

**ULTRASONOGRAPHIC EVALUATION OF PLACENTAL THICKNESS
IN NORMAL SINGLETON PREGNANCIES FOR ESTIMATION OF
GESTATIONAL AGE IN KENYATTA NATIONAL HOSPITAL**

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THE REQUIREMENT FOR THE AWARD OF DEGREE IN MASTER OF
MEDICINE IN DIAGNOSTIC IMAGING AND RADIATION MEDICINE.**

2020

CERTIFICATION AND DECLARATION OF COPYRIGHT

I, **Dr. Mosomi Abigaël**, declare that the work contained herein is my original idea and has not been presented at any other place in Kenya to the best of my knowledge.

Signature..... Date.....

Approval by Supervisors

This research proposal has been submitted with my approval as a University supervisor

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DEDICATION

This research is dedicated to my brother the late Newborn Orora Machani Mosomi, whom we eagerly wait to meet on the resurrection morning.

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LIST OF ABBREVIATIONS

- **AC-** Abdominal circumference
- **BPD-** Bi parietal diameter
- **CRL –** Crown rump length
- **DDIRM -** Department of diagnostic imaging and radiation medicine
- **EDD –** Expected date of delivery
- **ERC –** Ethics and research committee
- **FL-** femur length
- **FW-** fetal weight
- **GA –** Gestational age
- **GS –** Gestational sac
- **HCG-** Human chorionic gonadotropin
- **HC-** Head circumference
- **KNH-** Kenyatta national hospital
- **KSH -** Kenyan shillings
- **LMP –** Last menstrual period
- **PT-** Placental thickness
- **RPC-** Retroplacental complex
- **SD-** Standard deviation
- **UON -** University of Nairobi
- **US-** Ultrasound

ABSTRACT

Background

Ultrasonography is so far the most effective and safest method of estimating gestational age (GA). A new parameter, placental thickness (PT), can be used to evaluate the placental growth and estimate the age of the fetus in normal pregnancies. Studies have shown as a general rule that placental thickness in mm corresponds to the GA in weeks.

Aim

The goal of the study was to correlate placental thickness, measured at the level of insertion of the umbilical cord, using the ultrasonographic GA in uncomplicated.

The mean value together with corresponding standard deviation was computed from the 14th to 40th gestational week.

Methodology

A prospective cross-sectional descriptive study was done in Kenyatta National Hospital, department of radiology.

The study was carried out over a period of six months, from June 2019 to December 2019. All patients referred for obstetric scans were normal singleton pregnancy between 14-40 weeks meeting the inclusion criteria. Two hundred and fifty two patients meeting the inclusion criteria were conveniently selected.

Results

The placental thickness was found to increase with increase in gestational age. A strong positive correlation was found between the two. Placental thickness was thicker by 1-3mm up to 22 weeks gestation, almost exact at 23-33 weeks and was less by 0.5-5mm after 33 weeks.

A strong positive correlation was demonstrated between the placental thickness and the fetal biometric parameters.

Placental location did not affect the placental thickness.

Conclusion

- Placental thickness increases with increase in gestational age.
- A strong positive correlation exists between placental thickness and gestational age.
- A positive correlation between placental thickness and fetal biometric parameters is found.
- There was no statistically significant difference in the placental thickness in relation to the placental location.

Recommendations

- Placental thickness can be added and used with the fetal biometric parameters to estimate gestational age in normal singleton pregnancies.

CHAPTER ONE

1.1 Introduction

The placenta provides the physiological connection between the gravid woman and the developing fetus (1). It is a tremendously vascularized organ whose main purpose include supplying nutrients, oxygen and hormones to the fetus (2). It is formed by the interaction of decidua basalis of the endometrium and chorionic villi of the fetus at implantation site at about 8-10 weeks. True definition of the placenta is possible at about 10-11 weeks after conception (3).

Ultrasound is an excellent tool for precise evaluation of GA. It is a vital component of all obstetric examinations and currently the best way to estimate the gestational age. Currently, several sonographically derived fetal parameters including CRL, BPD, FL, HC and AC are used to date pregnancy. They are however fetal based and there may be some drawbacks in these parameters in cases such as congenital abnormalities and genetic variations. Hence, there may be a need of an additional parameter for augmenting gestational age estimation with fewer errors. Ultrasound has been used to evaluate the position of the placenta and its structural changes as it matures (1,2). One auxiliary parameter used to evaluate the placenta is placental thickness as it is notably easy to perform and clinically beneficial. Abnormal placental thickness is well known as an indicator in far-ranging pathologic occurrence, although it can be used in uncomplicated cases to evaluate the placental thickness. Knowledge of the thickness of the placental can make contributions to the control of a risky pregnancy (3). Studies have demonstrated the role of PT as an up-to-date parameter for approximating gestational age and PT nomograms in relation to GA have been published (4–6). However, there has been no local study undertaken to show whether the parameter can be useful in GA estimation.

The optimum possible antepartum care and successful deliveries of babies relies on the precise knowledge of GA determination, and is a critical component of antenatal care. Gestational age can regularly be over and under estimated as the traditional gestational age estimation is established totally on ultrasonography considering the fetal biometric parameters can be affected by genetic variations and congenital abnormalities. Accurate establishment of gestational age is key for deciding the timing figuring out termination of pregnancy, fetal growth monitoring,

scheduling of invasive approaches that includes sampling of chorionic villus, amniocentesis and biochemical tests interpretation such as maternal serum biomarkers screening e.g. alpha fetoprotein levels.

The patient's menstrual history is considered adequate for the purpose of establishing EDD, only if LMP was normal in duration, amount of flow, or if prior menstrual periods came at regular intervals and if the patient did not use oral contraceptives within the last 3 months of her last period. Unfortunately, approximately 30% of patients do not fulfill these criteria, making estimation of EDD based on LMP unreliable. Clinical parameters which are widely accepted for estimation of maturity are GA and fetal weight.

In addition to the customary fetal biometric parameters, diverse research have been accomplished attempting to infer a relationship between the PT and GA (7–10).

Placental thickness can be a reassuring parameter for estimation of gestational age because of increase in its the thickness with gestational age (4).

1.2 Literature review

The placenta is a materno-fetal organ with vital metabolic, endocrine and immunological roles. Placental agenesis begins in 8th to 10 week of gestation and is usually accomplished by 4th month reaching maximal growth at term.(11)

In the recent past, the placenta was only assessed after delivery. Ultrasonography has furnished a secure and non-invasive approach for assessing the fetus and placenta. Apart from the numerous fetal parameters like CRL, BPD, HC, AC, FL, placental thickness, can be used as a new parameter to estimate the GA.

1.2.1. The placenta

Embryogenesis

Placental development is characterized by the speedy proliferation of the trophoblast and development of chorionic sac and villi. By the end of week three, the anatomic arrangements crucial for physiologic exchange between the mother and fetus is mounted. By week eight, the chorionic villi that covered the entire chorionic sac become compressed, degenerated and become avascular forming the chorion laeve. The chorion frondosum is formed by the villi associated with decidua basalis which branch profusely and increase in number. The cytotrophoblastic shell attaches the fetal to the maternal part of the placenta. The persistent area of chorionic villi determines the shape of the placenta. Increase in size and thickness of the placenta continues until the fetus is about 18 weeks old. Fifteen to thirty percent of the decidua is covered by the fully developed placenta which weighs approximately one sixth that of the fetus (11).

Shape, size, location and appearance

The placenta is a flattened round vascularized organ weighing 480-600 grams (a sixth to a seventh of the fetal weight). It is visualized transabdominally between 8th to 10th week as a focal thickening of the decidua as far visible as a discoid structure with homogenous echotexture by the 12th week. Its echotexture changes from an echogenic gestational sac wall thickening to fine, granular, homogeneous texture.

The retroplacental complex is of low echogenicity and is 10-20 millimeters (mm) deep to the placenta and should be routinely assessed.

Normally, the cord inserts in the central portion, but occasionally, it may insert eccentrically near the margins (battledore placenta) or below the border of the placenta (velamentous insertion).

Doppler assessment of the umbilical artery has shown low resistance, high diastolic flow indicative of the normal placenta.

The placenta can be located anteriorly, fundal, posteriorly or laterally. Early reviews of placental localization through ultrasonography had been posted through Donald (1968), Kobayashi (1970) and Gottesfield (1966).

Generally, wide based placentas are thin. Pregnancy outcome correlation can be achieved by evaluating placental length, volume, and thickness. In general, PT of more than 40 mm before 24 weeks' gestation is considered abnormal.

Functions of the placenta

The placenta plays an important role in transportation of nutrients, production of hormones (HCG, estrogen, progesterone, human placental lactogen) metabolism e.g. Synthesis of glycogen, excretion (urea, uric acid and creatinine). It also plays a role in immunity where by IgG antibodies pass through the placenta to provide immunity in utero and acts as a selective maternal-fetal barrier against transmission of microbes (12).

Ultrasonographic Scanning protocol

The placenta is evaluated in every obstetric scan with documentation of the size, site, echotexture and distance from the internal cervical os for evaluation of the various types of placenta previa.

In succenturiate placenta (accessory placental lobe), the position and the connecting tissues and membranes are noted.

The texture, morphology or any abnormality is evaluated and documented. Placental thickness is measured and correlated with the clinical information.

Transabdominal, transperineal or endovaginal ultrasound can be used. Endovaginal scanning allows early visualization of the placenta and umbilical cord. Its proximity to the cervix makes it an ideal method for evaluating placenta previa in late pregnancy. There is no need of a full bladder in endovaginal scanning.

Transperineal scanning is an important supplement to an obstetric ultrasound protocol when endovaginal sonography is a contraindication or is unavailable.

An empty bladder may hinder visualization of the cervix, but an overly distended bladder can cause a false-positive impression of placenta previa.

