DETERMINING LOCAL REFERENCE RANGES OF UTERINE AND UMBILICAL DOPPLER INDICES IN HEALTHY SINGLETON GESTATION KENYAN WOMEN IN SECOND AND THIRD TRIMESTERS

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DECLARATION

I, **Dr. Nanabhai Burhanuddin Mustansir,** 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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Signature…… Date…….....

DEDICATION

I dedicate this work to my mum, my wife Tasneem and son Mohammed for their continued support and prayers during my period of study.

ACKNOWLEDGEMENT

I am grateful to the Almighty Allah for the good health and the stoicism to complete this study

I recognize the dedication, support and encouragement extended to me by my supervisor- Dr. A. Aywak.

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LIST OF ABBREVIATIONS

ANC- Antenatal clinic

BP- Blood Pressure

DDIRM - Department of Diagnostic Imaging and Radiation Medicine

ERC – Ethics and Research Committee

GA- Gestational age

IUGR- Intrauterine Growth Restriction

KNH- Kenyatta National Hospital

KSH- Kenyan Shillings

LMP- Last Monthly Period

PI- Pulsatility Index

RI- Resistive Index

UON - University of Nairobi

US- Ultrasound

ABSTRACT

Background
Uterine and Umbilical artery Doppler ultrasound is a safe and an important tool in assessing fetal well-being thus predicting normal and abnormal indices during pregnancy.

Objectives
To evaluate the uterine and umbilical artery Resistive and pulsatility indices in healthy singleton Kenyan women and determine the local reference ranges. .

Methodology

This was a prospective longitudinal study that included 202 singleton pregnant mothers done at Kenyatta National Hospital Radiology department and Antenatal Clinic. Using B-mode,colour and pulsed Doppler ultrasound the RI and PI for both uterine and umbilical arteries were obtained during the second trimester (21-25 weeks) after which the patients in the study who did not develop any of the exclusion criteria were scanned again in the third trimester(31-35 weeks). All scans were done independently by the Principal investigator and certified by a qualified radiologist at each visit. Data collection forms were used to record the mentioned parameters at every ultrasound session and Independent Student's T-test done on the mean RI and PI values using SPSS(Version 21).A comparison was made to other similar studies worldwide

Results

The mean of the normal uterine and umbilical artery values were similar to most published reference values from other parts of the world. No correlation between these indices and maternal parameters were found in this study.

Conclusion

Uterine and umbilical artery Doppler indices among normal singleton Kenyan women are similar to those of the developed world, therefore using reference values from those studies may be used in our environment. Future research with a more extensive longitudinal study and shorter scan intervals may be required to provide data covering all GAs and to validate the preliminary findings from this report.

1.0 CHAPTER ONE

Introduction

Doppler ultrasound is an important noninvasive tool used in evaluating uterine and umbilical arteries that detect obstetric complications(1). The indices identify uteroplacental insufficiency which increases the risk of maternal and fetal complications during pregnancy, labor, and delivery(1,2). In developing countries,Kenya included hemorrhage(39%) and maternal hypertensive disorders (9.1%) are some of the disease entities accounting for the largest proportion of maternal death[1].The World Health Organization report of 2015 documented a maternal mortality rate of 510/100,000 live births in Kenya(3).

During pregnancy vascular structures in the uterus and placenta are modified leading to neovascularization in the placenta which includes blood flow redistribution and circulating blood volume alteration(2). Hypertensive disorders in pregnancy cause abnormal vascular modifications leading to abnormal hemodynamics and complications of impaired placentation. Complications include placenta abruptio, preeclampsia, intrauterine growth restriction [IUGR] which could lead to intrauterine death.

Indicators of pregnancy that are at high risk of developing impaired placental complications may have abnormal waveforms such as absent/reverse end diastolic flow or a high mean resistance more than the 95th percentile for Resistive Index or Pulsatility Index. The relationship between abnormal Doppler indices of the uterine and umbilical arteries in hypertensive pregnancy disorders, fetal growth restriction and adverse pregnancy outcomes is well documented. (4,5). Preeclampsia and/or fetal growth restriction can be predicted in the second trimester by uterine artery Doppler studies. (5).
FitzGerald and Drumm (6) together with other researchers(7,8) documented that on fetal umbilical artery Doppler ultrasound high resistance waveforms were obtained in preeclamptic patients. Fetal umbilical artery Doppler ultrasound is normally performed in fetuses suspected of outcomes such as stillbirth, oligohydramnios, IUGR and preterm delivery.

Obstetrics parameters used for Doppler studies include end-diastolic velocity (EDV), peak systolic velocity (PSV), pulsatility index (PI), resistance index (RI), and systolic to diastolic ratio (S/D ratio).

PI and RI measures resistance to flow in a blood vessel and resistance to flow in a blood vessel distal to the part being assessed at an instant in a cardiac cycle, respectively. The S/D ratio on the other hand is the ratio of the PSV to the EDV.

2.0 CHAPTER TWO

Literature review

2.1-Studies involving both umbilical and uterine artery Doppler indices.

One of the earlier studies done in the world involving both the uterine and umbilical artery doppler indices was done in 1997 by Kurmanavicus et al (9) at the university of Zurich Switerland,in which 1675 subjects were involved between 24 to 42 weeks.This study concluded that as the gestational age increased the doppler indices decreased: mean Uterine artery RI decreased from 0.49 to 0.45 and mean umbilical RI decreased from 0.72 to 0.54 between 24 to 42 weeks respectively.

Udo et al in 2017 carried out a study on roles of Doppler studies in predicting pregnancy outcomes in 500 Nigerian pregnant women in which they concluded that Doppler indicesafter which the conclusion was that Doppler studies may be used for predicting pregnancy induced hypertension and IUGR(10).

A longitudinal study done in 2017 by Adekanmi et al to establish umbilical and uterine Doppler indices in second and third trimester singleton women in Nigeria involving 102 patients showed the umbilical and uterine artery RI to be significantly lower than that of the developed world - Umbilical artery doppler indices – Mean P.I (1.00-0.8),Mean R.I (0.6-0.53); Uterine artery Dopper indices – Mean P.I (0.77-0.71),Mean RI (0.53-0.49).(11)

In the developed world, reference values for normal umbilical and uterine artery Doppler indices have been developed(4–9).However, in Africa few such studies have been documented. In the African population the reference values from the developed countries have been used but may not be appropriate in our environment as has been shown in a study done in Nigeria(10–12).No such study has been done in the East Africa region thus it intends to determine the RI, and PI values in healthy singleton gestation Kenyan women, and to determine the relationships between the Doppler indices and the subjects' clinicodemographic parameters.

