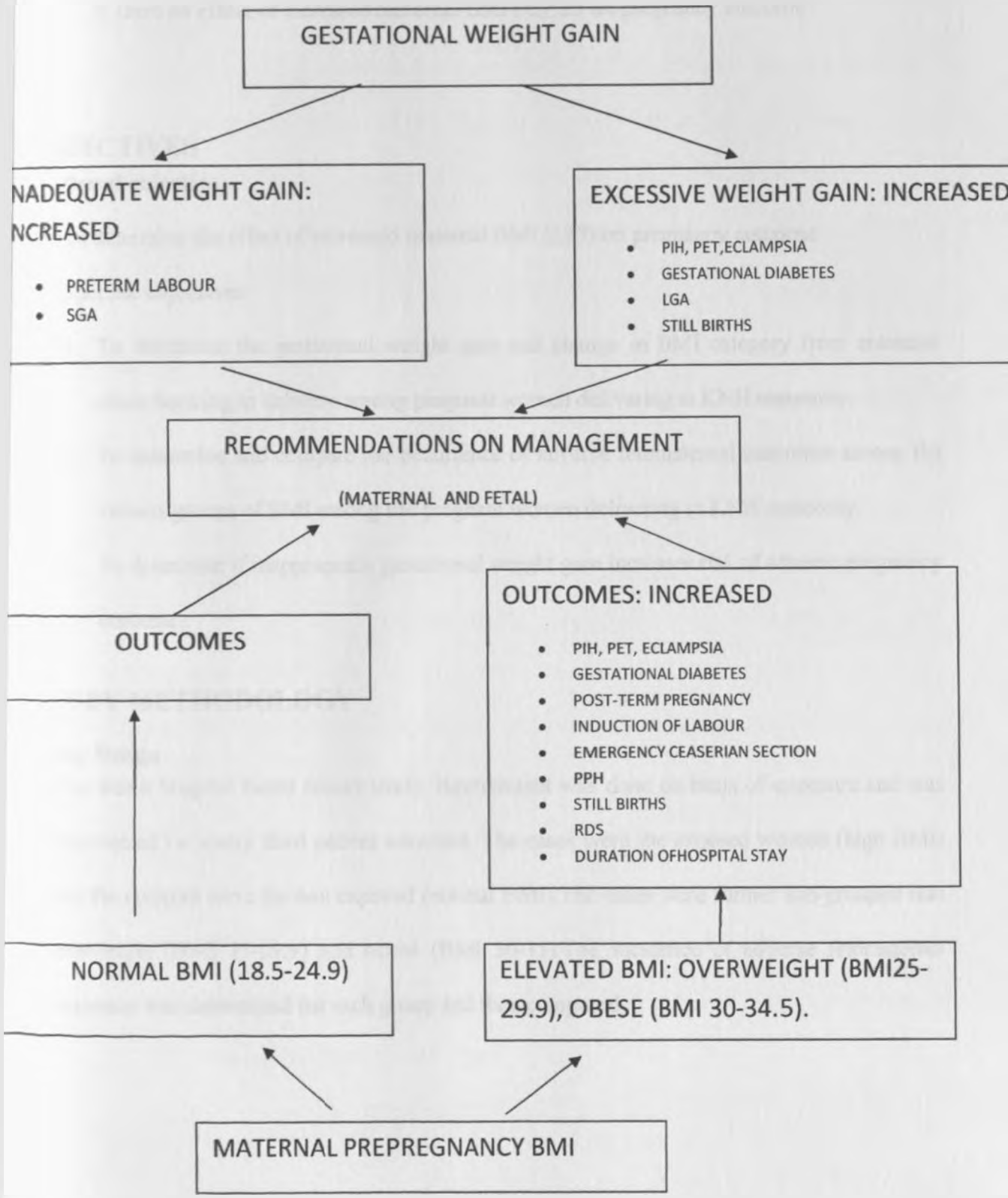
Outcomes of interest included:

1. Pregnancy induced hypertension (PIH) , PET and eclampsia
2. Gestational diabetes mellitus and glucose intolerance
3. Preterm labor
4. Post term delivery
5. Type of labor :spontaneous or induced and indication(s) for induction
6. Mode of delivery : normal vaginal or caesarian delivery and indications of the later
7. Postpartum hemorrhage
8. Maternal mortality
9. Length of hospital stay.

Neonatal outcomes

1. Perinatal mortality
2. LGA babies
3. SGA babies
4. Severe respiratory distress syndrome

DIAGRAMMATIC REPRESENTATION OF THE CONCEPTUAL FRAMEWORK



RESEARCH QUESTION

Is there an effect of increased maternal BMI i.e ≥ 25 on pregnancy outcome?

OBJECTIVES

Broad objective

To determine the effect of increased maternal BMI (≥25) on pregnancy outcome

Specific objectives

1. To determine the gestational weight gain and change in BMI category from antenatal clinic booking to delivery among pregnant women delivering at KNH maternity.
2. To determine and compare the occurrence of adverse fetomaternal outcomes among the various groups of BMI among the pregnant women delivering in KNH maternity.
3. To determine if inappropriate gestational weight gain increases risk of adverse pregnancy outcomes

STUDY METHODOLOGY

Study Design

This was a hospital based cohort study. Recruitment was done on basis of exposure and was randomized i.e. every third patient admitted. The cases were the exposed women (high BMI) and the controls were the non exposed (normal BMI).The cases were further sub-grouped into overweight (BMI 25-29.9) and obese (BMI 30-35).The incidence of adverse fetomaternal outcomes was determined for each group and then compared.

Study Population

This was comprised of women delivering in the K.N.H labour ward. The exposed were women with elevated BMI (>25) and the non exposed were women with normal BMI(18.5-24.9).The exposed were further divided into obese(BMI 30-34.9) and overweight(BMI 25-29.9) .A total of 400 women were recruited, 174 with normal BMI, 203 overweight and 23 obese

Study area

This study was carried out at the obstetric unit of the Kenyatta National hospital, a national referral hospital located in Nairobi, Kenya. It is situated about 5 kilometers from the city centre and has one of the busiest maternity units in Nairobi province with an average daily turnover of 50 patients in the maternity ward. The maternity ward has a bed capacity of 30.It also has 3 postnatal wards where the mothers are transferred to after delivery and managed until discharge. The maternity unity is accessorized with a fully functional maternity theatre where all caesarian sections and other obstetric surgeries are performed and anew born unit complete with a new born intensive care unit that caters for preterm and sickly newborns. The clientele served is mainly the middle and lower income groups. It is a nationwide referral hospital for complicated obstetric cases and therefore has a nationwide catchment area. It also has a busy antenatal clinic with a daily turnover of an average of 80 women most of who subsequently deliver in the hospital's maternity making KNH ideal for this study.

Sampling Frame

This included all consenting pregnant women at the KNH labor ward. The women satisfying the inclusion criteria were recruited randomly i.e. every third patient until the required sample size was attained.