Patient should be made comfortable during the scanning process and the chances of false-positive images of placenta previa reduced by varying degrees of the distension of the bladder (let patient fill her bladder then have her empty a cup of urine at a time).

Placental thickness measurement

The placentomyometrial interface midpoint, in a position that is not obstructed, should be identified.

Measurements are taken from the chorionic plate to the starting point of the basilar myometrium. The myometrium and retroplacental complex are excluded. In a centrally inserting placenta, the measurement can be taken at its insertion point. Ideally, the transducer is placed at right angles to the placenta.

The placental shape should be taken into consideration. In general, a 3 to 5 MHz transducer frequency gives a satisfactory resolution and depth penetration in all but the extremely obese patient. A 4 to 7 MHz abdominal transducer or a 5 to 10 MHz vaginal transducer can be used in early pregnancy.

In some cases, such as in large patients, third trimester pregnancy or when the fetus is lying over a posterior placenta, a lower frequency transducer produces better images. The gains should be adjusted until the placenta has a homogeneous and uniform granular echotexture. Both the chorionic plate and retroplacental zone should be clearly visualized.



Fig 1; sonographic image showing placental thickness measurement in a normal posterior placenta. The retroplacental complex is excluded (13).

1.2.2 Placental thickness and gestational age

Sandesh Ganjoo et al in 2014 analyzed the placental thickness for estimation of gestational age estimation in 300 patients of gravid mothers between 10 to 40 weeks. The study demonstrated that GA can be deduced from measuring the PT in patients who don't know their last menstrual period. It was then concluded that PT increased linearly with advancing GA (14)

Additionally, B.Suganya et al observed that PT increased with increase in gestational age. During the 22nd to the 35th week of gestation, the PT corresponded extremely closely with the GA in weeks. It was observed that the PT was higher by 1-4mm prior to 19 weeks and after 35 weeks gestation, it was lower by 1-2mm.(9).

Some studies have shown that PT increases with GA in a linear fashion and from 22nd to 35th week gestation, the PT closely matched the GA in weeks. Up to 21st week, the PT was higher by 1-4mm and after 35th week, it was lower by 1-2mm (4,15).

Studies by Tiwari et al, Tanzila et al and W.K. Hoddick et al consisting of 754, 210 and 200 antenatal women respectively showed that PT increased gradually with increase in GA. Of note is that it was found that the PT correlated very intimately with the gestational age in weeks suggestive of a powerful positive connection between the PT and GA. It was therefore concluded that PT is a good parameter in estimating gestational age in 2nd and 3rd trimester (16–18).

PT has been shown to increase with GA in a linear fashion between 11-40 weeks hence a strong positive correlation between PT and GA. A positive correlation has also been found between PT and fetal parameters; AC, HC, FL, BPD showing that there is a strong positive correlation between GA and fetal parameters. (7,8)

Nasreen Noor prospectively studied the placental thickness in 152 pregnant women with known LMP and regular periods. Placental thickness was measured by ultrasonography and correlated with fetal parameters such as FL, BPD, HC and the AC. A high positive interrelationship between the GA and PT at 18-37 weeks was found (19).

Tongsong and Boonyanurak showed an increase in PT with gestational age and they established a nomogram for PT from 9 to 37 weeks gestation.(20)

Sujit Pant et al, found that the gestational age almost parallels with the placental thickness till 35 weeks of gestation after which it falls by 1-3mm than the gestational age. The placental thickness showed a significant positive correlation with the gestational age. There was placental thickness increase with increase in GA from 14-35 weeks of gestation and lags behind the GA by 1-3 mm thereafter.(21)

Mathai BM et al studied the relationship of the PT measured with GA in uncomplicated and IUGR pregnancies and observed a positive correlation between placental thickness and gestational age in both normal and IUGR population.(22).

A study in Pakistan by Muhammad et al, where 200 antenatal women at 2nd and 3rd trimester of more than 12 weeks were included, showed PT increased from 16 mm to 39 mm at 12 and 40 weeks respectively. This showed a strong positive relationship between the PT and the GA and fetal weight.(23)

A longitudinal study by Wolf et al estimated placental volume and fetal weight in 18 patients using ultrasonographic measurement from 16 - 20 weeks gestation was done. A linear or sigmoid pattern was seen in the growth of the placenta and fetus in 7 normal cases (24)

Another study was done by Jauniaux et al in unselected 210 obstetric population between 16 and 28 weeks. In 168 normal pregnancies, significant interrelations were found between GA and

placental thickness, circumference, and volume and also between fetal abdominal and placental circumferences. (25)

A study by Ghosh UK et al, where 120 singleton pregnancies of 32 to 40 weeks of gestation were analyzed, both the placental diameter and thickness were measured. Placental diameter increased with increase in gestational age. It was found that in 75% of cases a single ultrasound measurement of PT can predict gestational age within +/- 14days in the last 8 weeks of pregnancy (26)

A study of 666 Nigerian women from the 14th to 40th week of gestation by Ohagwu et al (2008), showed a linear increase of PT with increase in GA. A fairly linear manner and remarkable interdependence was also seen between the PT and fetal biometric parameters (BPD and AC) in the 2nd and 3rd trimester (27)

1.2.3 Placental thickness and placental location

Lee et al (2012) conducted a study including 114 pregnant women in their 2nd trimester {18-22 weeks}. It was concluded that anterior placenta seems to be thinner than posterior placenta by approximately 7mm. Posterior placenta more than 40mm and anterior placenta more than 33mm could be abnormally thick (28)

Another study by Durnwald et al in 2004 where 167 normal singleton live pregnancies were analyzed and placental thickness measured, showed an increase in the thickness of the placenta with an increase in GA. In the 3rd trimester, the placental thickness of a posteriorly or fundally located placenta was significantly greater than an anterior placenta.(29)

A different study done in India in 2016 by K.K Nagar where placental location in each trimester was correlated with placental thickness for each trimester, found that the placental location does not affect the placental thickness. 'p' value in first trimester is 0.2707, 'p' value for second trimester is 0.9508 and 'p' value for third trimester was 0.7035. (30)

1.2.4. Placental thickness and other gestational dating parameters.

Ridhi Adhikari et al in 2015 analyzed placenta thickness in the estimation of gestational age in 150 antenatal women, between 11-40 weeks gestation. He showed a notable interconnection between PT and FL, BPD and AC in the 11th to 40th week of gestation. (7)

In addition to showing a positive correlation between PT and GA , Karthikeyan et al found a strong positive relationship between PT and fetal dating parameters and therefore concluded that placental thickness positively correlates with BPD, FL, HC and AC (8)

Ohagwu et al; 666 antenatal women in Nigeria were studied and a nomogram of placental thickness was established. They proved a significant association between placental thickness and gestational age as well as BPD and HC (27)

A different study conducted in Sudan involving 110 pregnant women by Arafa Ahmed et al (2014) in their 3rd trimester showed a significant positive correlation of PT with FL and BPD (31)

To the best of my knowledge, no local published studies have been done to show the above.

2.0 CHAPTER TWO

2.1 Study justification/rationale

Obstetric ultrasonography is a safe, efficient (32–35) non-invasive and cost friendly method in the evaluation of the fetal wellbeing.

CRL, FL, BPD and HC have routinely been used for gestational age estimation. Some of these parameters however are limiting in some instances such as intrauterine growth restriction (IUGR), diabetes mellitus (DM) etc. Wolfson et al (36) revealed that the BPD measurement is unreliable in the fetuses where the membranes had ruptured prematurely. Having placental thickness as an additional parameter will be useful in gestational age estimation and will increase the accuracy in GA estimation. Other regional and international studies have shown that there is a strong correlation between PT and GA. There is no local recorded study on ultrasonographic measurement of placental thickness in GA estimation.

This study aims to determine if PT can be used in estimation of gestational age and share and contribute to the scientific knowledge on gestational age estimation. The information will be useful to the radiologist, obstetrician, and pediatrician. Ultimately this data will be key to establishing our own local guidelines that will increase the accuracy of estimating GA.

2.2 Objectives

2.2.1 Broad objective

To study the correlation of placental thickness with the ultrasonographic gestational age in normal singleton pregnancies in Kenyatta National Hospital.

2.2.2 Specific objectives

1. To determine the placental thickness in normal singleton pregnancies in KNH.
2. To determine the biometric profile.
3. To correlate placental thickness with gestational age.
4. To correlate placental location with placental thickness.

3.0 CHAPTER THREE

3.1 Study design and methodology

Prospective cross-sectional descriptive study

3.2 Study area

Radiology department at Kenyatta National Hospital, Nairobi County, Kenya.

3.3 Study population

Patients referred for obstetric scans with a normal singleton pregnancy

Sample size

Will be calculated based on the formula

$$n = \frac{z_{\alpha}^2 \times (SD)^2}{d^2}$$

Where: $Z_{\alpha} = 1.96$ (standard normal deviate representing 95% level of confidence)

SD = standard deviation

d = Margin of error in mean placental thickness

$$n = \frac{1.96^2 \times (7.8)^2}{1^2}$$

Hence n= 233 patients

3.4 Inclusion criteria

- Patients referred for obstetric scans with a normal singleton pregnancy with a gestational age of 14 to 40 weeks at UoN/KNH department of Radiology or Department of Obstetrics.
- Antenatal mothers with no co-morbidity affecting pregnancy.
- Patients with written informed consent.

3.5 Exclusion criteria

1. Patients with multiple gestation, PIH, Diabetes, Congenital anomalies, IUGR.
2. Oligohydramnios or polyhydramnios
3. Placenta with morphological variation such as Succenturiate placenta, circumvallate placenta, placenta membranacea
4. Poor visualization of the placenta such as maternal obesity and posterior shadowing secondary to fetal structures in late 3rd trimester
5. Placenta with variation in cord insertion such as battledore and velamentous insertion.
6. Placenta with poor visualization of cord site.
7. Patients who chose to decline consent.
8. Patients with placental length of less than 15cm or more than 20cm.