2.2- Studies involving umbilical artery Doppler indices only

Earlier studies done by Hendricks et al(13),Fogarty et al(14) done in 1989 and 1990 respectively showed that as gestational age increases the Doppler indices decreases..

In Thailand,a study was done in 2000 to create standard reference ranges for umbilical artery Doppler indices by Chanprapaph P et al (15) where 332 partcipants were studied between 21-40 weeks . With gestational age the values of PI,RI and S / D ratio, RI, PI declined slowly. The mean values reduced respectively from, 1.270 to 0.967, 0.756 to 0.609 and 3.560 to 2.511

Acharya et al did a prospective longitudinal study in Norway to develop umbilical artery reference ranges in 513 women in 2004 and concluded that there is a continuous reduction throughout the progress of pregnancy and that longitudinal observations are more appropriate than cross-sectional studies(16).

The reason for the decrease in umbilical artery RI in the latter half of the pregnancy is due to fetal development as reported by Olofsson et al, Sweden in 2004(17).

Reference ranges for umbilical arteries were established by Ayoola et al for South Western Nigerian women in 2016 where 400 singleton pregnant mothers were recruited for the study and all 5 Doppler parameters were recorded and analyzed. Mean RI decreased from 1.265 to 0.829, mean PI decreased from 0.76 to 0.585 and S/D ratio decreased from 4.068 to 2.365. Readings were taken between 15-39 weeks and this study found that Doppler indices reduced with GA (12).

In 2017,an Indian pilot study by was done to postulate reference ranges for their population,200 patients were put on follow up for a period of 4-6 weeks.The study concluded that the umbilical resistive and pulsatility index showed a steady decrease over gestational age with a strong negative correlation.Mean UA PI ranged from 1.32 to 0.77 and mean UA RI ranged from 0.76 to 0.54. This was done between 18 and 40 weeks of gestation(18).

2.3-Studies involving uterine artery Doppler indices only

In 2008, Gomez et al did a research on 620 singleton pregnancies in the Mediterranean population to set reference ranges for the mean pulsatility index of uterine arteries .The findings demonstrated that between 11 weeks (mean PI 1.79.95th centile 2.70) and 34 weeks (mean PI 0.70.95th centile 0.99) mean uterine artery PI showed a progressive decrease with advancing gestation and this mean uterine PI can have clinical significance in the third trimester evaluation of patients with pregnancy-induced hypertension (19).

A review done in unselected populations for Doppler screening of second trimester uterine artery in 2008 by Papageorghiou et al (20)showed that raised resistance to flow in uterine arteries is associated with increased risk of potential pre-eclampsia developement, restriction of fetal growth and perinatal death.Therefore, women with normal impedance to flow into the uterine arteries constituted a population with low risk of developing uteroplacental insufficiency-related obstetric complications

A meta analysis of the use of uterine doppler ultrasound involving 135 studies and 120,678 patients concluded that in the second trimester, Doppler screening of the uterine artery provided a more accurate prediction than in the first-trimester and that abnormal waveforms of the uterine artery are better predictors of preeclampsia than restriction of fetal growth. A pulsatility index is the most accurate Doppler index (either alone or combined with notching), and should be used in clinical practice (21)

A cross-sectional study in Germany was done in 2012 to establish new Doppler reference ranges and involved 921 low risk pregnancies between 18 to 42 weeks. Reference curves for RI and PI reduced significantly with increasing gestation (RI: 18 weeks: 0.45; 42 weeks: 0.35 and PI: 18 weeks: 0.89; 42 weeks: 0.65).(22)

2.4 – Studies correlating uterine and umbilical Doppler parameters with the maternal age, gestational age and parity of the cohort.

Acharya et al and Ayoola et al both had similar maternal age distribution ranging from 18-43 years with a median of 30 years in their studies, but the recruited nulliparous women by Acharya et al(45%) was higher than Ayoola et al(20%) though non of the two parameters(parity and maternal age) were significant across the cohort groups when comparing the mean Doppler values.(12,23)

3.0 CHAPTER THREE

3.1 Study justification and rationale

The rising prevalence of maternal hypertensive disorders and its associated morbidity and mortality are a growing concern both locally and globally. Umbilical and uterine Doppler resistive and pulsatility indices are of important value in early detection of such disorders and can help prevent associated morbidity and mortality, therefore the knowledge of normal values is important in helping to predict and identify early obstetric complications.

Measurement of Doppler parameters using, Colour, pulsed wave Doppler and B-Mode ultrasound is a readily available, relatively cheap, safe and easy way to identify at-risk individuals and start appropriate management to avoid said complications.

No Kenyan studies have been done to measure the umbilical and uterine artery resistive indices. This study aims to fill the knowledge gap and provide local reference ranges that may change patient management and avoid preventable morbidities and mortalities.

If the data from this study can be used to change the standard operating protocols in pregnant mothers work-up and screening, it can eventually identify early obstetric complications and plan appropriate management subsequently reducing our national maternal mortality rate.

3.2 Objectives

3.2.1 Broad objective

To evaluate the uterine and umbilical artery RI and PI in healthy singleton Kenyan women and determine the local reference ranges.

3.2.2 Specific objectives

- To determine the RI and PI of the right and left uterine arteries in both the second and third trimester.
- To determine the RI and PI of the umbilical artery in the second and third trimester
- To correlate uterine and umbilical RI and PI with the maternal age, gestational age and parity of the cohort.
- To compare the uterine and umbilical RI and PI parameters locally with other studies done regionally and internationally.

4.0 CHAPTER FOUR

4.1 Study design and methodology
Prospective longitudinal descriptive study

4.2 Study area

a. Kenyatta National Hospital, Antenatal(ANC) Clinic.
The clinic is located in room 18 inside the main hospital block. It runs from Monday to Thursday from 8am to 1pm and an average of 1200 patients are seen per month.
The patients are attended to by trained reproductive health nurses, registrars training in obstetrics and gynecology as well as consultants obstetricians.
The patients also receive nutrition and general counseling. Patients' medical records are handled by qualified data clerks and records officers.

b. Kenyatta National Hospital, Radiology department
The department is located within the Accident and Emergency block in the main hospital. There are 3 functioning ultrasound machines.
The department is run primarily by registrars in radiology who are overseen by consultant radiologists.
The patients having been directed to the department will be seen by the principal investigator who will perform the Doppler ultrasounds on a single dedicated ultrasound machine.
Once the results are obtained they will be retained so as to transfer relevant data into the patients file.

4.3 Study population
Pregnant women with singleton gestation who fit the inclusion criteria below:

4.3.1 Inclusion criteria
- No demonstrable fetal abnormality
- Appropriate GA (21-25 weeks)
- Normal blood pressure (BP),
- Tested negative for proteinuria,
- Patients who gave informed consent to participate throughout the scan session.