Exposure of Interest

The exposure of interest was increased maternal BMI among pregnant women

Sample size estimation

Previous studies on the effect of maternal BMI on pregnancy outcomes have shown an overweight and obesity rate of 34% and a two fold increase of adverse fetomaternal outcomes [44, 45]

Exposure ----------> Increased BMI

Disease ----------> Adverse pregnancy outcome

$$n_1 = \frac{(Z_{\alpha/2}+Z_{1-\beta})2pq(r+1)}{r(P_1-P_2)^2}$$

And

$n_2 = rn_1$

n_1 = Number of exposed

n_2 = Number of unexposed

$Z_{\alpha/2}$= standard normal deviate for two-tailed test based on alpha level (relates to the confidence interval level)

$Z_{1-\beta}$ =standard normal deviate for one-tailed test based on beta level (relates to the power level)

r = ratio of unexposed to exposed=1

p_1 = proportion of exposed with disease and q_1 = 1-p =0.16

p_2 = proportion of unexposed with disease and q_2 = 1-p_2 =0.085

$p=p_1+rp_2$

$q=1-p$

To detect a 2-fold increase in the risk of poor pregnancy outcome (RR=2.0) among women with increased BMI compared with women with normal BMI, we need to recruit a minimum of 173 women in each group giving a total of 346 women

Inclusion Criteria

1. Pregnant women who give informed consent
2. Pregnant women with clear antenatal records with measures of interest.
3. Pregnant women who had antenatal booking at or before 20 weeks gestation
4. Pregnant women with BMI ≥18.5

Exclusion Criteria

1. Pregnant women in whom vaginal delivery was contraindicated
2. Pregnant women with pre-existing medical conditions such as diabetes, chronic hypertension, cardiac disease, thyroid disease
3. Pregnant women with multiple gestation

Variables measured

Outcomes that were compared among the different groups included:

Maternal adverse outcomes:

1. Pregnancy induced hypertension (PIH) ; including PET(diastolic blood pressure ≥90mmHg or systolic blood pressure ≥140mmHg on two occasions at least 4 or more hours apart or both arising after 20 weeks gestation with associated proteinuria; eclampsia defined as pre-eclampsia accompanied by convulsions or unexplained coma.
2. Gestational diabetes mellitus defined as carbohydrate intolerance of variable severity first diagnosed during pregnancy after 24 weeks gestation
3. Preterm labor defined as uterine contractions resulting in cervical changes before 37 completed weeks of gestation.
4. Post term delivery defined as delivery after 41 completed weeks of gestation
5. Type of labor :spontaneous or induced and indication(s) for induction
6. Mode of delivery : normal vaginal or caesarian delivery and indications of the later
7. Postpartum complications including postpartum hemorrhage defined as blood loss ≥500mls at normal vaginal delivery or ≥1000mls following caesarian delivery
8. Maternal mortality

9. Length of hospital stay.

Neonatal outcomes:

1. Perinatal mortality death(defined as still birth or neonatal death within 24 hours of delivery)
2. LGA babies with birth weight >90th percentile for gestational age or macrosomia >4kg
3. SGA babies with birth weight < 10th percentile for gestational age or low birth weight < 2kg
4. Severe respiratory distress syndrome necessitating NBU admission

MATERIALS AND METHODS

Procedures and observations

The women satisfying the inclusion criteria were recruited into the study in first stage of labor at the KNH labor ward randomly i.e. every third woman. Informed consent was then obtained. Sociodermographic variables were collected from the antenatal cards and interview and these included age, marital status, level of education, area of residence, smoking status, occupation; spouse's education level and occupation and area of residence. Parity, gestation age and diagnosis on admission were recorded from the patient files. Gestational age was calculated using the last menstrual period (LMP) or obstetric ultrasound if LMP was unknown. Booking BMI was calculated from the antenatal cards from the weight in kilograms at booking and the height in cm using the formula BMI= weight in kilograms ÷ height in meters^2. The BMI obtained was classified into normal, overweight or obese. Pre-pregnancy weight could not be

reliably obtained from study population as many of these women did not commonly weigh themselves and had poor recall. BMI at booking visit was used as it could be verified and in addition, the IOM revised guidelines show that first trimester weight gain is on average 0.5-2kg. Delivery BMI was calculated using the weight of the woman on admission using the aforementioned formula. Pregnancy weight gain was obtained from the difference of weight at booking and weight at delivery in kilograms and compared to the IOM recommendations and classified as inadequate, adequate or excessive. Change in BMI category during pregnancy was established by comparing the booking and delivery BMI. A short antenatal history was obtained about any pregnancy related complications including elevated blood pressure, glucose intolerance, PPROM, APH and any use of medication during this period. Other observations of interest including a blood pressure and random blood sugar were obtained and recorded. Maternal outcomes of interest were recorded including type of labor (induced or spontaneous and indications of the former), type of delivery (spontaneous vaginal or caesarian section and indications of the later) and amount of blood loss during delivery in milliliters and maternal mortality from the delivery records. Neonatal outcomes included type of birth (i.e. still birth or live birth), birth weight in grams, severe respiratory distress syndrome, gestation at delivery (i.e. preterm, term or post-term) were obtained from delivery and new born notes. Any admissions to the new born unit were recorded as well as the indications for the same. The women were then followed up until discharge from the hospital. All the data was collected in a pretested data sheet.

Data collection

Collection of data for this study was carried out by one research assistant under the supervision of the researcher with use of a pretested questionnaire (appendix 2). The research assistant was

trained on the purpose and methodology of the study. During data collection, the rese assistant went to the labour ward and recruited women into the study after explaining purpose and methods of the study and obtaining informed consent. Special attention was g to the informed consent form.

To reduce recall bias, information on booking visit was recorded from the patient ante cards. The participant's weight, blood pressure and random blood sugar were then obtained recorded by the research assistants.

The participants were interviewed and the information obtained entered into the questionna and followed up until delivery. Outcomes of interest were recorded from the admission, lab delivery, operation and neonatal notes in the inpatient files.

In order to avoid double participant recruitment, the participants' admission (in-patient) numbers were entered into a register upon recruitment for serialization. This register was counter-checked on a daily basis for any double entries and if any were discovered, one of questionnaires was withdrawn and discarded and the serialization rectified before recruitm was continued. Upon completion of the questionnaire, the researchers collected the questionnaires and verified that vital information has been completed.

Quality control of data

In order to ensure that the data that was collected during this study was of the highest qual possible, the following measures were taken:

1. The questions used in the questionnaire were selected from existing tools that had b used for similar studies.

2. All tools that were used for this study were pretested on a population outside of the hospital to ensure that they are appropriate to the study group.
3. All research assistants were trained on the study methodology and use of the tools prior to their application. The research assistant filled in the questionnaire to cater for the participants who couldn't read and write.
4. In order to avoid double participant recruitment, the participants' admission (in-patient) numbers were entered into a register upon recruitment for serialization. This register was counter-checked on a daily basis for any double entries and if it is so discovered, one of the questionnaires was withdrawn and discarded and the serialization rectified before recruitment was continued.

Data storage

All the raw data in this study was collected by the principal investigator and her trained assistants. The questionnaires were checked for completeness and filed. They were then stored in a lockable cabinet in the researcher's office.