3.6 Materials and methodology

A prospective cross sectional study comprising of 233 uncomplicated gravid women were clinically evaluated and referred to the department of Radiology, UoN/Kenyatta National Hospital (KNH) for an obstetric ultrasound, during the study period from June 2019 to December 2019. These clients/patients were examined for PT, GA and FW ultrasonographically after a detailed history was taken. Subjects were incorporated into the study in the event they met the inclusion criteria. Before the scanning was done, a written informed consent was acquired. Antenatal women with uncomplicated pregnancy of GA from 14 weeks to 40 weeks referred to radiology department, KNH for routine antenatal scanning were part of the study. Those who did not meet the inclusion criteria were excluded. The grey scale real time ultrasound examinations was carried out using a GE logic P6 pro ultrasound equipment system that had a Hadlock feed-in system. The transducer of the machines used had a frequency of 3.5-5 MHz

The principal investigator did the clinical evaluation of the study participants referred to the KNH- radiology department. Scanning of the patients was done by the principal investigator too. Ultrasonography was done when patient was in supine position with a moderately distended bladder. Coupling gel was applied. The transducer was positioned perpendicular to both the chorionic and basal plates. Placental thickness was measured in millimeters at the level of cord insertion or its midpoint. Three placental measurements were taken during the relaxed phase of the uterus and the average calculated.

The images were stored in soft copy and reviewed on a weekly basis by a consultant radiologist that is specialized in sonography. In case of any discrepancy, a second radiology consultant reviewed the images and a consensus arrived at.

Examination method

1. A thorough history regarding the medical condition and the obstetric history was taken.
2. The procedure was explained to the patient in details with reassurance of confidentiality of the patient.
3. Written and informed consent for doing the ultrasound was taken.
4. Routine ultrasound scanning was done with a 3.5-5 MHZ transducer, transabdominally on a moderately full bladder, patient lying supine in a comfortable position.
5. BPD, HC, FL and AC were measured. BPD was measured at the level of the thalamus and the third ventricle. The calipers was placed from the outer skull to the inner skull in the near and far field respectively. The HC was measured around the outside of the skull. AC was measured at the level of visualization of the portal vein and stomach. The circumference was drawn at the outer skin. Lastly, FL was measured with the shaft of the bone as near to perpendicular to the scan plane as possible. The distal femoral epiphysis was excluded (37).
6. Placental thickness was measured at the site of cord insertion or at its midpoint with the transducer perpendicular to the placenta. The myometrium and retroplacental complex were excluded from the measurement as they are not part of the placenta.
7. The images were stored in soft copy and reviewed on a weekly basis by a consultant radiologist that is specialized in sonography. In case of any discrepancy, a second radiology consultant will review the images and a consensus reached.

Timing of the study

Timing will be done between the 14th week and the 40th week of gestation.

Scanner and transducer used

A GE logic P6 pro ultrasound scanner with a Hadlock feed in system and the probe of 3.5-5 MHZ convex array transducer will be used to examine the gravid women and produced grey scale images. Hard copies of the cases will be obtained using thermal printer and photographs



Fig 2; GE logic P6 pro.

Source; KNH, ultrasound room 33

Photographer; Abigael Mosomi

3.7 Quality assurance protocol

Quality assurance is an integral part of clinical care and especially in sonography which has a high operator and technique dependence. The scans will be done by the principal investigator. 3 measurements of the placental thickness will be done and a mean value calculated. Each placenta will be measured to a 1mm precision at the insertion of the umbilical cord or its mid-point.

The images will be stored in soft copy and reviewed on a weekly basis by a consultant radiologist that is specialized in sonography. In case of any discrepancy, a second radiology consultant will review the images and a consensus reached.

A single machine; GE logic P6 pro will be used for reproducibility of the results.

Quality assurance will be accomplished through careful documentation of obstetric ultrasound examination results, organized and reliable archiving of reports and images.

3.8 Ethical consideration

Strict ethical considerations will be ensured in this research. The ethical committee from KNH-UON will be requested to approve the research. The study will proceed once the ethical and research committee have approved the study.

The patient's personal information will be held with high secrecy. The information that will be acquired will be used for clinical management and patient's academic purposes only.

The examination requested by the primary physician is the only examination that will be done. Written informed consent will be acquired from all patients enrolled in the study.

3.9 Data collection

A structured data collection form (appendix 1) will be used by the principal researcher at the time of the study.

3.10 Statistics

The PT in mm and the respective standard deviation (SD) for every individual GA from 14 weeks to 40 weeks will be measured. Calculation of the 95% confidence interval will be done.

The correlation analysis will be done to quantify the connection between GA in weeks and PT in mm.

The statistical software SPSS 23 will be used to analyze the data. Graphs and tables will be generated using Microsoft word and Excel.

Results will be presented in tabular and graphical format. Frequencies and frequency distribution will be calculated and correlation between variables will be done.

4.0 CHAPTER FOUR

4.1 Results and Statistical analysis

This study was conducted in KNH on 252 participants who consented to the study with a gestational age of 14-40 weeks that met the criteria for inclusion.

The distribution of ages ranged from 18-45 years. One hundred and twenty two (48.8%) were more than 30 years and 8 (3.2 %) were below 21 years of age. The mean age of the patients was 30.4 (Standard deviation =5.8) years, while the median age was 30.0 (IQR=9.0) years.

Among the 252 patients, 58 (23%) were primigravid and 194 (77%) were multigravid as demonstrated on table 1.

One hundred and seventy three (68.7%) were sure of their last normal menstrual period (LNMP) whereas 79 (31.3%) were not sure. One hundred and eighty six patients had regular LNMP whereas 66 had irregular menses.

Table 1: Patient characteristics

	Frequency	Percent
Maternal age		
<21 Years	8	3.2
21-25 Years	49	19.4
26-30 Years	73	29.0
>30	122	48.4
Parity		
Primigravid	58	23.0
Multigravid	194	77.0
Menstrual history		
Regular	186	73.8
Irregular	66	26.2
LNMP available		
Yes	173	68.7
No	79	31.3
Placenta location		
Anterior	115	45.6
Posterior	88	34.9
Lateral	3	1.2
Fundal	46	18.3
Presentation of fetus		
Cephalic	174	69.0
Breech	57	22.6
Transverse Lie	21	8.3

Statistical Package for Social Sciences, SPSS version 23.0 was used to analyze the data. Using Pearson's correlation analysis, the degree of relationship between placental thickness and, BPD, FL, HC and AC was established. Regression analysis was used to derive statistical relationships between placental thickness and, BPD, FL, HC and AC, while the best-fit approach was used to plot linear graphs of the relationship between placental thickness and growth parameter.

It was found that the correlation between placental thickness and gestational age was very strong ($r=0.939$), with the linear regression, $y=3.66+0.87x$, determining the relationship as demonstrated in figure 3.

Placental thickness increases with increase in gestational age.

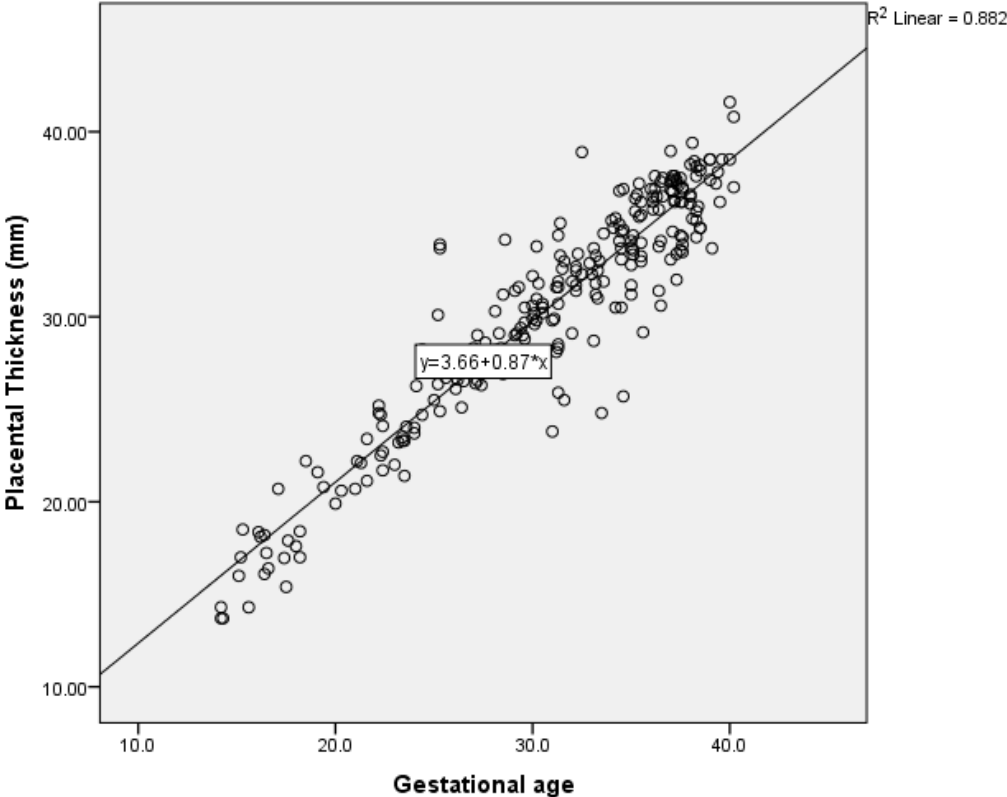


Figure 3; graph showing a strong positive linear correlation between GA and placental thickness ($r=0.939$)