4.3.2 Exclusion criteria
- Patients who decline to consent.
- History of diabetes, chronic hypertension, alcohol and drug abuse.
- Uterine anomaly, fetal anomaly,
- Use of medication for hypertension, corticosteroids use,
- History of Sickle cell, or vascular disorders that may affect Doppler measurements

4.4 Sample size

Sample size calculation will be done with the use of the formula:

$$n = \frac{{Z_{1-\propto/2}}^2 SD^2}{d^2}$$

n = Desired sample size per arm

$Z_{1-\propto}$ = value from standard normal distribution corresponding to desired confidence level - two tail (Z=1.96 for 95% CI)

d^2 = Precision around the prevelance of the of the mean set as 0.005

SD = standard deviation value for 'Umbilical artery Resistive index in third trimester ' as reported in the Nigerian study for Normal second and third trimester uterine and umbilical doppler indices among healthy singleton gestation Nigerian women

$$n = \frac{1.96^2 x 0.53^2}{0.005} = 215$$

A sample of 215 women will be required for the study

4.5 Methodology

A prospective longitudinal study was conducted on patients visiting the ANC clinic in KNH who met the specified criteria.

Only pregnant women at gestational ages (GA) below 20 weeks were recruited. We estimated the GA from the last menstrual period (LMP) in patients with reliable dates. Where patients were unsure of the GA; dating was based on the obstetrics USSs done in the first 13 weeks of pregnancy. Maternal blood pressure and urine samples for urinalysis to rule out proteinuria were taken as well.

Patient selection was done by convenience sampling at the ANC clinic where a detailed history was extracted from eligible individuals and relevant information concerning the procedure was discussed.
The sampling was done from Monday to Thursday, when the ANC clinic functions and all information was extracted before the patient had their doctor's visit. They were then advised to come to the Radiology Department for their ultrasound on completion of their clinic visit, preferably the same day in the afternoon, so as to avoid repeat travel to KNH.

For the eligible patients, demographic information, obstetric data and blood pressure readings were fillen in a data collection form and they were expected to sign a written informed consent form, after which they would be invited to the KNH-DDIRM where a clinical

evaluation and Doppler ultrasound would be performed to assess for umbilical and uterine artery RI and PI.
After the second trimester ultrasound had been done, the patient was given an appointment date in her third trimester(31-35 weeks) in which she would be assessed again to see if she still met the inclusion criteria after which the second Doppler ultrasound was performed.

The research assistant (Reproductive health Nurse at ANC) assisted the principal investigator in recruiting patients, filling in the data collection form, taking maternal blood pressure, sending patients for urinalysis to rule out proteinuria and to send the patient to KNH-DDIRM for the Doppler ultrasound.

4.5.1 Ultrasound Examination

Patients that were included into the study were invited to the Kenyatta National Hospital Department of Radiology where the Doppler ultrasound of the uterine and umbilical arteries was done using standard protocol. The examination was conducted by the principal investigator using a convex array transducer (3.5-5 MHz) on a GE Logiq P6 ultrasound machine. The RI and PI were generated with automatic tracing of the spectral waveforms by the ultrasound machine.
Hard copies of the cases were acquired using thermal printer and photographs.

All scans were done independently by the Principal Investigator and certified by a qualified radiologist at each visit.

Figure 1-GE logic P6

4.5.1.1 Uterine artery Doppler technique

To investigate the uterine arteries, a transabdominal approach was used whereby the patient was put in the semi-recumbent position and transducer was placed longitudinally in either the right or left iliac fossae with a medial angulation so as to visualize the cervix and uterus(24). Using color flow, the uterine artery was seen traversing the external iliac artery. At about 1cm to the cross over point, pulsed wave Doppler was placed with a gate size of 2mm to generate the wave pattern. Angle of insonation was set below 20^{o} and the wall filter kept at 50-60 Hz(24). Measurements of the RI and PI of the uterine artery were carried out on three consecutive waveforms and the mean value was measured and documented in the form of data collection.