Data Handling and analysis:

The questionnaires were collected and sorted at Kenyatta National Hospital researcher's offices. The filled questionnaires were be stored at Kenyatta National Hospital under lock and key during data collection and entry and later moved to safe keeping place offsite. Data was entered into a password protected Microsoft Access database. Once entry was completed, the principal investigator compared the contents of the database with the hard copy files of the participants to identify any data entry errors.

Data Analysis

Using Statistical Package of Social Science™ (SPSS) version 17.0 for Windows (SPSS, Chicago, IL, USA) data analysis was done. Descriptive analysis was performed to characterize the number and type of patient outcome. To obtain insight into the social demographics factors of the patients, a frequency table was be used with accompanying percentages. Bivariate comparison of continuous symmetric characteristic was performed using t-test and using the Mann-Whitney test for non-symmetric characteristics. Fisher exact test and chi square test, as appropriate was used for comparison of categorical characteristics.

Correlation between variables was tested using the Pearson correlation co-efficient. Statistical significance as defined as a two tailed p-value of less than or equal to 0.05.

Data dissemination

The results of this study were bound in a master's thesis book disseminated to colleagues and the department of Obstetrics and Gynecology in KNH. This would enable in creation of evidence based guidelines on management of pregnant women with weight as a health issue. The findings would be presented in scientific conferences, published in scientific journals.

ETHICAL CONSIDERATIONS

Study approval

The study was approved by the Department of Obstetrics and Gynecology before submission to the KNH/UON ERC and approval was granted (appendix

Informed consent

Recruitment into this study was wholly voluntary, no incentives were given. Eligible mothers were approached given a consent-seeking information sheet (Appendix 1). The investigator was available to answer any further enquiries that arose.

Confidentiality

The interviews were done in privacy. All data forms in this study contained only the serial numbers given. No names appeared on any form. All used data forms were filed and kept in a locked filing drawer in the researcher's office. Statistician records will be kept under lock and a soft copy in a password protected file in the research support unit computer.

Discrimination

Refusal of consent did not lead to discrimination in care. No change of treatment or management was effected if no consent is given.

Benefits of the Study to Participants

The patients' information on health status was obtained and the participants were educated on the same.

Women diagnosed to have any health problems were referred appropriately.

STUDY LIMITATIONS

1. The weight and height measurements were obtained early in pregnancy. However the ideal time for this would have been in the prepregnacy period but women were note to seldom take these measurements and as such were not available .Weight gain in the first trimester has been shown to be on average 0.5-2kg sand did not significantly affect th e result
2. The poor recording of maternal weight in the antenatal cards and antenatal booking in late pregnancy disqualified many women from the study interfering with the sampling procedures. This may have resulted in selection bias.

RESULTS

A total of 400 women were recruited into the study. Of these women, 174 were non exposed and 226 were exposed. The exposed group had 203 overweight and 23 obese women. The results are presented below in tables and figures

Sociodermographic characteristics

A comparison of sociodermographic characteristics or the women in the three BMI groups was done and is presented in Table 2

Table 2: Sociodermographic characteristics of women in the different BMI groups

Characteristic		Normal (BMI 18.5-24.9) N=174	Overweight (BMI 25-29.9) N=203	Obese (BMI30-34.9) N=23	P value
Age	(mean)	24.3(SD 3.35)	25.4(SD 4.63)	29.6(SD4 3)	0.268
Parity	(mean)	0.6(SD 0.8)	1.2(SD 1.5)	0.8(SD 0.9)	0.425
Marital Status	Single	35(20.11)	34(16.75)	2(8.69)	0.148
	Married/Cohabiting	134(77.01)	163(83.25)	21(91.30)	
	Separated	5(2.87)	1(4.93)	0(0.00)	
Type of Residence	Rental	168(96.55)	195(96.06)	23(100)	0.744
	Own home	6(3.44)	8(3.94)	0(0.00)	
Occupation of respondent	Unemployed	83(47.70)	72(35.46)	6(26.09)	0.007
	Self employed	43(24.71)	89(43.84)	6(26.09)	
	Salaried	35(20.11)	34(16.74)	9(39.13)	
	Casual	13(7.47)	6(2.94)	2(8.69)	
Education of respondent	None	4(2.22)	2(0.99)	0(0.00)	0.561
	Primary	48(27.58)	60(29.55)	3(13.04)	
	Secondary	82(47.13)	96(47.29)	12(52.17)	
	Tertiary	40(22.98)	45(22.16)	8(34.78)	
Education of spouse	None	1(5.74)	0(0.00)	0(0.00)	0.994
	Primary	19(10.91)	22(10.84)	2(8.69)	
	Secondary	81(46.55)	97(47.78)	14(60.86)	
	Tertiary	40(22.98)	49(24.14)	7(30.43)	
	N/A	40(22.98)	35(17.24)	0(0.00)	
Occupation of spouse	Unemployed	1(5.75)	0(0.00)	0(0.00)	0.539
	Self employed	61(35.05)	68(33.50)	9(39.13)	
	Salaried	32(18.39)	54(26.60)	8(34.78)	
	Casual	40(22.98)	46(22.66)	6(26.09)	
	N/A	40(22.98)	35(17.24)	0(0.00)	

(Values expressed as mean (SD) median or number (per cent))

Women in the obese group were significantly older with an average age of 29.6 years (SD 4.3) while the mean ages of women in the overweight and normal BMI groups were comparable at 25 4 years (SD4.62) and 24.3 years (SD 4.62) respectively. More women were married or cohabiting in the obese group 21(91.3%) in comparison with the ones in the normal BMI group 134 (77.01%).The obese group had the highest education levels with 8(34.78%) having tertiary education compared with 40(22.98%) and 45 (22.16%) in normal BMI and overweight groups respectively. Employment levels were also higher in the increased BMI groups compared with the normal BMI group. The parity was highest in the overweight group with an average of 1.2 (SD1.5) compared with the normal and obese group with averages of 0.6(SD 0.8) and 0.8(SD 0.9).

Antenatal Booking Characteristics

The women recruited into the study had booked antenatal clinic by 20 weeks gestation. A comparison of the booking characteristics of the three BMI groups was done and is presented in Table 3. No differences were found in the booking time for the groups. The average BMI time was done with no differences found.

Table 3: Antenatal booking characteristics of the women in the different BMI groups

		Booking week(by LMP or scan)	Weight at booking(Kg)	BMI at booking
1. Normal	Mean	16.81	57.1552	22.5220
	Std. Deviation	3.625	6.20157	1.50381
2.Overweight	Mean	16.12	71.2586	27.3563
	Std. Deviation	3.435	5.95493	1.21579
3. Obese	Mean	16.96	86.7609	31.8119
	Std. Deviation	3.082	8.68367	2.05205

Gestational Weight Gain

A comparison pregnancy weight gain characteristics was done for the three groups and is presented in Table 4 and Figure 1.