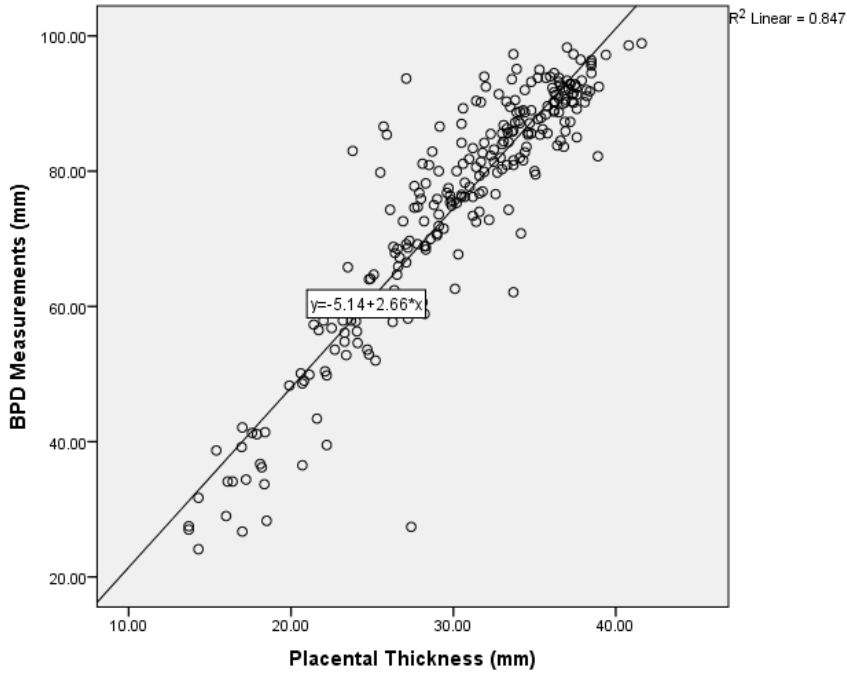


Figure 4. Graph of biparietal diameter (BPD) against placental thickness showing a significant positive correlation between BPD and PT. ($r=0.920$)

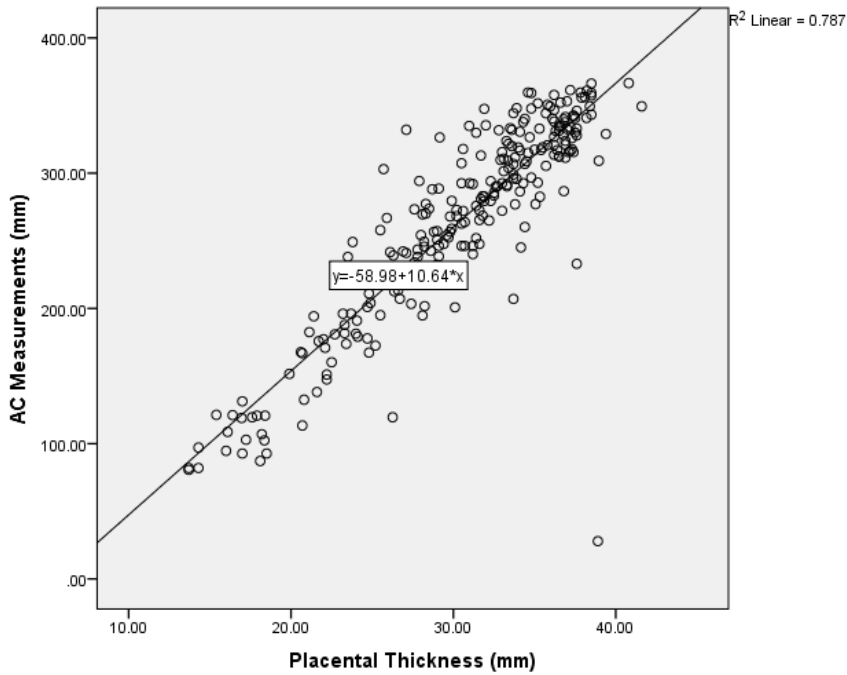


Figure 5. Graph of abdominal circumference (AC) against placental thickness showing a significant positive correlation between AC and PT. (0.887)

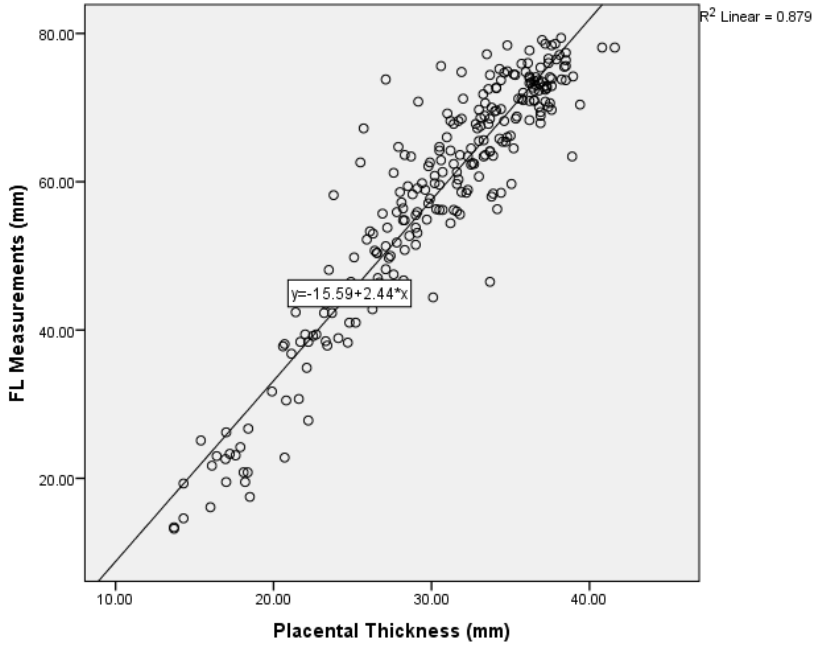


Figure 6. Graph of femur length (FL) against placental thickness demonstrating a positive correlation between FL and PT. ($r=0.937$)

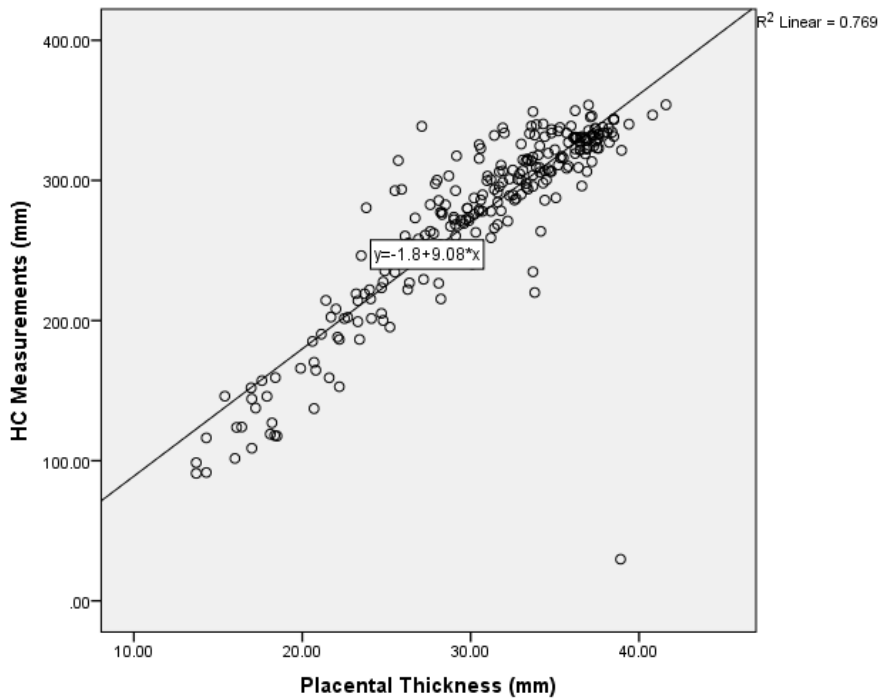


Figure 7. Graph of head circumference (HC) against placental thickness demonstrating a significant positive correlation between HC and PT. ($r=0.887$)

Correlations					
		BPD (mm)	AC (mm)	FL (mm)	HC (mm)
Placental Thickness (mm)	Pearson Correlation	.920**	.887**	.937**	.877**
	p-value	.000	.000	.000	.000
	N	252	252	252	252
**. Correlation is significant at the 0.01 level (2-tailed).					

The following linear mathematical relationships between BPD, AC, FL, HC and placental thickness were established in the second and third trimesters:

$$y [\text{BPD}(\text{mm})] = 5.14 (\text{placental thickness}(\text{mm})) \pm 2.66$$

$$(4) (r = 0.920).$$

$$y [\text{AC}(\text{mm})] = 58.98 (\text{placental thickness}(\text{mm})) \pm 10.64$$

$$(5) (r = 0.887).$$

$$y [\text{FL}(\text{mm})] = 15.59 (\text{placental thickness}(\text{mm})) \pm 2.44$$

$$(6) (r = 0.937).$$

$$y [\text{HC}(\text{mm})] = 1.8 (\text{placental thickness}(\text{mm})) \pm 9.08$$

$$(7) (r = 0.877).$$

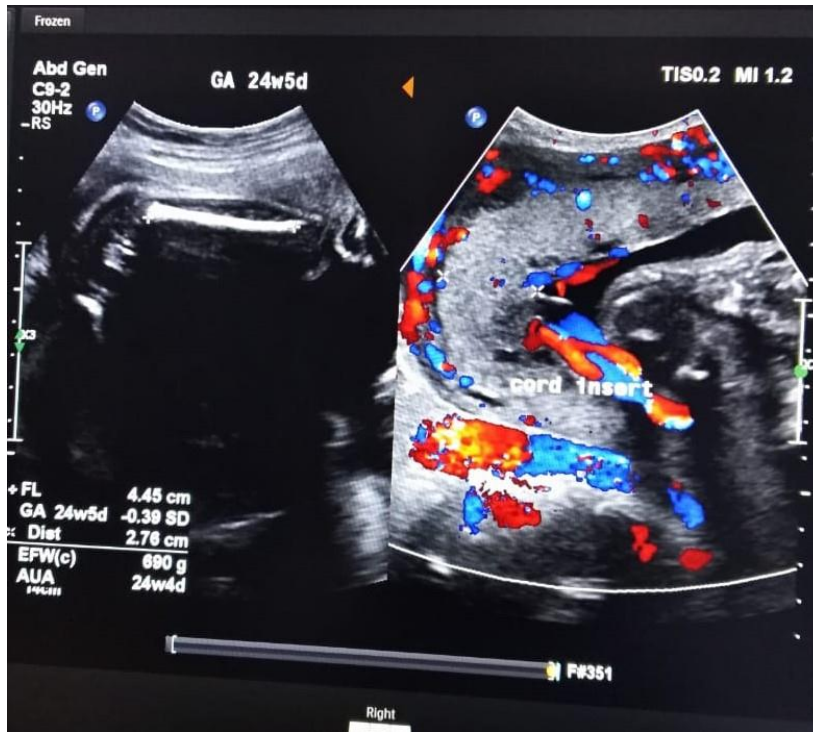
These equations are displayed in the graphs in the Figures

4, 5, 6 and 7.