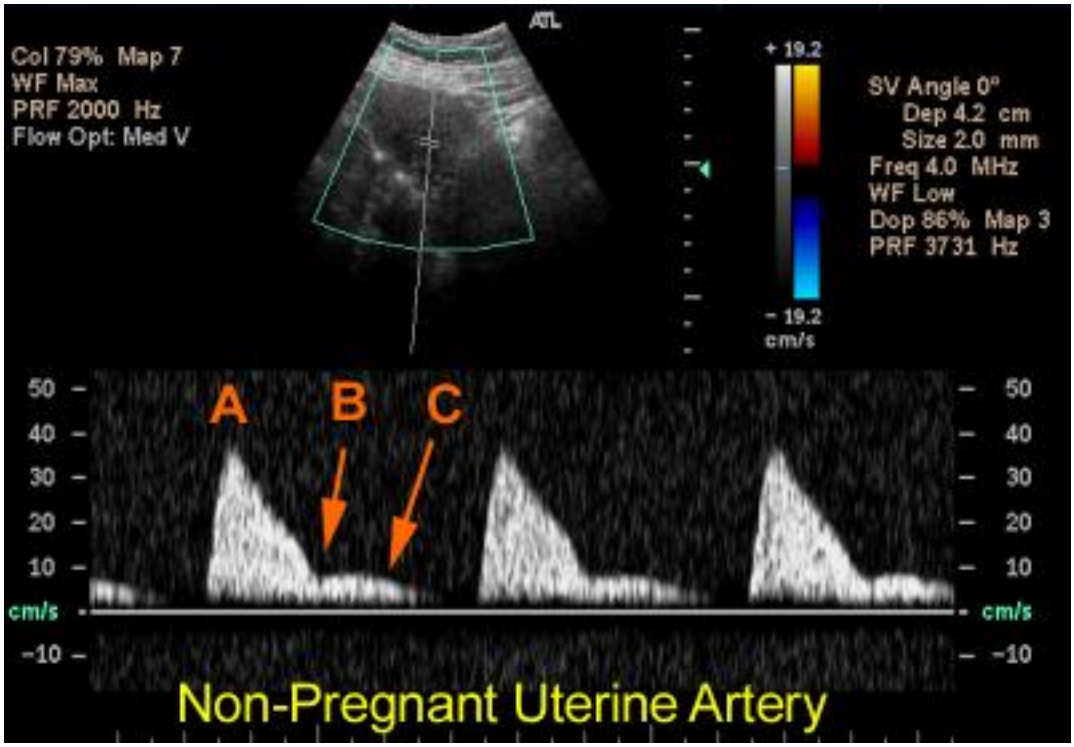


Figure 2- Doppler waveform for a non-pregnant uterine artery

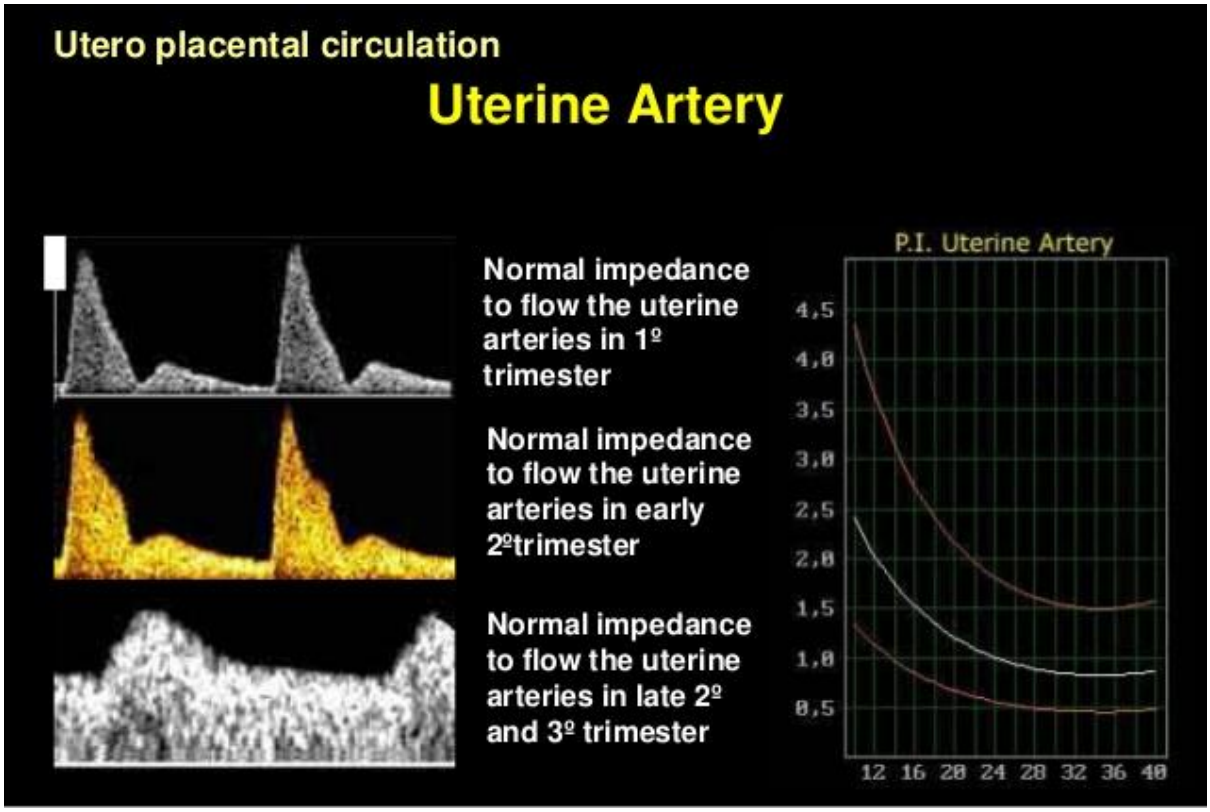


Figure 3-Doppler waveforms of uterus artery in the 3 trimesters

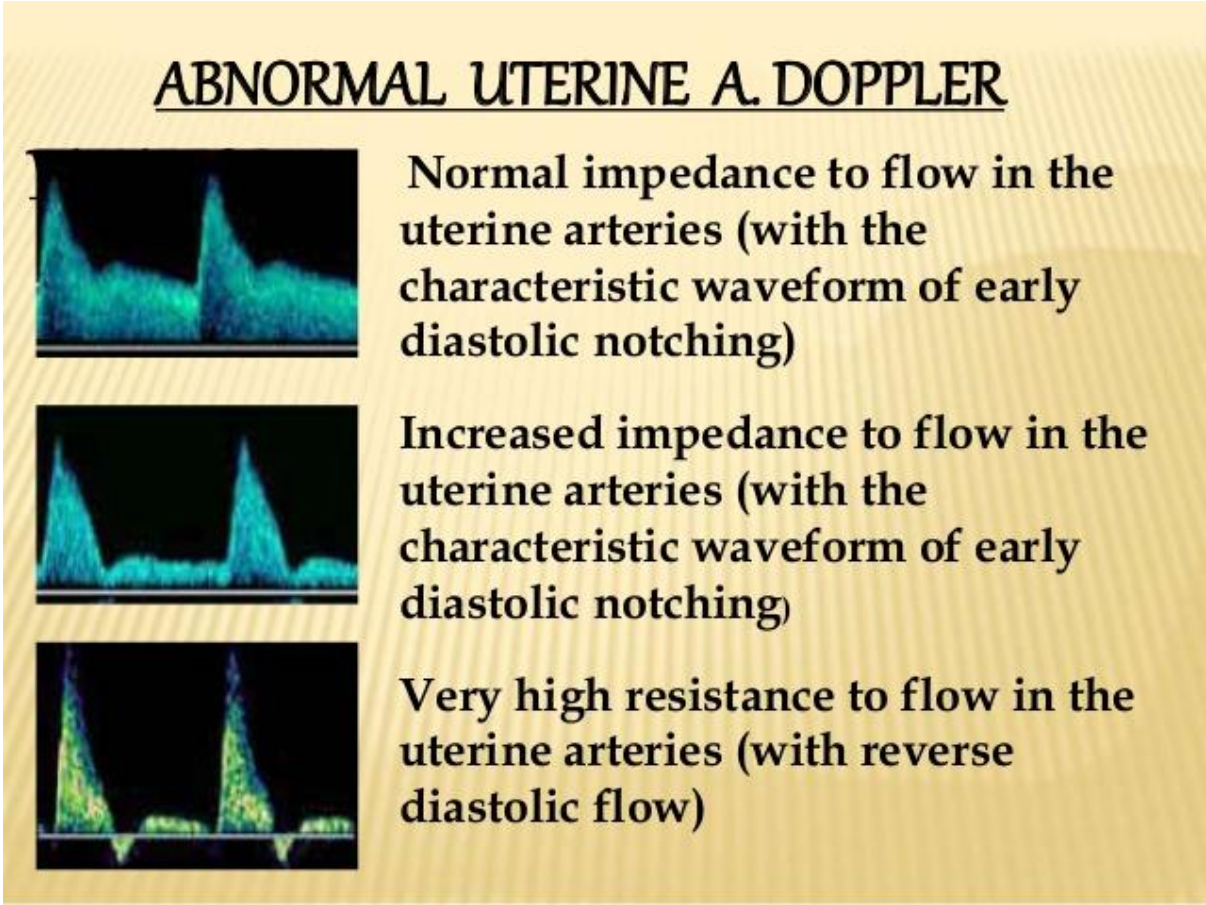


Figure 4-Abnormal uterine artery waveforms

4.5.1.2 Umbilical artery Doppler technique

Using the B-mode and Colour Doppler mode in ultrasonography a free floating loop of umbilical cord was identified. Angle of insonation was less than 60° and sampling gate was set at 2mm(24,25). Measurements of the umbilical artery RI and PI were made on three consecutive waveforms and the mean value was calculated and recorded in the Data Collection form.