Figure 1: Bar graph showing gestational weight gain in the different BMI groups

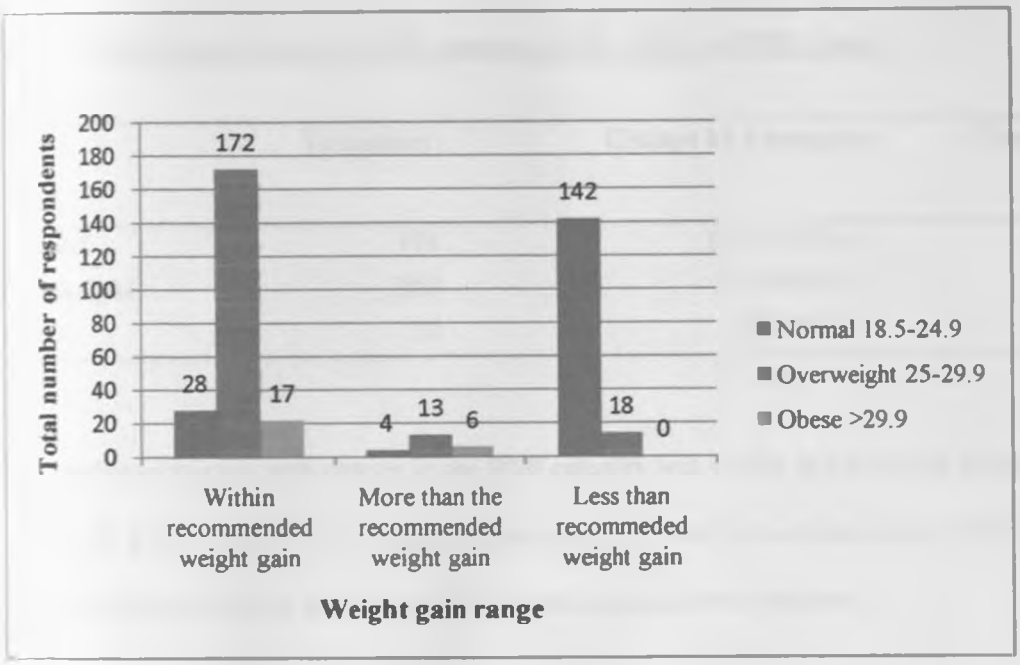


Table 4: Weight gain by booking BMI compared to IOM recommendations

	Normal BMI (BMI 18.5-24.9) N=173	Overweight (BMI 25-29.9) N=293	Obese (BMI 30-34.9) N=23	P value
Inadequate	142(82.0%)	18(8.86%)	0(0.00%)	0.001
Normal	28(16.18%)	172(84.73%)	17(73.91%)	0.004
Excessive	4(2.31%)	13(6.40%)	6(26.09%)	0.003

The weight gain was noted to be inadequate in majority of the women with normal BMI 142 (84.73%) with only 28 (16.09%) gaining the recommended weight. Majority of the women on the overweight and

obese groups had the recommended weight gain with values of 172(84.72%) and 17(73.91%) respectively. Excessive weight gain was highest in the obese group with 6(26.07%) compared with the overweight and normal groups with 13(6.4%) and 4(2.30%) respectively.

Table 5: **Gestational change in BMI category in the different BMI groups**

BMI	Frequency	Change by 1 category	Change by 2 categories
Normal	174	121(69.55%)	4(2.29%)
Overweight	203	132(65.02%)	0
Obese	23	7(30.43%)	0

The number of women with change in one BMI category was similar in the normal BMI and overweight group with 65.02% and 69.55% change respectively and lower in the obese group with 52.17% change to the morbidly obese group. Increase of BMI by two categories was minimal.

Obstetric outcomes

The frequency of each pregnancy, labour and delivery characteristics was determined for each BMI group and is presented in Table 6 while neonatal outcomes are presented in Table 10.The risk of each of the adverse outcomes and interventions in the abnormal BMI groups compared to the normal BMI group is presented in Table 7.

Table 6: **Pregnancy, labour and delivery characteristics of women in each BMI group**

Characteristic		Normal BMI (BMI 19.5-24.9) N=176	Overweight (BMI 25-29.9) N= 203	Obese (BMI 30-34.5) N=23
Hypertension	PIH	12(6.81%)	16(7.8%)	4(17.31%)
	Pre-eclampsia	13(7.39)	30(14.77%)	7(30.43%)
	Eclampsia	5(2.84)	9(4.43%)	1(4.34%)
Random Blood Sugar	Normal	159(90.34%)	172(84.72%)	13(56.52%)
	Glucose intolerance	12(6.81%)	22(10.83%)	4(17.39%)
	Gestational Diabetes	5(2.84%)	9(4.43%)	2(8.69%)
Gestation at delivery	Preterm	38(21.58%)	42(20.68%)	2(8.6%)
	Term	100(56.8%)	117(57.63%)	14(60.8%)
	Post-term	38(21.59%)	44(21.67%)	7(30.43%)
Type of labour	Spontaneous	112(63.3%	88(43.435)	8(34.78%)
	Induced	26(14.77%)	48(23.66%)	7(30.43%)
Duration of active labour(hours)	Average	6.72(SD 2.136)	6.70(SD 1.711)	7.18 (SD 3.25)
Delivery type	Vaginal	132(75.00%)	127(62.65%)	14(60.83%)
	Caesarian section	44(25.00%)	76(37.43%)	9(39.1%)
Blood loss(mls)	Normal delivery	202.61 (SD 164.03)	205.87 (SD 81.58)	264.11 (SD 69.72)
	Caesarian section	400.57 (SD 76.82)	455.37 (SD 123.4)	487.5 (SD 111.3)
	Average loss	303(SD 171.521)	330.05(SD 140.77)	375(SD 129.329)
Postpartum hemorrhage		3(1.48)	4(1.97)	1(4.34)
Duration of hospital stay	Average in days	3.63(SD 3.224)	3.91(SD 2.213)	4.64(SD 3.230)

(Values expressed as mean (SD) or number (per cent))

Table 7: **Risks of obstetric complications in the different BMI groups compared to normal (OR 1)**

Outcome	Overweight			Obese		
	Odds Ratio	95% Confidence Interval		Odds Ratio	95% Confidence Interval	
		Lower	Upper		Lower	Upper
Post term	.973(p=0.918)	.583	1.625	1.346(p=0.556)	.499	3.633
Pre term	.929(p= 0.71)	.554	1.558	.385(p=0.208)	.083	1.786
Impaired glucose	1.330(p=0.622)	.426	4.153	3.947(p=0.094)	.704	22.122
Gestational Diabetes	0.540(p= 0.07)	0.495	0.603	0.92 (p= 0.002)	0.057	0.149
Small for gestational age	.712(p=0.138)	.453	1.117	.496(p=0.227)	.156	1.576
Large for gestation age	2.385(p=0.052)	.971	5.857	4.327(p=0.023)	1.123	16.672
Severe RDS	.761(p=0.331)	.438	1.321	.708(p=0.596)	.197	2.551
Early neonatal deaths	1.158(p=0.849)	.256	5.247	.887(p=0.536)	.843	.932
Induced labour				4.300(p=0.038)	1.390	13.310
Caesarean Section	1.712(p=0.020)	1.090	2.690	2.350(p=0.012)	.896	6.817
Postpartum hemorrhage	0.31(p=0.036)	0.098	0.981	0.855(p=0.213)	0.839	0.932
Pregnancy Induced hypertension	1.320(p=0.481)	.605	2.897	4.340(p=0.015)	1.200	15.910
Pre-Eclapmsia	2.368(p=0.012)	1.190	4.700	6.080(p=0.001)	1.960	19.120
Eclampsia	1.788(p=0.302)	.658	5.460	2.630(p=0.781)	.328	24.580
Still birth	3.170(p=0.035)	1.020	9.800	.884(p=0.047)	.840	.930

The incidence of both pre-eclampsia and PIH increased with increasing BMI resulting in an OR 6.80 (95% CI 1.960-19.20) for pre-eclampsia and OR 4.340 (95% CI 1.200-15.910) in the obese compared to the normal BMI group.