Analysis of variance (ANOVA) was used to test the differences in the means of placental thickness for the placenta location. The mean placental thickness differed slightly in relation to the location but was not statistically significant ($p=0.727$).

Table 2: Placenta Location and Thickness

	Frequency	Mean	SD
Anterior	114	30.0	5.8
Posterior	89	30.4	6.4
Lateral	3	32.5	6.7
Fundal	46	31.1	6.8
Total	252	30.4	6.2
p-value	0.727		



Review		Report	
Institution: KENYATTA NATIONAL HOSPITAL			
Referring Physician:		Performed By:	
Physician of Record:			
Comments:			
OB: Study Info			
<input type="checkbox"/> Diabetes Type:			
G:	P:	A:	Ectopic:
OB: Summary			
AUA: 24w4d GA(LMP): 24w5d LMP: 05/10/2018 EDD: 12/07/2019 (c) EDD(AUA): 13/07/2019		EDD(LMP): 12/07/2019 HC/AC: 1.16 (1.05 -1.21) FL/BPD: 75%(71-87%) FL/AC: 23%(20-24%) Fetuses Count: 1	
		EFW	
		Weight	698g(+/-102g) 1lb 9oz (+/-4oz)
		Author	Hadlock (AC,FL,HC,BPD)
		LMP Percentile	29% (approx. 3-97%)
		AUA Percentile	
		Author	Hadlock

5.0 CHAPTER FIVE

5.1 Discussion

The placenta is a very vascular fetal organ, the main function of which is to exchange nutrients and metabolic products and gasses between the bloodstreams of mother and fetus. During the growth period of the fetus the size of the placenta increases to allow it to perform its vital functions

As the embryo grows and develops a vascular system, it needs to establish a much more efficient way to obtain nutrients and eliminate waste products by creating an efficient interface between its vascular system and that of its mother.

The placenta is also a major endocrine organ and also produces a number of protein hormones.

A total of 252 gravid women, who consented to the study, of gestational age 14 - 40 weeks were studied for their placental thickness to determine whether the placental thickness can be used for estimating gestation age by ultrasonography in normal Kenyan singleton pregnancies.

The biometric profile was determined, and the GA was calculated to correlate the PT with gestational age.

The mean placental thickness values for various gestational ages was determined from 14 – 40 weeks. The PT was observed to increase gradually from 14.3 mm at 14 weeks to 40.8 mm at 40 weeks gestation.

Similar findings of a gradual rise in placental thickness were demonstrated by Tongsong and Boonyanurak (20), Muhammad et al (23) and Ohagwu CC et al (27).

In the present study, the mean PT was slightly higher by 1-3 mm for the corresponding gestational age up to 22 weeks. Placental thickness in mm almost matched with the corresponding gestational age in weeks from 23 weeks to 33 weeks of gestation. After 33 weeks, placental thickness started decreasing by 0.5 to 5 mm to corresponding gestational age till 40 weeks.

Our study results are also closely consistent with Anupama Jain et al (6) Mittal et al (4) and Aditi Tiwari (16) by who reported placental thickness to match from 22 to 35 weeks of gestation.

The relationship between PT and GA was assessed in this study using Pearson correlation, ($r = 0.939$) having shown a strong linear correlation between the two. (Figure 1).

This agrees with studies done by Mital and Nyberg et al (4,15) and T. Karthikeyan et al (8)

Other studies have shown the same strong positive association between the placental thickness and gestational age. (6-9, 14-27).

The placental thickness had a positive correlation with other fetal biometrics. Correlation coefficient being 0.92, 0.887, 0.937 and 0.877 for BPD, AC, FL and HC respectively with p value <0.0001 for all. This is consistent with Karthikeyan et al (8) and Ridhi Adhikari et al (7) study where they correlated placental thickness to all the four fetal biometric parameters and found a strong positive correlation .

Our study results are also in keeping with Ohagwu et al (27) and Ahmed et al (31), which demonstrated a strong positive correlation of placental thickness and some of the four of the fetal biometrics.

In the current study, association between placental thickness and placental location was calculated using analysis of variance (ANOVA). The mean placental thickness differed slightly in relation to the location but was not statistically significant ($p=0.727$) This is in keeping with an Indian study by K Nagar et al (2016).

However this is contrary to researches done by Lee et al (28) and Durnwald et al (29) who found that anterior placenta seems to be thinner than posterior placenta.

5.2 Conclusion

The placental thickness was found to increase with increase in gestational age suggestive of a strong positive correlation between the two. Placental thickness was thicker by 1-3mm up to 22 weeks gestation, almost exact at 23-33 weeks and was less by 0.5-5mm after 33 weeks.

A strong positive correlation was demonstrated between the placental thickness and the fetal biometric parameters.

Placental location did not affect the placental thickness.

5.3 Limitations

- Our study was a cross-sectional study with a relative smaller sample size hence this may not confidently reflect the country's population.
- This study was done at a tertiary hospital and therefore cannot be a full representation of the Kenyan population.

5.4 Recommendations

- Placental assessment can be added as one of the parameters to estimate GA.
- A meta-analysis can be carried out involving studies done in other hospitals in other parts of the country and other regional countries
- Create awareness among radiologists, sonographer and sonologist on the availability and accuracy of PT in estimation of gestational age in normal singleton pregnancies.
- Conducting a multi-center study to have a better reflection of the country's population.

TIMELINE OF EVENT

	NOVEMBER 2018-MARCH 2019	April 2019- May 2019	June 2019-Dec 2019	Jan 2020-feb 2020	March 2020- april 2020
Proposal write up	X				
Submission to ERC and corrections		X			
Data collection			X		
Data entry and analysis				X	
Report writing and dissertation submission					X

BUDGET

ITEM	QUANTITY	UNIT PRICE(Ksh)	TOTAL COST(Ksh)
Notebooks	4 pcs	60.00	240.00
Printing paper	3 packets	500.00	1,500.00
Files	3 pcs	80	240.00
Cartridge	1 pc	15,000	15,000.00
Internet surfing	250 GB	20 per GB	5,000.00
Writing pens	20 pcs	20.00	400.00
Telephone airtime			5,000.00
Flash discs	2 pcs	1500.00	3,000.00
Thermal paper	10 pcs	2000.00	20,000.00
Drinking water	30 liters	400 per liter	12,000.00
Photocopies of data collection tool	240 copies	5.00 per page (8 pages per tool)	8,470.00
Photocopy of final proposal	6 copies	5.00 per page (47pages)	1,260
Binding copies of proposal	6 copies	50.00	300.00
Ethical review fees	1	2000.00	2000.00
Miscellaneous			
Biostatistician	1		
Contingency (10% of total cost)			
Subtotal			

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APPENDICES

APPENDIX 1: Data Collection Tool

PATIENT CHARACTERISTICS	
Maternal age	
Parity	
LNMP	
Ultrasound number	
Menstrual history; regular/irregular	
Indication	
Medical disorder	
Contacts	

MATERNAL AGE

<21 YEARS	
21-25 YEARS	
25-30 YEARS	
>30 YEARS	

PLACENTAL LOCATION.

ANTERIOR	
POSTERIOR	
LATERAL	
FUNDAL	

PRESENTATION OF FETUS.