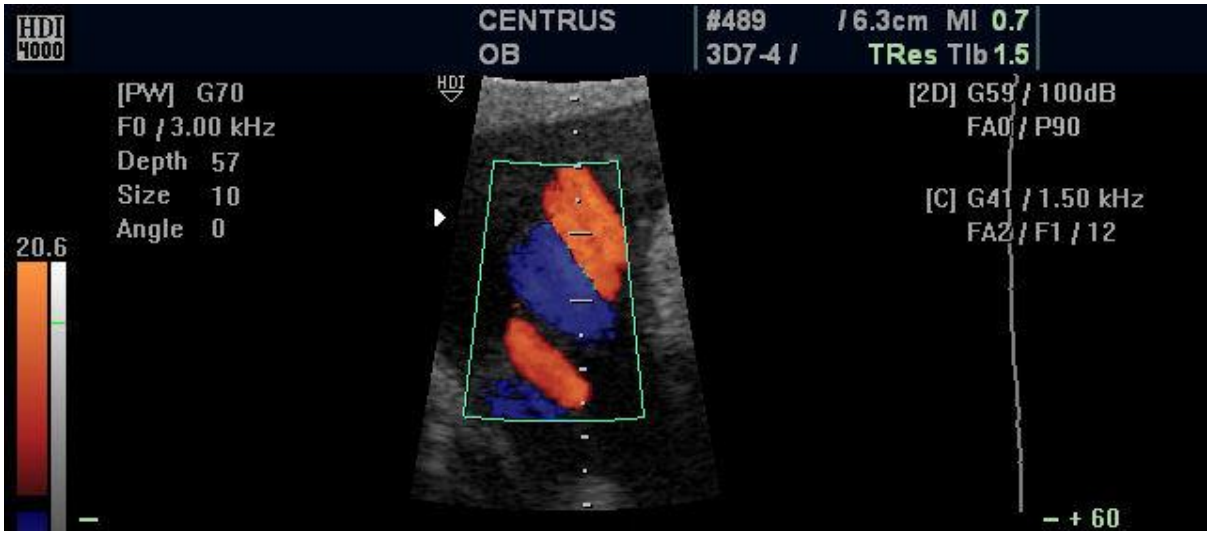


Figure 5-Free floating umbilical cord loop

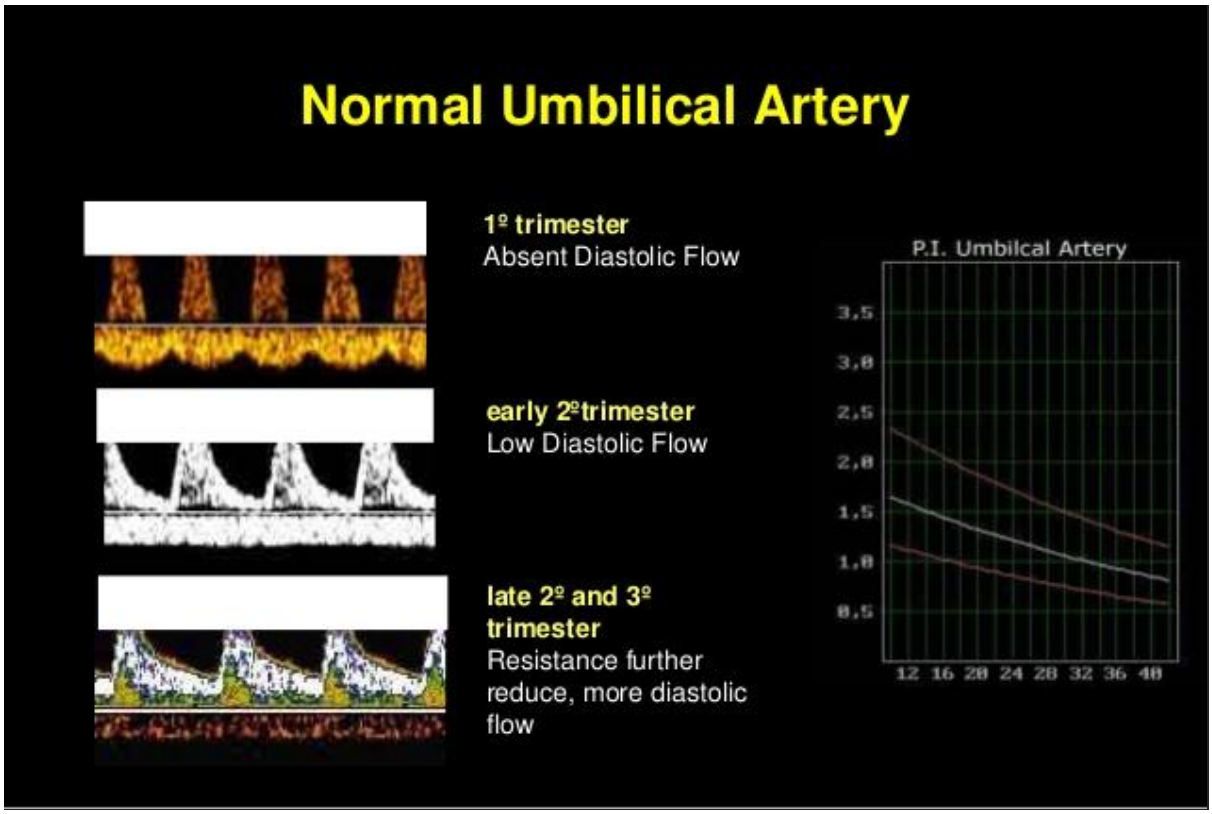


Figure 6-Normal flow velocity of umbilical artery in the 3 trimesters

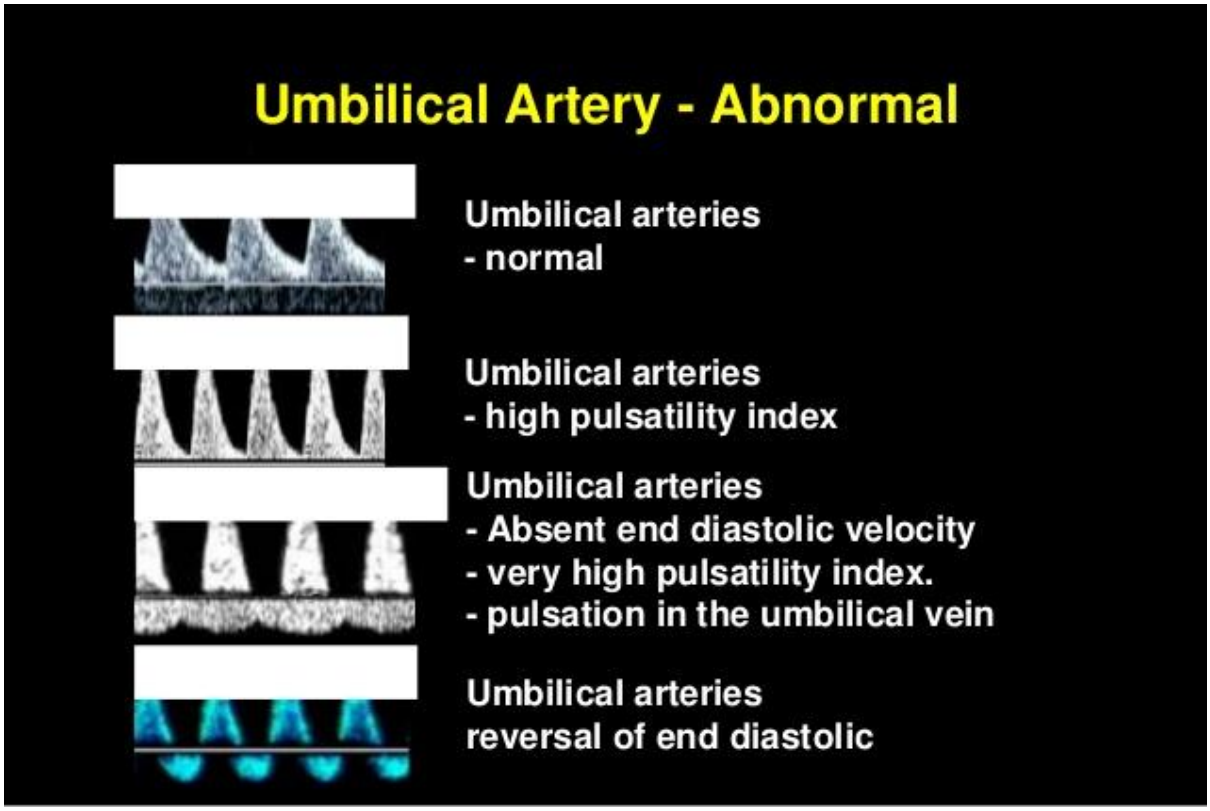


Figure 7-Abnormal umbilical artery waveforms

4.6 Ethical Consideration

Ethical considerations was taken into account in the process of this research. The Kenyatta National Hospital ethics committee was requested to approve the research. The study began with the approval of the Ethics and Research Committee

Patient's personal information e.g. names were not used in the study in order to uphold confidentiality. Information acquired was not used for any other purpose besides in the clinical management of patients and academics.

No examination was done on the patients apart from the one requested by the primary physician. Informed consent was obtained from all patients/ or guardians enrolled in this study.

4.7 Statistics

Data was entered and analyzed with the use of Statistical Package for Social Sciences version 21. Demographic characteristics was summarized and presented as means and standard deviations, medians and interquartile range, frequencies and proportions where applicable. Independent Student's T-tests was used to compare Doppler indices parameters of the right and left uterine arteries, the umbilical artery in both the second and third trimester. Pearson correlation was used to correlate uterine and umbilical parameters with the maternal age, gestational age as well as parity.

5.0 CHAPTER FIVE

Results

There were two hundred and fifteen patients enrolled who met the inclusion criteria and gave informed consent to participate in the study. Two hundred and two (94%) completed both scans, while thirteen were either lost to follow-up, refused a repeat scan or had a high BP which contributed to a rate of 6%.The cohort age group, which were mostly primigravida people, ranged from 19 to 43 years with a mean age of 31.1 ± 5.4 years. The majority of patients (43.6%) were below 30 years of age, while those 40 years of age and older were only 5.4% Systolic BP mostly ranged between 100 and 120 mmHg, while the diastolic BP ranged between 60 and 80 mmHg. [Table 1].

Parameters	**Frequency (n=202)**	**Percentage**
Age group (years)		
<30	88	43.6
30-34	50	24.8
35-39	53	26.2
≥ 40	11	5.4
Parity		
0	51	25.2
1	74	36.6
2	54	26.7
≥3	23	11.4
Systolic BP (mmHg)		
<100	25	12.4
100-109	58	28.7