The risk of glucose intolerance increased with increasing maternal BMI and was highest in the obese group OR 3.947(95% CI 0.704-12.122) compared with the normal BMI group.

The frequency of preterm labour (before 37 completed weeks of gestation) was noted to decrease with increasing maternal BMI with 8.6% in obese compared with 21.58% in the normal BMI group. After adjustment for confounders, this was not statistically significant.

Post term delivery (after 41 completed weeks of gestation) was highest in the obese group OR 1.346 (CI 0.499-3.633).The incidence was comparable in the overweight and normal BMI groups.

Caesarian section delivery was more common in the abnormal BMI groups with risk being highest in the obese group OR 2.350 (CI 0.896-6.817).The main indication for this in all the BMI groups was NRFS accounting for 4 (44.44%) in the obese compared to 25(32.89%)and 17(38.64%) in the overweight and normal BMI respectively. These are summarized in Table 8 below.

Table 8: Indications for Emergency Caesarian section in the different BMI categories

Indication	Normal (BMI 19.5-24.9) N=44	Overweight (BMI 25-29.9) N=76	Obese (BMI 30-34.9) N=9
APH	0(0.00)	3(3.94%)	0(0.00%)
Breech presentation	4(9.09%)	6(7.89%)	1(11.11%)
Cord prolapsed	1(2.27%)	3(3.94%)	0(0.00%)
CPD	9(20.45%)	16(21.05%)	1(11.11)%
Failed Induction	7(15.65%)	16(21.05%)	1(11.11%)
Failed VBAC	6(13.64%)	13(17.10%)	0(0.00%)
NRFS	17(38.64%)	25(32.89%)	5(55.55%)

The mean blood loss during delivery increased with increasing BMI with the greatest loss being in the obese group with a mean loss of 264.11mls (SD 69.72) for normal delivery and 487.5mls (SD 111.3) for caesarian delivery compared to 202.61mls (SD 164.03) and 400.57mls (SD 76.82) respectively in the normal BMI group. This difference was however not statistically significant. PPH was highest in the obese group at 1(4.34%) compared with normal BMI group with 3(1.48%)

Table 9: Indications for induction of labour

Indication	Normal (BMI 19.5-24.5) N=26	Overweight (BMI 25-29.5) N=48	Obese (BMI 30-30.5) N=7
Decreased fetal movements	0(0.00%)	2(4.16%)	0(0.00%)
Pre-eclampsia and Eclampsia	8(30.77%)	8(16.67%)	1(14.28%)
Recurrent false labor	2(7.68%)	7(14.58%)	2(28.57%)
IUFD	2(7.69%)	5(10.41%)	0(0.00%)
Post-term pregnancy	11(42.30%)	17(35.41%)	3(42.85%)
PROM	2(7.69%)	8(16.67%)	0(0.00%)
Rhesus negative at term	1(3.86%)	1(2.08%)	1(14.28%)

The risk of induction of labour increased with rising maternal BMI with the risk being highest in the obese group OR 4.300 (CI 1.390-13.310).The frequency of failed induction was highest in the overweight group (33.33%) compared with the normal (26.92%) and obese (28.57%) groups The main indications for induction of labour in the obese group were post term pregnancy(42.85%) and recurrent false labour (28.57) while those in the overweight group were post term pregnancy(35.41%) , pre-eclampsia(16.67%) and PROM(16.67%).The indications for induction of labour are summarized in Table 9.

The duration of active labour was longest in the obese group with mean of 7.18 hours(SD 3.25) compared with 6.70 hours(CI 1.711) in overweight and 6.72 hours (SD 2.136) in the normal BMI groups. This was however not found to be statistically significant.

Table 10: Neonatal outcomes in the different BMI groups

Characteristic		Normal (BMI 19.5-24.5) N=176	Overweight (BMI 25-29.5) N=203	Obese (BMI 30-34.5) N=23
Still births		4(2.27%)	12(5.91%)	1(4.31%)
Live births		172(97.72%)	189(93.10%)	22(95.65%)
Birth weight	2500-4000g	105(59.65%)	129(63.54%)	14(60.87%)
	<2500g	61(34.65%)	51(25.12%)	5(21.74%)
	>4000g	10(5.685)	23(11.33%)	4(17.39%)
Severe RDS necessitating NBU admission		32(18.8%)	29(14.29%)	3(13.04%)
Early neonatal deaths <24 hrs		3	4	3
Perinatal mortalities(still births + early neonatal deaths)		7(4.79%)	16(7.88%)	4(17.39%)

The still birth rates were higher in the overweight group 12(5.91%) and obese 1(4.31%) compared with the normal BMI group 4(2.27%).This was statistically significant with OR 3.170(CI 1.020-9.800) in overweight.

The incidence of low birth weight i.e. birth weight less than 2500g was lower in the higher BMI groups being lowest in obese 5(21.75%) and highest in the normal BMI group 64 (34.65%).On adjustment for confounders, this was found to be statistically insignificant.

The incidence of macrosomia (birth weight >4000g) was higher in overweight and obese groups with OR 2.385 (CI 0.971-5.857) and OR 4.327 (CI 1.123-16.672) respectively when compared to the group with normal BMI.

The average duration of hospital stay was longer in the obese group with a mean of 4.64 days (SD3.230) compared to 3.91 days (SD2.213) and 3.63days (SD3.224) in the overweight and obese groups respectively.

Severe respiratory distress necessitating admission in the new born unit was highest in the normal BMI group at 32(18.8%) with compared 29(14.29%) in overweight and 3(13.04%) in obese group. On adjustment for preterm deliveries, this was not found to be statistically significant.

The perinatal mortality (still births and deaths within 24 hours of birth) was highest in the obese at 17.39% compared with 7.88% in overweight and 7% in normal BMI group.