CEPHALIC	
BREECH	
TRANSVERSE LIE	

OTHER GESTATIONAL AGE ESTIMATION PARAMETERS

	Measurement(mm)	GA (weeks)
BPD		
AC		
FL		
HC		

PLACENTAL THICKNESS

1 st measurement	2 nd measurement	3 rd measurement	Mean (mm)

APPENDIX 2: Data Analysis Tool

Table 1; placental thickness and gestational age (N=233)

Gestational age (weeks)	Number of measurements (n)	Mean and SD	P value
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
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39			
40			

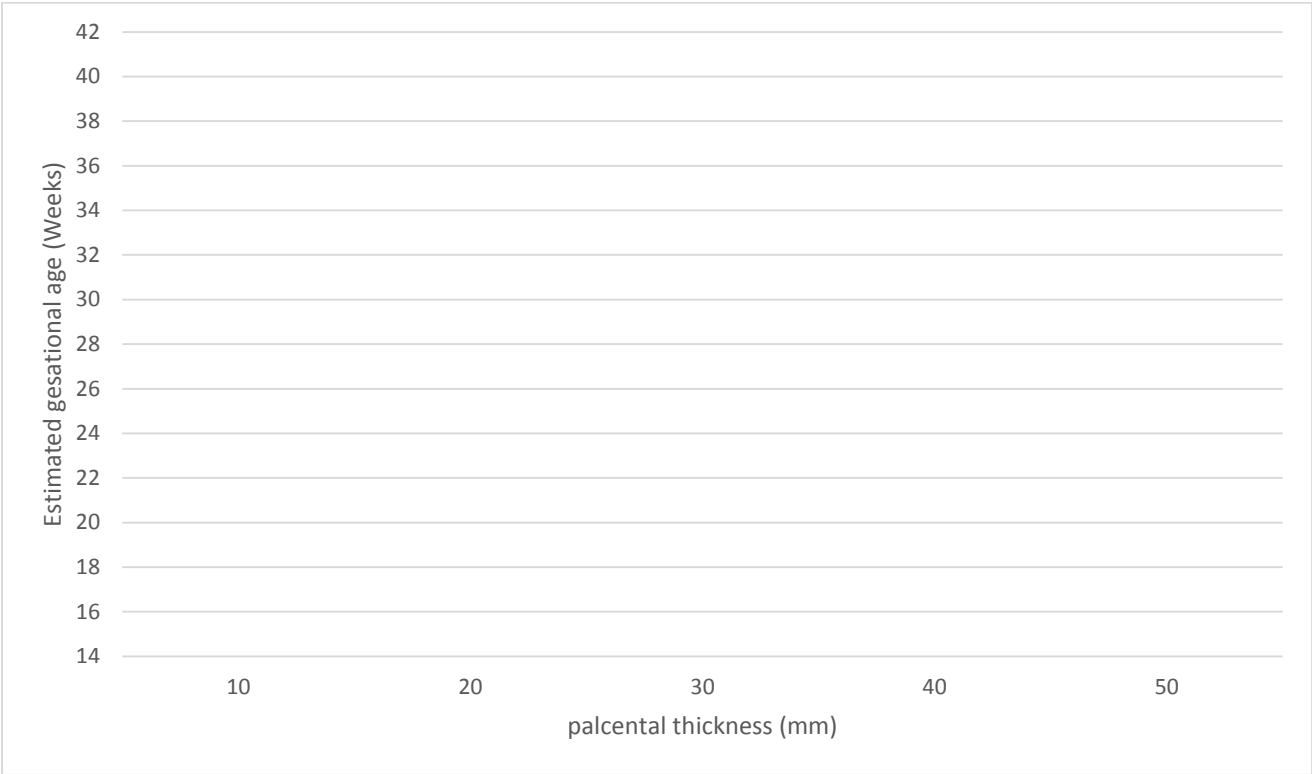
Table 2; placental thickness and biometric parameters (N=233)

GA (weeks)	Placental thickness (mm)	BPD-GA (weeks)	HC-GA (weeks)	AC-GA (weeks)	FL-GA (weeks)	P value
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
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39						
40						

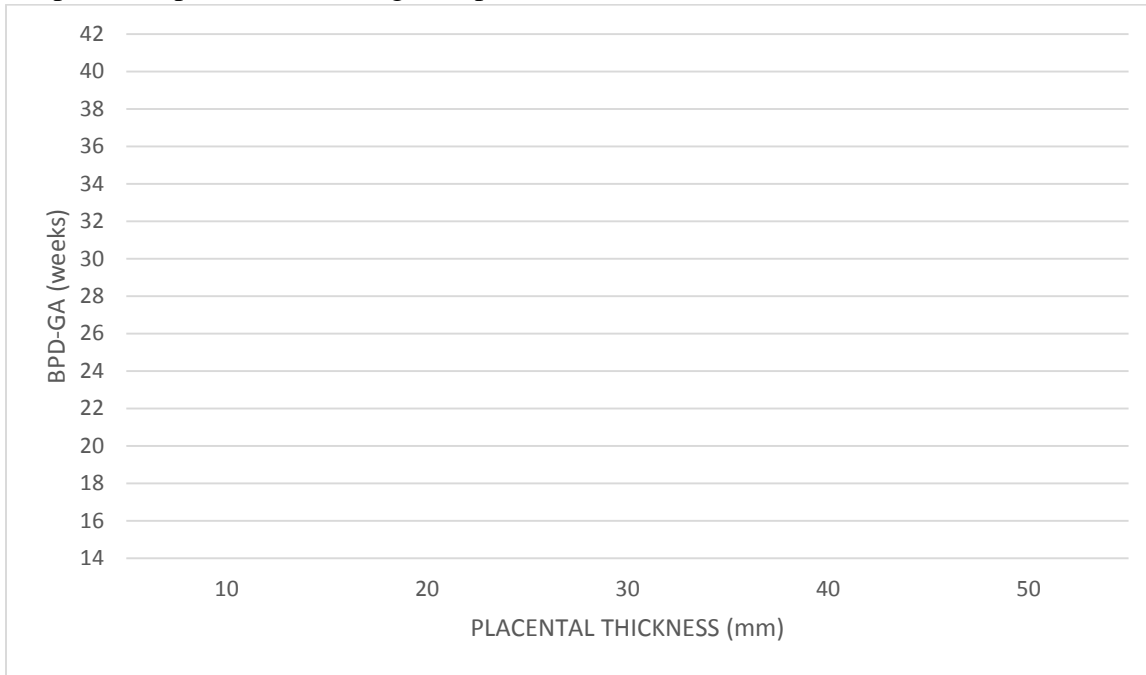
Table 3; Placental location and mean placental thickness.

Placental position	Number of cases(n)	percentage	Mean placental thickness (mm)
Anterior			
Posterior			
Fundal			
Lateral			

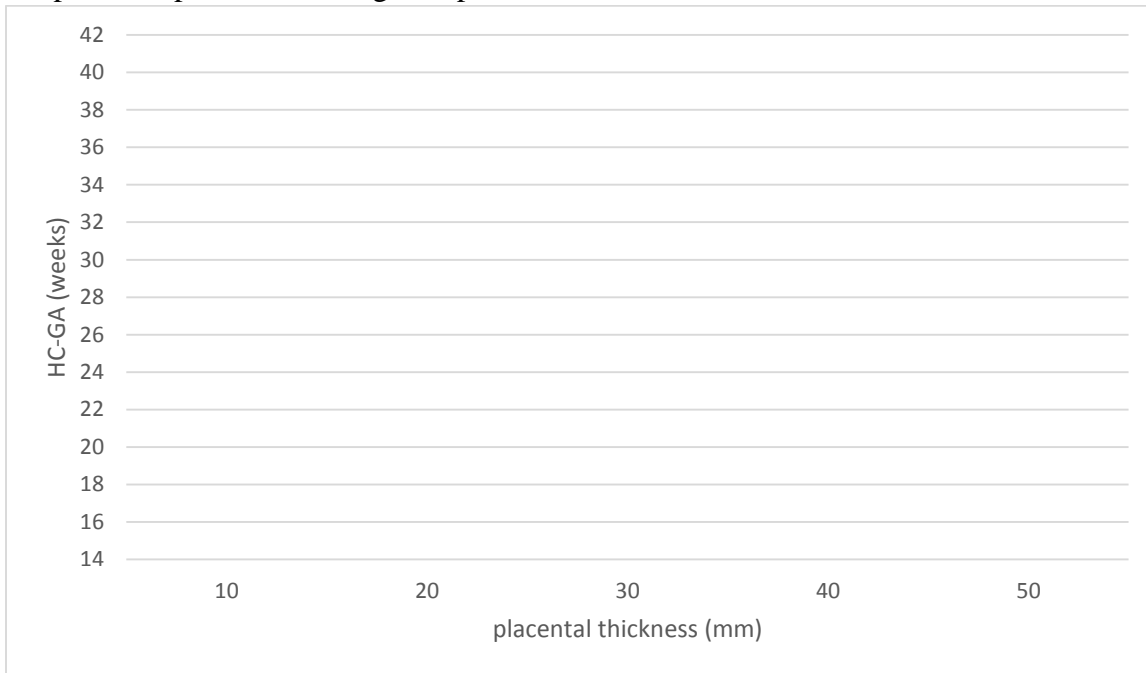
Graph 1; graph of estimated GA against placental thickness in second and third trimester



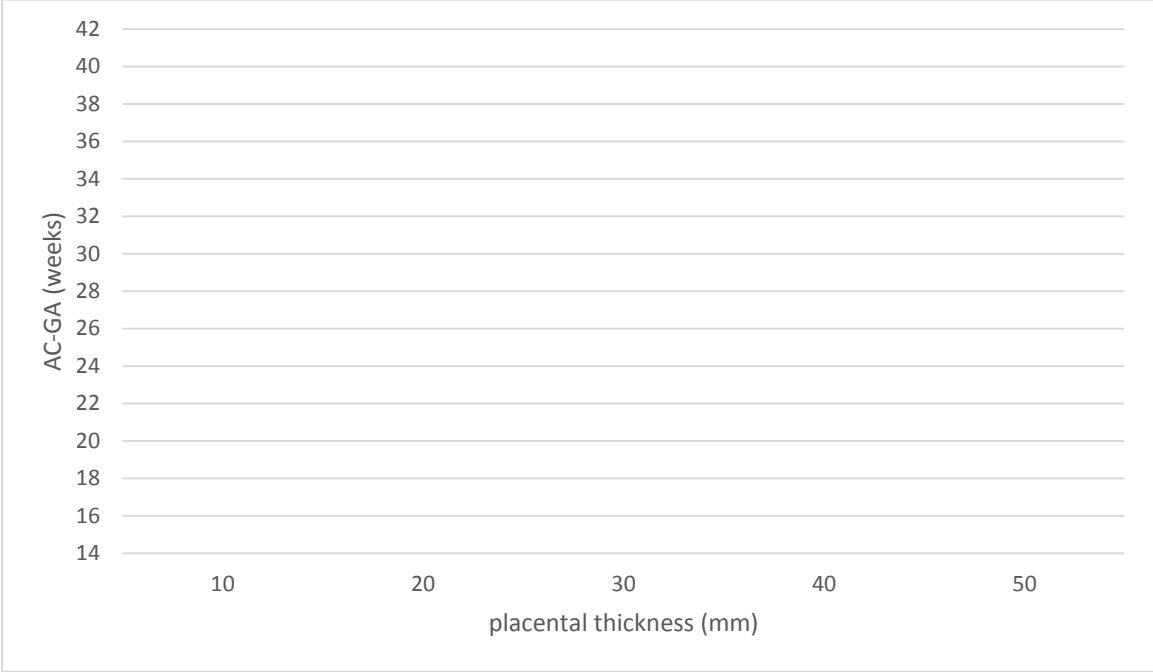
Graph 2; Graph of BPD-GA against placental thickness