110-119	71	35.1
≥120	48	23.8
Diastolic BP(mmHg)		
<60	14	6.9
60-69	76	37.6
70-79	91	45.0
≥80	21	10.4

BP- Blood Pressure

5.1 Uterine artery Doppler indices

In [Table 2] and [Table 3] respectively, mean values and standard deviations of the RI and PI of the uterine arteries on both sides in the second and third trimester scans are shown. The Kolmogorov-Smirnov test of normality showed a normal distribution of these indices

Variables	**Mean± SD**		**t**	***P***
	Right uterine artery	**Left uterine artery**		
RI	0.54±0.13	0.55±0.15	-1.279	0.202
PI	0.91±0.62	0.93±0.56	-0.505	0.614

SD- Standard Deviation; RI-Resistance index; PI- Pulsatility index

Table 1-Uterine artery Doppler indices at second trimester scan

Variables	Mean± SD		t	P
	Right uterine artery	Left uterine artery		
RI	0.46±0.08	0.49±0.12	-3.301	0.001
PI	0.68±0.19	0.77±0.37	-3.169	0.002

SD- Standard Deviation; RI-Resistance index; PI- Pulsatility index

Table 2- Uterine artery Doppler indices at third trimester

Variables	Second trimester (21-25 weeks)			Third trimester (31-35 weeks)		
	Mean ± 2SD			Mean ± 2SD		
	Right Uterine artery	Left uterine artery	P	Right Uterine artery	Left uterine artery	P
RI	0.54±0.13	0.55±0.15	0.202	0.46±0.08	0.49±0.12	0.001
PI	0.91±0.62	0.93±0.56	0.614	0.68±0.19	0.77±0.37	0.002

SD- Standard Deviation; RI-Resistance index; PI- Pulsatility index

Table 3-Comparison of Doppler indices in both right and left uterine arteries at 21-25 weeks and 31-35 weeks

In the second trimester scan the mean right and left uterine RI was 0.54 ± 0.13 and 0.55 ± 0.15, while the PI was 0.91 ± 0.62 and 0.93 ± 0.56. There was no statistically significant difference in the uterine artery indices on the right and left side [Table 2] In the third trimester scan, the right and left RIs were 0.46 ± 0.08 and 0.49 ± 0.12, and the PIs were 0.68 ± 0.19 and 0.77 ± 0.37, respectively. The RI and PI showed significant differences between the right and left uterine arteries, with higher mean values reported by the left uterine artery on both scans.
Comparison was made of the mean of right and left UtADIs in the second and third trimesters. In the second trimester the RI was 0.55 ± 0.11 while in the third trimester scan 0.48 ± 0.08 and the PI was 0.92 ± 0.51 in the second trimester and in third trimester scan 0.72 ± 0.22. In the third trimester, both showed a significant decrease which was statistically significant (P= < 0.001 for both RI and PI) [Table 5].