Effect of gestational weight gain on pregnancy outcomes

Table 11: **Risk of adverse pregnancy outcomes in relation to gestational weight gain**

Outcome	Inadequate weight gain			Excess weight gain		
	Odds Ratio	95% Confidence Interval		Odds Ratio	95% Confidenc Interval	
		Lower	Upper		Lower	Upp
Post term	1.007 (p=0.979)	0.607	1.669	0.826(p=0.751)	0.253	2.6
Pre term	1.188 (p=0.051)	0.709	1.989	0.475 (p=0.334)	0.102	2.2
Impaired glucose	0.182 (p=0.014)	0.040	0.824	1.018 (p=0.987)	0.123	8.4
Gestational Diabetes	0.521 (p=0.057)	0.470	0.578	3.054 (p=0.309)	0.319	29.2
Small for gestational age	1.365 (p=0.017)	0.872	2.136	0.340 (p=0.145)	0.075	1.5
Large for gestation age	0.371 (p=0.024)	0.153	0.903	0.818 (p=0.799)	0.174	3.8
Severe RDS	1.985 (p=0.016)	1.132	3.482	2.024 (p=0.238)	0.615	6.5
Early neonatal deaths	1.136 (p=0.876)	0.226	5.703	3.992 (p=0.214)	0.387	39.7
Induced labour				0.733 (p=0.615)	0.218	2.4
Caeseraen Section	0.517 (p=0.003)	0.331	0.807	0.877 (p=0.795)	0.326	2.3
Postpaturm haemorhage	3.003 (p=0.530)	0.938	9.617	2.967 (p=0.322)	0.312	28.2
Pregnancy Induced hypertension	0.67 (p=0.305)	0.312	1.44	1.352 (p=0.707)	0.280	6.5
Pre-Eclapmsia	0.355 (p=0.003)	0.177	0.714	1.431(p=0.533)	0.435	4.7
Eclampsia	2.014 (p=0.203)	0.672	6.037	0.924 (p=0.522)	0.884	0.9
Still birth	0.707 (p=0.483)	0.268	1.866	0.917 (p=0.321)	0.881	0.9

Inadequate gestational weight gain was associated with increased risk of RDS OR 1.985(p =0.016), SGA OR 1.1365 (p=0.017) and preterm labour OR 1.88 (p=0.051) and decreased risk of

PET OR 0.355 (p=0.003), caesarian section delivery OR.517 (p=0.003) and induction of labour OR 0.483 (p=0.008)

Excessive weight gain in pregnancy was not shown o have any statistically significant correlation with pregnancy outcome.

DISCUSSION

This study found that increased maternal BMI predisposed women to increased incidence of adverse maternal and neonatal outcomes and correlated better to these outcomes compared to gestational weight gain. This adds to the growing evidence that BMI is a major determinant of obstetric outcomes. There was a linear relationship between increasing maternal BMI and risk of developing pre-eclampsia, pregnancy induced hypertension, induction of labour, caesarian delivery, LGA, glucose intolerance and still births. These results were similar to other studies that have shown an increasing association between increasing maternal BMI and adverse obstetric outcomes and increased intervention rates such as caesarian delivery and induction of labour[18,19,38,46,48].

The previous studies have shown a strong association between increasing maternal BMI and pregnancy induced hypertension .A met analysis done showed that the risk of pre-eclampsia doubled with each 5-7kg /m^2 increase in pre-pregnancy BMI [45] This study found two times increased risk in the overweight and six times increased risk in the obese women. These findings were similar to those of Sebire et al[20] that showed increased risk with OR 1.44(1.28-1.62) in overweight and OR 2.14(1.85-2.47)in overweight. Batacharya et al[18] that showed increased risk with OR 7.2(4.7 -11.2) in obese Along with hyperinsulinemia, maternal overweight and obesity are associated with hyperlipidemia, which reduces prostacyclin secretion and enhances peroxidase production, resulting in vasoconstriction and platelet aggregation, which increases the risk of pre-eclampsia.

There was an increased risk of glucose intolerance found in the overweight and obese women found in this study with OR 1.330(0.426- 4.53) in overweight and 3.947(0.704-22.12) in obese.

These results were similar to findings by Sebire et al[20] with OR 1.68(1.53-1.84) in overweight and OR 3.6(3.15-3.98) in obese. Insulin resistance and hyperinsulinemia are hallmark features of gestational diabetes and obesity. Both fasting and postprandial plasma insulin levels are higher in obese pregnant women. Achieving glycemic control with diet and insulin is essential to enhance pregnancy outcomes in these women.

In contrast to studies done previously, increased maternal BMI did not increase the risk of preterm labor (delivery before 37 completed weeks) in this study with OR 0.929(0.544-1.559)in overweight and OR 0.385(0.083-1.22) .These findings were similar to those of Cnattingius[39] that found no association between preterm delivery before 37 weeks and prepregnancy weight (OR 0.78) and, Sebire et al[20] with OR 0.73(0.65-0.82) in overweight and OR 0.81(0.69-0.95) in obese that found that delivery before 32 weeks was significantly less likely in the obese. In contrast, Batacharya et al[18] found a two fold increase in preterm labour in the overweight and obese mothers OR 2.0(1.3-3.2).

With regard to IUGR and SGA babies, increased maternal BMI was found to be protective as the frequency of these outcomes decreased with increasing BMI after correction for preterm labour in this study with OR of 0.712(0.453-1.117) in overweight and 0.490(0.156-1.576) in obese. This was similar to finding by Addo in Ghana[46] with OR 0.85(0.53-1.37)This is in contrast to findings by Batacharya et al[18] who found increased risk with OR 1.72(1.2-2-0) in obese This was thought to be a result of the adequate gestational weight gain noted in majority of the women with increased BMI as compared to the normal BMI group in which 81.61% had inadequate weight gain. Despite the increased frequency of PET in the obese and overweight, IUGR and SGA were not significantly increased in these groups. However increased maternal BMI was shown to increase the risk of having a macrosomic baby. This risk was increased

fourfold obese group (OR 4.327)overweight and twofold in the overweight(OR 2.385) .Previous studies have shown that obese women have an 18-26% chance of delivering a macrosomic baby even after controlling for maternal diabetes[45] .It has been shown that maternal hyperinsulinemia contributes to fetal macrosomia in the obese women. The original Pedersen hypothesis [44]suggested that increased glucose concentrations in the diabetic mother led to foetal hyperglycaemia and hyperinsulinaemia causing increased foetal growth. Obesity is associated with maternal insulin resistance and foetal hyperinsulinaemia even in the absence of maternal diabetes. Insulin resistant individuals have higher fasting plasma triglyceride levels and greater leucine turnover. Amino acids are insulin secretagogues and an increased flux on amino acids could stimulate foetal hyperinsulinaemia. Triglycerides are energy rich and placental lipases can cleave triglyceride and transfer free fatty acids to the foetus. The combination of an increased energy flux to the foetus and foetal hyperinsulinaemia may explain the increased frequency of large for gestational age infants seen in the obese non-diabetic women in this study.