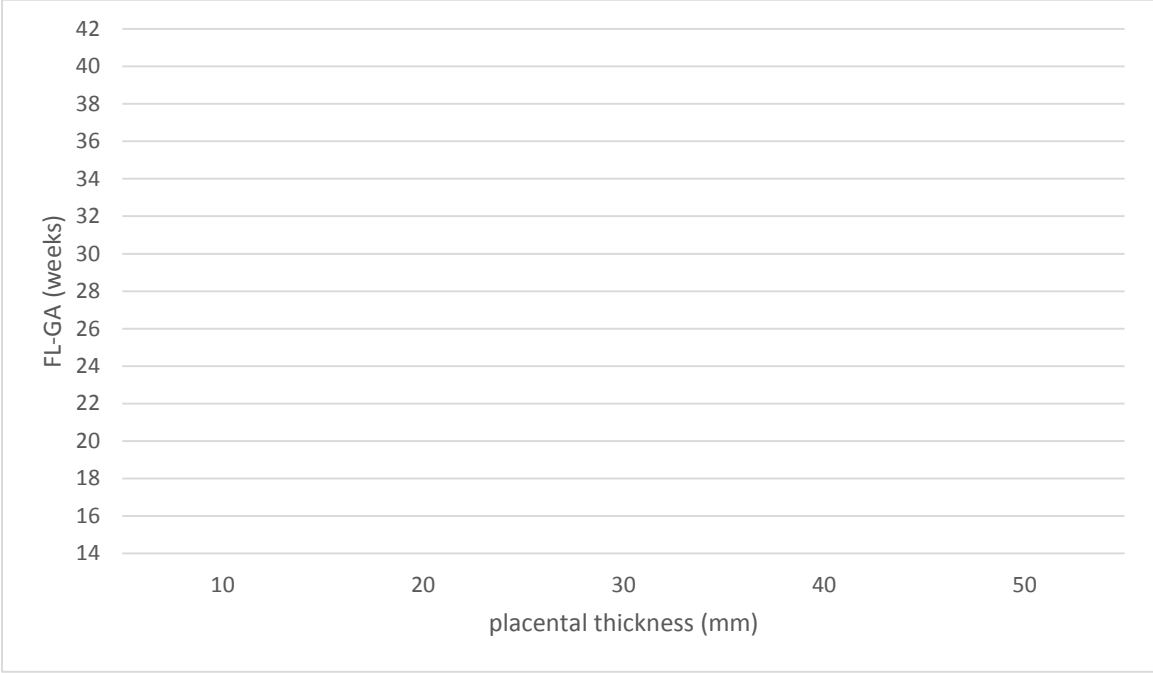
Graph 3; Graph of HC-GA against placental thickness



Graph 4; Graph of AC-GA against placental thickness



Graph 5; Graph of FL-GA against placental thickness



APPENDIX 3; Consent Form for Participation in the Study

This consent has 3 parts

- Participant information sheet
- Consent form for signing
- Statement by the researcher.

PARTICIPANT INFORMATION SHEET

Investigator's statement.

I am Dr. R Mosomi Nyanduko Abigael, a postgraduate student at the University of Nairobi, department of diagnostic imaging and radiation medicine. I am conducting a study on the placental thickness in determination of the fetal gestational age. Ultrasound will be used for the study. There are no radiations with ultrasound. You will be required to lie supine (on your back) with a moderately filled urinary bladder. No procedural pain will be experienced.

This consent form is to help you decide whether you want to be part of the study or not. It would be a pleasure if you are part of the study.

You are free to ask any questions before, during and after the study. Please read through the form.

Brief description of the study.

The placenta is an indispensable organ that plays a major role in the development of the growing fetus. Parameters such as BPD, FL, HC and AC are used to estimate the gestational age. The placental thickness increases in size with the increase in gestational age. Many studies done elsewhere worldwide have shown this. Some studies have shown thicker variations in black population.

This study therefore aims to show the correlation of placental thickness and gestational age in KNH and help create local data and hence play a critical role in management of gravid mother and the fetus.

Benefits and risks

This study will provide a database that will help diagnostic radiologists and obstetricians in better estimation of gestational age of the fetus.

No risks will be encountered during the study.

Duration of study

6 months.

Confidentiality

All information will be treated with confidentiality and any relevant medical information regarding the results and the data collected will be accessible to the researcher.

The information may be looked at by the supervisors where relevant to the study.

Information obtained will be kept under lock and key and soft copy information will be password protected. No specific information of any participant will be revealed to any person without their permission in writing. Your names/~~relatives~~relative's names will not appear on any of the records used for this study.

Right to refuse or withdraw

You are free to choose whether or not to participate in the study. You will suffer neither penalties nor loss of any benefits for declining to participate in the study. Refusal or withdrawal from the study will not deny treatment of any form.

Compensation

There will be no compensation financial or otherwise for the participants, no preferential treatment, gift or reward.

PARTICIPANT CONSENT FORM AND PARTICIPANTS STATEMENT

I hereby confirm that the doctor has explained to me about the above study and I understand fully. I have been given the opportunity to ask questions which have been adequately answered.

I understand that my participation is voluntary and that I have not been forced to participate. I understand that I can decline without giving any reason, without my medical care or legal rights being affected.

I understand that I will not receive any compensation either financial or otherwise, and will not receive any preferential treatment, gift or reward, for participating in the above study.

I understand that my personal information will be kept confidential, but that any relevant medical information regarding the results of my scans and the data collected will be accessible to the researcher, and may be looked at by her supervisors where relevant to the study. I give them permission to have access to this information.

I hereby consent to take part in the above study

Respondent’s Signature

STATEMENT BY RESEARCHER/RESEARCH ASSISTANT

I hereby confirm that I have accurately read out the contents of the information sheet to the participant.

To the best of my ability, I have made sure the participant understands the following.

Participation in this study is on voluntary basis and no compensation will be given.

Refusal to participate or withdraw from the study at any point will not in any way compromise the quality of care accorded to the patient.

All the information that shall be given will be treated with confidentiality.

Name: _____

Signature: _____

Date: _____

Respondent's Code

Date

CONTACTS

RESEARCHER

Dr Mosomi Nyanduko Abigael,
Department of diagnostic radiology and radiation medicine,
University of Nairobi,
P.O Box 51-00202
NAIROBI.

Telephone number: 0727919885

Email address: amosomi@yahoo.com

If you have any questions on your rights as a research participant you can contact
Kenya National Hospital Ethics and Research Committee whose task is to ensure research
participants are protected from harm.

KENYATTA NATIONAL HOSPITAL/UNIVERSITY OF NAIROBI
ETHICS AND RESEARCH REVIEW COMMITTEE KNH/UON/ERC

University of Nairobi

College of Health Sciences

P.O Box 19676-00202

Tel. (254)0202726300 Ext 44355

Kenyatta National Hospital

P.O Box 20723-00202

Tel. (254)020 726300 Ext 44102, 44355

Fax: 725272

E-mail: uonknh_erc@uonbi.ac.ke

APPENDIX 4: Fomu ya Idhini ya Kushiriki Katika Utafiti

KAULI YA MTAFITI.

Jina langu ni Dr. Mosomi Abigael Nyanduko, mwanafunzi wa uzamili katika Chuo Kikuu cha Nairobi idara ya radiologia na dawa mionzi. Ninafanya utafiti wa unene wa kondo la nyuma kwa kutumika kufanya uamuzi wa umri wa ujauzito.

Ultrasound itatumika katika utafiti. Hakuna mionzi wakati ultrasound inatumika. Utapaswa kulala kwa mgongo (kulala chali) na ukiwa na kibofu cha mkojo kikiwa kimejaa kiasi. Hakuna uchungu utahisi wakati utaratibu unatendeka.

Madhumuni ya fomu hii ya idhini ni kukusaidia kuamua kama unataka kushiriki katika utafiti huu au la. Itakuwa ni furaha yangu ukishiriki katika hii utafiti.

Unao uhuru wa kuuliza maswali yoyote kabla, wakati wa na baada ya utafiti. Tafadhali soma fomu hii Kwa makini.

MAELEZO MAFUPI KUHUSU UTAFITI.

Kondo la nyuma ni kiungo cha muhimu ambacho huwa na jukumu kuu kwa kukuwa kwa kijusi.

Vigezo vinavyo tumika kama mduara biparietal, fupa la upaja urefu, mduara kichwa na mduara tumbo hutumika kukadiria umri wa ujauzito. Unene wa kondo la nyuma huongezeka wakati umri wa ujauzito unapongezeka. Utafiti, ambayo imefanywa pengine duniani, imeonyesha hii.

Malengo ya utafiti wangu ni kuonyesha uhusiano wa unene wa kondo la nyuma na umri wa ujauzito katika KNH.

FAIDA NA MADHARA.

Utafiti huu utatoa msingi utakaosaidia wanaradiologia na madaktari wa uzazi na magonjwa wa wanawake Kwa kuboresha makaridio wa aumri wa ujauzito.

Hakuna madhara itatendeka wakati wa utafiti.

MUDA WA UTAFITI.

Miezi sita.