Variables	Mean± SD		t	P
	Second Trimester (21-25 weeks)	Third trimester (31-35 weeks)		
RI	0.55±0.11	0.48±0.08	6.540	<0.001
PI	0.92±0.51	0.72±0.22	5.025	<0.001

SD- Standard Deviation; RI-Resistance index; PI- Pulsatility index

Table 4- Comparison of the mean values of both uterine arteries indices at the second and third trimester scan

5.2 Umbilical artery Doppler parameters

The mean values and the standard deviation in the second and third trimesters for the umbilical artery Doppler parameters are as shown in[Table 6]. In the third trimester scan all of the parameters showed a significant change in their mean value. The mean values of the RI and PI were significantly reduced between the second and third trimesters[Table 6].

Variables	**Mean± SD**		**t**	***P***
	Second Trimester (21-25 weeks)	**Third trimester (31-35 weeks)**		
RI	0.70±0.13	0.61±0.08	8.711	<0.001
PI	1.22±0.63	0.93±0.27	6.251	<0.001

SD- Standard Deviation; PSV-Peak Systolic velocity; EDV-End Diastolic velocity; S/D-Systolic to diastolic ; RI-Resistance index; PI- Pulsatility index

Table 5-The umbilical artery Doppler velocimetry at the second and third trimester

5.3 Correlation between Doppler indices and maternal parameters

There was a negative weak correlation between the GA and second trimester uterine parameters for RI and PI, though only the correlation between GA and RI was statistically significant (p=0.036), all the other parameters showed no correlation with the maternal characteristics in the second and third trimester.

	Second Trimester uterine artery parameters		**Third trimester uterine artery parameters**	
	RI r(*P*)	**PI r(*P*)**	**RI r(*P*)**	**PI r(*P*)**
Age of Mothers	-0.028 (0.694)	-0.034 (0.631)	0.068 (0.334)	0.046 (0.514)
Parity	0.010 (0.886)	0.030 (0.677)	-0.005 (0.948)	0.001 (0.990)
GA	-0.147 (0.036)	-0.125 (0.077)	0.055 (0.434)	0.038 (0.587)

RI- Resistance index; PI- Pulsatility index; GA- Gestational age

Table 6-Correlation of Maternal age, gestational age and parity of cohort with the uterine artery Doppler parameters

There was a negative weak correlation between the GA and second trimester umbilical parameters for RI and PI, with both being statistically significant (p<0.001). All the other parameters showed no correlation with the maternal characteristics in the second and third trimester. Though, the correlation between the age of the mothers and the PI in the third trimester showed a positive weak correlation (r=0.132), this was not statistically significant (p=0.06).

	Second Trimester umbilical artery parameters		Third trimester umbilical artery parameters	
	RI r(*P*)	**PI r(*P*)**	**RI r(*P*)**	**PI r(*P*)**
Age of Mothers	0.017 (0.812)	0.048 (0.499)	0.099 (0.163)	0.132 (0.060)
Parity	0.008 (0.915)	-0.019 (0.788)	0.061 (0.392)	0.058 (0.409)
GA	-0.259 (<0.001)	-0.194 (<0.001)	-0.005 (0.945)	0.074 (0.295)

RI- Resistance index; PI- Pulsatility index; GA- Gestational age

Table 7- Correlation of Maternal age, gestational age and parity of cohort with the uterine artery Doppler parameters

6.0 CHAPTER SIX

6.1 Discussion

Doppler ultrasound is a proven non-invasive tool for examining uteroplacental and fetoplacental circulations during pregnancy, which is easily accessible and cheap. Uterine and umbilical Doppler ultrasound have been used to detect complications of pregnancy and fetal abnormality (2)

In this study, the normal mean values of uterine and umbilical artery Doppler indices for gravid normal singleton gestation in Kenyan women were documented. This will be useful in managing at-risk patients with abnormal vascular changes in preeclampsia associated with impaired placentation which is more common among black African women.

Normal UtADI and UmADI values were derived from a longitudinal study of the uterine and umbilical arteries in the second (21-25 weeks) and third trimesters (31-35 weeks) using a transabdominal approach performed on a healthy pregnant cohort that served as its own control. Due to the vulnerability of pregnancy to intrinsic and extrinsic causes, the longitudinal method was reported to be effective in assessing vascular changes in pregnancy states. (26) . Most of the literature studies recruited an average of 20 patients for each GA for approximately 20-40 weeks using a cross-sectional approach.(9,15,16,19). This small sample size per GA may have restricted the generalizability of its findings, we assume. In this study a relatively larger sample size was assessed at those categorical GAs to boost the generalizability of the findings.

In this study, the mean UtADIs RI, and PI at 21-25 weeks and 31-35 weeks indicate reduced vascular resistance and increased blood flow to the placental bed as normal pregnancy progresses.(27)(28).This is also in line with the results of many other researchers.(9,15,19,29,30)

The mean RI and PI values of UtADI in the right and left uterine arteries derived in this study were similar to those of Lakhkar and Ahamed (30) in India, Bahlmann et al(22) in Germany, Peixoto et al(22) in Brazil, Gomez et al in Spain (22) and Oloyede and Iketubosin (31) and Adekanmi et al (11) in Nigeria At these GAs only Kurmanavicius et al (9) registered lower UtADI to our knowledge in Thailand. That we assume may be due to the limited number of patients enrolled at each GA, methodological differences or equipment. We suspect also that racial differences may play an important role in these observations

In umbilical arteries, UmADIs also showed significant differences in the third trimester compared to the second trimester. This is assumed to be due to reduced vascular resistance in the feto-placental unit with increased GA. In this analysis, the UmADI values (RI was 0.70±0.13 and 0.61±0.08, and PI was 1.22±0.63 and 0.93±0.27 respectively in the second and third trimester scans) were equally consistent with most previously reported results.(13,15,17,30)