There was found to be an increased risk of still births in the overweight (OR 3.170) but not in the obese group, compared to the normal BMI group. This was similar to findings by Cnatingus[39] where the odds ratios for late fetal death were increased among women with higher body-mass indexes as compared with lean women, as follows: normal women, 2.2(1.2 - 4.1); overweight women 3.2 (1.6 -6.2);and obese women, 4.3 (2.0 -9.3). It has been hypothesized that rapid fetal growth induced by maternal hyperinsulinemia coupled with placental insufficiency may result in antepaturm fetal demise[37,38]. In addition, hypertension, glucose intolerance and placental abruption that are commoner in this group may contribute significantly to these findings[40].

The duration of labour was found to be higher in the obese group compared to the normal BMI group in this study. This may have resulted from increased labour induction rates and dystocia

from fetal macrosomia and pelvic soft tissues. . However, the prolonged duration of active and total labor in obese women is difficult to attribute entirely to the increased incidence of pregnancy-related complications. Several prior reports have found a similar association between maternal obesity and prolonged duration of labor. It has also been shown that obese women have poor uterine contractility and poor response to oxytocin infusion [37].

This study found that there was an increase in average blood loss during delivery with increasing BMI but the risk of PPH was not significantly increased. Other studies done have had conflicting results on the same with Addo[46] and Batacharya et al [18] finding increased risk in the obese with OR 1.81 and 1.5 respectively .Measurement of blood loss is subjective and definition of PPH may vary making it difficult to comparisons across studies. Obviously it appears that women with higher BMI should bleed more, this is at least in part due to increased incidence of induced labour and operative deliveries. It is possible that uterine contractility may be suboptimal in these women. The increased risk of postpartum hemorrhage in obese women, even after accounting for such predisposing factors as caesarean section may be explained by more bleeding from the relatively larger area of implantation of the placenta usually associated with a large for gestational age foetus[44].

This study demonstrated an increase in risk of labour induction in women with increased BMI The indications for labor induction also varied in the BMI categories, particularly in regard to conditions generally associated with obesity, such as hypertensive disorders of pregnancy and post term pregnancy. Risk of failed inductions was also found to increase with elevated BMI. These findings, along with the increased requirements of predelivery oxytocin, may be explained by the pharmacokinetic and pharmacodynamic properties of drugs. The relative increase in volume of distribution found in obese women has a dilutional effect on both the ripening agent

and oxytocin during the course of labor induction. This could potentially result in a reduced tissue response and a subsequent need for increased doses and duration of drug administration.

Numerous investigators have demonstrated a proportional increase in rates of cesarean delivery corresponding to the level of maternal obesity Similar findings were demonstrated in this study with OR 2.350(0.896-6.817) in obese and OR 1.720(1.09-2.690) in overweight. These results are similar to those by Addo[46] , Batacharya et al[18] and Sebire[20] with OR of 2.74(2.07-3.64), 2.8(2.0-2.9) and 1.83(1.74-1.93) in the obese respectively. Some have attributed this finding to a higher likelihood of pregnancy-related complications in obese women and a subsequent increase in labor inductions. Pooblan conducted a met analysis on a cohort study performed from 1966 to 2007 and found a higher risk of caesarian section in the overweight and obese group compared to normal BMI group. The relevance of the raised caesarean section rate in this group is considerable because of their increased risk of associated complications, such as anaesthetic and infectious morbidity. The increase in caesarean sections may in part have been a consequence of the increased rate of large for gestational age infants leading to cephalopelvic disproportion during labour, increased rates of induction of labour or it is possible that uterine contractility may be suboptimal in a subgroup of obese women, or there may be increased fat deposition in the soft tissues of the pelvis. The main indications for caesarian section in this study were CPD, NRFS and failed induction.

Severe respiratory distress necessitating new born unit admission was found to be lower in the overweight and obese groups but on adjustment for preterm delivery no significant difference was found. Previous studies have shown increased incidence of RDS and poor five minute Apgar scores in mothers with elevated BMI as a result of delayed lung maturity in mothers with GDM, prolonged labour and MAS[49].

This study showed a small but significant increase in foetal death related to a raised maternal BMI, having made allowance for medical complications with OR 3.170(1.020-9.800).This is similar to findings by Addo [46] and Sebire[20] with OR 3.12(0.86-2.25) and1.40(1.14-1.70) in the overweight respectively. The combination of rapid foetal growth induced by the endogenous hyperinsulinaemia in obese women and the functional limitations of the placenta to transfer sufficient oxygen to meet the requirements of the foetus, may lead to hypoxia and death in some cases. Lucas et al [40] reported that the relative risk of neonatal death is greater infants born to obese mothers than to thin women, and suggested that this may be secondary to the altered metabolic milieu in obesity reducing the infant's ability to adapt to postnatal life. The reason for the increased susceptibility to infectious disease is not described by these epidemiological data and may be a topic for further research.

Duration of hospital stay increased with increasing BMI being highest in the obese group. This may have resulted from increased medical complications including hypertension and diabetes and increased interventions such as caesarian section delivery and induction of labour. This was associated with higher hospital costs and debilitation for longer periods resulting in decreased economic productivity of these women.

Studies done have shown that suboptimal weight gain in pregnancy has been associated with poor pregnancy has been associated with poor pregnancy outcomes [18, 32, 48]. However, the ideal weight gain in pregnancy has remained controversial with revisions being made severally over the years. Excessive weight gain in pregnancy has been associated with increased risk of pre-eclampsia, PIH, GDM, fetal macrosomia, caesarian section, induction of labour and still birth rates[32, 40]. Inadequate weight gain has been associated with increased incidence of SGA babies and preterm labor. In this study, most of the women in the obese and overweight group achieved

the recommended weight gain with a small percentage having excessive weight gain while majority of the women with normal BMI had inadequate weight gain. In this study, excessive maternal weight gain was not associated with increased adverse obstetric outcomes. However, inadequate weight gain was associated with increased SGA babies and preterm labour. This was similar to findings by Sae-kyung et al[48] where a study done on Korean women showed that there was no positive linear association between gestational weight gain and obstetric outcomes. In normal weight women, maternal and neonatal complications were significantly increased with inadequate weight gain during pregnancy ($p < 0.0001$and $p< 0.0180$, respectively).

This study adds to the increasing evidence suggesting that increased BMI is associated with numerous maternal and perinatal risks. Managing these problems and reducing their occurrence can pose a challenge to obstetrical care providers. The feasibility of lifestyle interventions (physical exercise and diet) during pregnancy and its potential to improve pregnancy outcomes should be considered. Although the obese and overweight women included in our study were receiving adequate antenatal care, they experienced many adverse pregnancy outcomes. Health education to control body weight before pregnancy is warranted. Obese women should consider losing weight through diet modification and exercise before becoming pregnant. They should continue exercising and keep a close watch on their weight gain during pregnancy and should consider consulting a dietitian when necessary.

Recent reviews on obesity and pregnancy have highlighted several issues relevant to research and management policy. Firstly, the lack of standard definitions of overweight and obesity makes comparison of findings across studies difficult. While most reports define obesity as an increased body mass index of greater than or equal to 30 Kg/m^2 (IOM), others have defined it as increased waist circumference, increased waist – hip ratio or body weight of more than 90 Kg.