HAKI YA KUKATAA AU KUJIONDOA KATIKA UTAFITI

Una uhuru wakuchagua kushiriki katika utafiti. Hautateseka au kunyimwa huduma unayohitaji Kwa kutoshiriki katika utafiti huu.

SIRI YA UTAFITI

Taarifa zote namatokeo ya utafiti huu zitalindwa vilivyo na kuwekwa katika hali ya siri. Hakuna taarifa maalum ya mshiriki yeyote zitaafanuliwa Kwa mtu yeyote bila ya idhini yako Kwa maandishi. Majina yako hayataonekana kwenye kumbukumbu za Utafiti huu.

FIDIA

Hakutakuwa na fidia ya kifedha au vinginevyo kwa washiriki , hakuna upendeleo , zawadi au malipo.

FOMU YA KUIDHINISHA KUSHIRIKI KATIKA UTAFITI

Mimi natoa dhibitisho kwamba daktari amenieleza vikamilifu kuhusu utafiti ambao kichwa chake kimetajwa hapo juu. Ninakiri kuwa pia nimepewa fursa ya kuuliza maswali kuhusu utafiti huu na nimeridhika na majibu niliyopewa na daktari/mtafiti msaidizi.

Ninaelewa kwamba kushiriki katika utafiti huu ni kwa hiari yangu mwenyewe na sijalazimishwa.

Natambua kwamba sitapokea fidia yoyote iwe fedha au vinginevyo, wala sitapokea matibabu yoyote ya upendeleo, takrima au tuzo kwa ajili yakushiriki kwangu katika utafiti huu.

Naelewa kuwa taarifa zangu za kibinafsi zitakuwa siri. Ingawa hivyo taarifa kuhusu matokeo ya uchunguzi zitakazokusanywa wakatiwa utafiti huu zitaangaliwa na kuchambuliwa na mtafiti mkuu pamoja na wasimamizi wake pindi itakavyohitajika.

Ninatoa idhini yangu kushiriki katika utafiti huu.

Sahihi ya mshiriki: _____

Tarehe: _____

DHIBITISHO LA MTAFFITI/MTAFFITI MSAIDIZI

Ninadhibitisha ya kuwa nimemwelezea mshiriki mambo yafuatayo kuhusu utafiti

huu;

Kwamba kushiriki ni kwa hiari yake.

Hakuna fidia yoyote itakayopeanwa kwa kushiriki katika utafiti.

Mshiriki anaweza kubadili uamuzi wa kuendelea kushiriki katika utafiti huu bila ya kuadhiri huduma ya matibabu yake.

Haki za mshiriki zitalindwa na habari zitakazotolewa na mshiriki zitawekwa siri wakati wote na zitatumika kwa ajili ya utafiti huu pekee yake

Jina: _____

Sahihi: _____

Tarehe: _____

Kwa maelezo zaidi unaweza kuwasiliana na mtafiti mkuu kupitia anwani ifuatayo:

Dk. Mosomi Abigael Nyanduko

Idara ya radiologia na dawa mionzi

Chuo Kikuu cha Nairobi

Sanduku la Posta 51-00202

Nairobi.

Nambari ya simu -0727919885

Au

KNH-UoN-ERC secretariat

Katibu wa utafiti

Chuo Kikuu cha Nairobi-Hospitali kuu ya Kenyatta

Sanduku la Posta 20723-00202 KNH

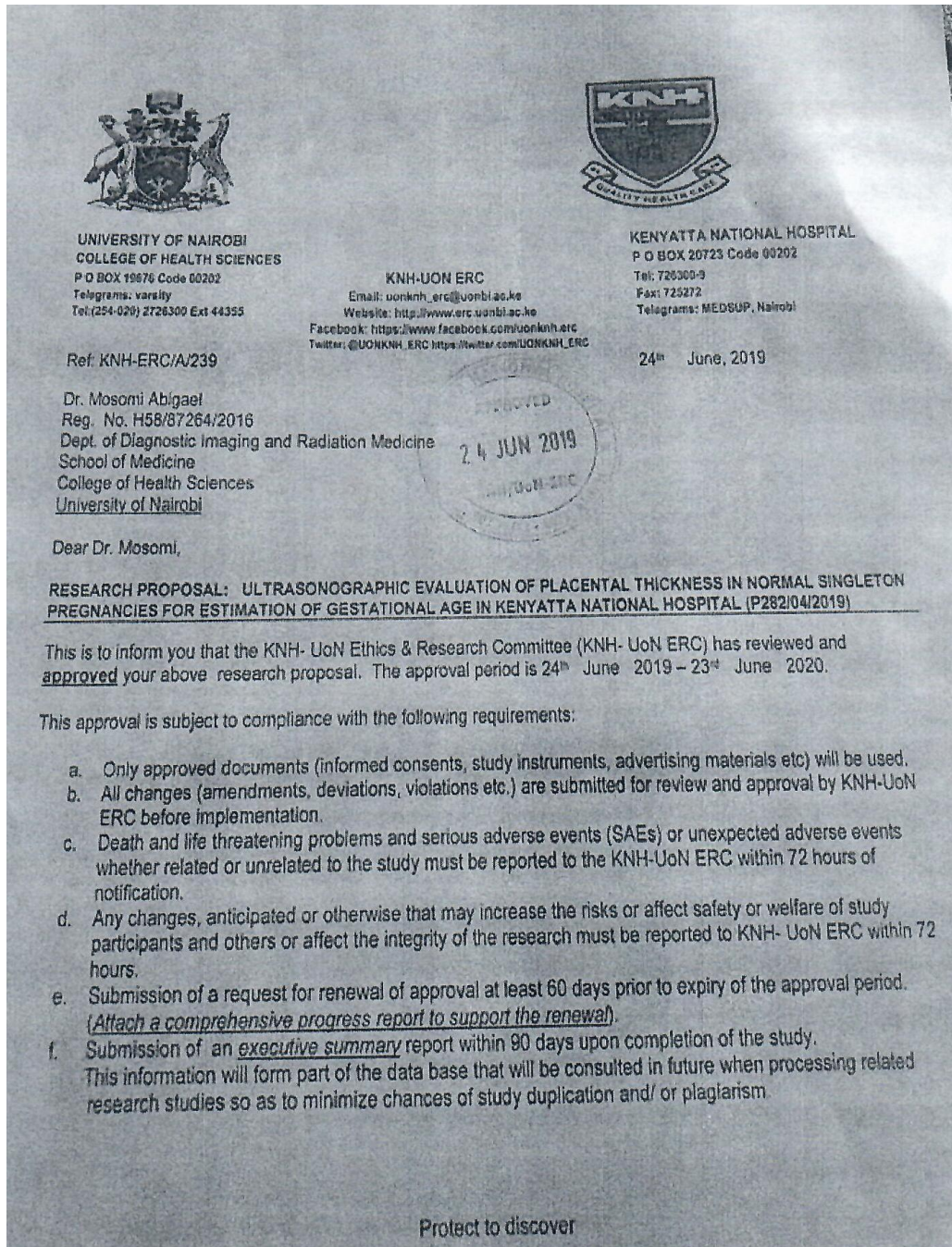
Nairobi.

Nambari ya simu: 72600-9

Fax: 725272

Barua pepe: UoNknherc@uonbi.ac.ke

APPENDIX 5: KNH Ethical Approval Letter




— Resub P 282/4/2019.

DR. MOSOMI ABIGAIL
H56/R7264/2019

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

Yours sincerely,


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

- c.c. The Principal, College of Health Sciences, UoN
 The Director, CS, KNH
 The Chairperson, KNH- UoN ERC
 The Assistant Director, Health Information, KNH
 The Dean, School of Medicine, UoN
 The Chair, Dept. of Diagnostic Imaging and Radiation Medicine, UoN
Supervisors: Dr. Angeline Aywak (UoN), Dr. Rodrigues John(KNH), Dr. Enock Anyenda (UoN)

APPENDIX 6: ERC Approval Form

KNH/R&P/FORM/01



KENYATTA NATIONAL HOSPITAL
P.O. Box 20723-00202 Nairobi

Tel.: 2726300/2726450/2726565
Research & Programs: Ext. 44705
Fax: 2725272
Email: knhresearch@gmail.com

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
..... DR. MUSAHI XBIGAEL N.
2. Email address: 51-00202 NRB Tel No. 0727919885
3. Contact person (if different from PI).....
4. Email address: amb.comi@gmail.com Tel No. 0727919885
5. Study Title
..... ULTRASONOGRAPHIC EVALUATION OF PLACENTAL THICKNESS IN NORMAL KENYAN SINGLETON PREGNANCIES FOR ESTIMATION OF GESTATIONAL AGE
6. Department where the study will be conducted KNH-DEPARTMENT OF RADIOLOGY
(Please attach copy of Abstract)
7. Endorsed by Research Coordinator of the KNH Department where the study will be conducted.
Name: JOHN C. MWANGI RODRIGUES Signature [Signature] Date 12/07/19
8. Endorsed by KNH Head of Department where study will be conducted.
Name: Dr. PATRICIA A. OTHIENO Signature [Signature] Date 12/07/2019
9. KNH UoN Ethics Research Committee approved study number _____
(Please attach copy of ERC approval)
10. I MUSAHI XBIGAEL N. _____ commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Research and Programs.
Signature [Signature] Date 12/07/19
11. Study Registration number (Dept/Number/Year) Radiology 1 / 16 / 2019
(To be completed by Research and Programs Department)
12. Research and Program Stamp _____



All studies conducted at Kenyatta National Hospital **must** be registered with the Department of Research and Programs and investigators **must commit** to share results with the hospital.

APPENDIX 7: Turnitin Originality Report

ULTRASONOGRAPHIC EVALUATION OF PLACENTAL THICKNESS IN NORMAL SINGLETON PREGNANCIES FOR ESTIMATION OF GESTATIONAL AGE IN KENYATTA NATIONAL HOSPITAL.

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