This makes comparison of studies difficult and may have implications in the management of normal pregnancy, as recommended gestational weight gain is dependent on women's prepregnancy BMI categories.

Krishnamoorthy et al[41] suggest that all pregnancies in obese women be acknowledged as high risk and managed according to strict guidelines. Management should include prepregnancy counseling to reduce weight; shared antenatal care and appropriate management of complications. The evidence for obesity as an important complication in pregnancy is mounting; it is time to inform practice based on this evidence.

CONCLUSIONS

This study showed that increased maternal BMI is associated with increased risk of adverse obstetric outcomes and increased intervention rates .These include increased risk of PIH, pre-eclampsia, fetal macrosomia, post term pregnancy, induction of labour , ceaserian delivery and still births.

Excessive gestational weight gain did not result in increased risk of adverse outcomes; however, inadequate weight gain was associated with increased risk of preterm labour and SGA.

RECOMMENDATIONS

Preconception nutritional counseling is important for management of obesity before pregnancy.

Inappropriate weight gain in pregnancy should be recognized early enough and acted upon to reduce the attendant complications

A nationwide community-based prospective study should be done to provide in-depth knowledge about the prevalence and impact of different categories of BMI on pregnancy outcomes among different socioeconomic and ethnic groups.

Policy makers need to recognize increased BMI as a health issue is prevalent in our population and formulate guidelines on management of these women to optimize maternal and fetal outcomes.

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APPENDIX 1: CONSENT FORM

INFORMED CONSENT FOR STUDY ON EFFECT OF BMI ON PREGNANCY OUTCOMES

This Informed Consent Form has two parts:

- **Information Sheet (to inform you about the research)**
- **Certificate of Consent (for signatures if you agree to take part)**

PART I: Information Sheet

Introduction

My name is Dr. Milka Muthoni Kihara Ritho. I am a doctor who is studying to specialize in the field of Obstetrics and Gynecology. I' m currently conducting research that is titled **"EFFECT OF INCREASED MATERNAL BMI ON PREGNANCY OUTCOMES"** I'm conducting a study to understand how weight affects the outcome of pregnancy.

Type of Research

In this study we will invite women who come to labor ward. I will collect information from the women who accept to join this research by interviewing them and filling a questionnaire and taking some measurements.

Voluntary Participation

Your participation in this research is entirely voluntary. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this hospital.

Procedures and Protocol

If you agree to be part of this study, I will ask you some questions and fill a questionnaire, then I will weigh you and measure your height, blood pressure and blood sugar. You will then be followed up until you deliver.

Side Effects

There are no side effects expected in this process.

Risks

There are no risks in participating in this study.

Benefits

You will be informed about your BMI and its effect on your health. In addition; you will be referred appropriately if any complications or health issues are detected. Your participation will be very helpful in improving the way we manage pregnant women.

Confidentiality

The information that we collect from this research project will be kept confidential. Any information about you will have a number on it instead of your name. We will not be sharing the identity of those participating in the research.

Sharing the Results

The knowledge that we get from doing this research will be shared with the policy makers in this hospital and Ministry of Medical Services and other doctors through publication and conferences. Confidential information will not be shared.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this hospital in any way.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Dr. Muthoni Ritho

Chief investigator

Tel: 0722330947

This proposal has been reviewed and approved by Kenyatta National Hospital Ethics Committee, which is a committee whose task it is to make sure that research participants are protected from harm.

PART II: Certificate of Consent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____ (Day/month/year)

If Non -literate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that an interview will be conducted to collect information.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

APPENDIX 2: DATA SHEET FOR EFFECT OF MATERNAL BMI ON PREGNANCY OUTCOMES

Serial number_____

EFFECT OF BMI ON PREGNANCY OUTCOMES QUESTIONNAIRE

Date: __/__/___ Interviewer's code_____

Instructions: Please respond to the following questions by 'ticking' or 'writing' your response appropriately. THANK YOU!

Section A: Sociodemographic characteristics

1. Marital status
   ☐ Single ☐ Married/cohabiting ☐ Separated/divorced
2. Area of Residence:_____
3. Type of residence
   ☐ Rental ☐ Own home
4. **Respondent**
   Educational level
   ☐ None ☐ Primary ☐ Secondary ☐ Tertiary

   Occupation
   ☐ Unemployed ☐Self employed ☐Salaried ☐Casual
5. **Spouse**
   Educational level
   ☐ None ☐ Primary ☐ Secondary ☐ Tertiary

   Occupation
   ☐ Unemployed ☐Self employed ☐Salaried ☐Casual

Booking week(gestation by LMP or ultrasound scan)	
Weight at booking (kg)	
Weight at term/delivery (kg)	
Height (cm)	
BMI At booking	
BMI At Term	

Weight gain during pregnancy(wt at delivery – wt at booking	

Section B Obstetrics and gynecology history

6. Parity_____

7. Last menstrual period_____

8. Current Gestation_____

Section C Outcomes

9. Bp_____

10. Random blood sugar_____

☐ Pregnancy induced hypertension
☐ Preeclampsia
☐ Eclampsia

11. Gestation at delivery:
☐Preterm delivery (<37 weeks gestation)
☐Post term delivery (>41 weeks gestation)
☐Term delivery (38-40 weeks gestation)

12. Type of delivery
☐ Normal vaginal delivery
☐ Caesarean section
☐ Elective indication……..
☐ Emergency indication ……

13. previous scar
☐ Successful VBA
☐ Failed VBAC

14. Type of labor
☐ Spontaneous
☐ Induced indication……

15. Labour
Prelabour rapture of membranes_____Duration in hrs_____
Duration of labour in hours_____
Amount of blood loss in mls_____

16. Neonatal Outcome
☐ Live birth
☐ Still birth

17. Severe respiratory distress necessitating NBU admission
☐ Yes

☐ No

18. Early Neonatal death
☐ Age < 24 hours ☐ 1-7 days

19. Diagnosis_____

20. Birth weight
☐ <2700g
☐ 2700g - 3999g
☐ >4000g

21. Length of hospital stay in days_____

APPENDIX 3: ETHICAL APPPROVAL

KENYATTA NATIONAL HOSPITAL
Hospital Rd. along. Ngong Rd.
P.O. Box 20723, Nairobi
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP", Nairobi
Email: KNHplan@Ken.Healthnet.org

3rd August 2011

Ref: KNH-ERC/ A/203

Dr. Milka Muthoni Kihara Ritho
Dept. of Obs/Gynae
School of Medicine
University of Nairobi

Dear Dr. Ritho

Research proposal: "Effect of increased maternal body mass index on pregnancy outcome at Kenyatta National Hospital: Cohort study" **(P135/04/2011)**

This is to inform you that the KNH/UON-Ethics & Research Committee has reviewed and **approved** your above revised research proposal. The approval periods are 3rd August 2011 – 2nd August 2012.

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. The Deputy Director CS, KNH
The Dean, School of Medicine, UON
The HOD, Records, KNH
Supervisors: Dr. Omondi Ogutu, Dept. of Obs/Gynae, UON
Dr. Lubano Kizito,Dept. of Obs/Gynae, UON