In Thailand, Chanprapaph et al. (15) reported RI at 0.756, 0.72, 0.679, and 0.62, and PI at 1.27, 1.256, 1.11, and 0.958 at 21, 25, 31, and 35 weeks, respectively, Lakhkar and Ahamed (30)reported an RI at 0.73, 0.70, and 0.65, and PI at 1.26, 1.13, and 1.00 at 20, 28, and 34 weeks, Kurmanavicius et al.(9) reported umbilical artery RI at 0.71, 0.65, and 0.63 at 25, 31 and 35 weeks in Switzerland. Acharya et al. has documented an RI of 0.74, 0.69, 0.63, and 0.58 at 21, 25, 31, and 35 weeks(23). In the second and third trimester scans, only Adekanmi et al (11) from Nigeria reported lower UmADIs with values of (RI: 0.60±0.11 and 0.53±0.11, and PI: 1.00±0.20 and 0.80±0.20) to our knowledge. The variations in mean RI and PI values may

be due to variations in the number of patients recruited at these GAs in this study or differences in the procedure and equipment used.

In this study, the correlation of UtADIs RI and PI with maternal age, parity, and GA showed no strong significant associations between these variables, in keeping with Chanthasenanon et al.(32) which did not document any correlation in the uterine arteries. Unlike Pirhonen et al.(33)and Prefumo et al. (34) where the association between PI and maternal age and parity and RI was observed, respectively, these may be due to the majority of our cohort being primigravidas and also mainly belonging to the age range below 30.

6.2 Conclusion

From this study, we have deduced that the preliminary reference values for the UtADIs and UmADIs in healthy pregnant Kenyan women in Kenyatta National Hospital,Nairobi show similar values with most published reference values from other parts of the world.

6.3 Limitations of study

- Patients declining the repeat third trimester scan.
- Patients being lost to follow up in ANC

6.4 Recommendations

- A larger study incorporating the whole of the country can be done to determine a conclusive reference value range for our population.
- Future research with a more extensive longitudinal study and shorter scan intervals will be required to provide data covering all GAs and to validate the preliminary findings from this report.

6.5 Disclosures

6.5.1 Financial support and sponsorship

Nil.

6.5.2 Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Betrán AP, Wojdyla D, Posner SF, et al. National estimates for maternal mortality: An analysis based on the WHO systematic review of maternal mortality and morbidity. *BMC Public Health*. 2005;

2. Paul L. Allan, Paul A Dubbins, Myron A. Pozniak WNM. Clinical Doppler Ultrasound. In: *Clinical Doppler Ultrasound. 2nd edition*. 2006

3. WHO, UNICEF, UNFPA, et al. Trends in Maternal Mortality: 1990 to 2015. 2015.

4. Aquilina J, Harrington K. Pregnancy hypertension and uterine artery Doppler ultrasound. *Curr Opin Obs. Gynecol*. 1996;

5. Campbell S, Pearce JM, Hackett G, et al. Qualitative assessment of uteroplacental blood flow: early screening test for high-risk pregnancies. *Obstet. Gynecol.* 1986;

6. FitzGerald DE, Drumm JE. Non-invasive measurement of human fetal circulation using ultrasound: A new method. *Br. Med. J.* 1977;

7. Campbell S, Griffin DR, Pearce JM, et al. NEW DOPPLER TECHNIQUE FOR ASSESSING UTEROPLACENTAL BLOOD FLOW. *Lancet*. 1983;

8. Berkowitz GS, Chitkara U, Rosenberg J, et al. Sonographic estimation of fetal weight and Doppler analysis of umbilical artery velocimetry in the prediction of intrauterine growth retardation: A prospective study. *Am. J. Obstet. Gynecol.* 1988;

9. Kurmanavicius J, Florio I, Wisser J, et al. Reference resistance indices of the umbilical, fetal middle cerebral and uterine arteries at 24-42 weeks of gestation. *Ultrasound Obstet. Gynecol.* 1997;

10. D.U. Udo, B.O. Igbinedion, A. Akhigbe EE. Assessment of Uterine and Umbilical Arteries Doppler Indices in Third Trimester Pregnancy-Induced Hypertension in UBTH, Benin-City. *Niger. Med. Pract.* 2017;71(3–4):33–38.

11. Adekanmi A, Roberts A, Adeyinka A, et al. Normal second and third trimester uterine and umbilical doppler indices among healthy singleton gestation Nigerian women. *West African J. Radiol.* 2017;24(1):1–7.

12. Ayoola OO, Bulus P, Loto OM, et al. Normogram of umbilical artery Doppler indices in singleton pregnancies in south-western Nigerian women. *J. Obstet. Gynaecol. Res.* 2016;

13. Hendricks SK, Sorensen TK, Wang KY, Bushnell JM, Seguin EM ZR. Doppler umbilical

artery waveform indices--normal values from fourteen to forty-two weeks. *Am J Obs. Gynecol.* 161(3):761–765.

14. Fogarty P, Beattie B, Harper A, et al. Continuous wave doppler flow velocity waveforms from the umbilical artery in normal pregnancy. *J. Perinat. Med.* 1990;

15. MD PC, MD CW, MD. TT. Umbilical Artery Doppler Waveform Indices in Normal Pregnancies. *Thai J. Obstet. Gynaecol.* 2000;12:103–107.

16. Acharya G, Wilsgaard T, Berntsen GKR, et al. Reference ranges for serial measurements of blood velocity and pulsatility index at the intra-abdominal portion, and fetal and placental ends of the umbilical artery. *Ultrasound Obstet. Gynecol.* 2005;

17. Olofsson P, Olofsson H, Molin J, et al. Low umbilical artery vascular flow resistance and fetal outcome. *Acta Obstet. Gynecol. Scand.* 2004;

18. Srikumar S, Debnath J, Ravikumar R, Bandhu HC MV. Doppler indices of the umbilical and fetal middle cerebral artery at 18-40 weeks of normal gestation: A pilot study. *Med J Armed Forces India.* 2017;73(3):232–241.

19. Gómez O, Figueras F, Fernández S, et al. Reference ranges for uterine artery mean pulsatility index at 11-41 weeks of gestation. *Ultrasound Obstet. Gynecol.* 2008;

20. Papageorghiou AT, Yu CKH, Cicero S, et al. Second-trimester uterine artery Doppler screening in unselected populations: A review. *J. Matern. Neonatal Med.* 2002;

21. Cnossen JS, Morris RK, Ter Riet G, et al. Use of uterine artery Doppler ultrasonography to predict pre-eclampsia and intrauterine growth restriction: A systematic review and bivariable meta-analysis. *CMAJ*. 2008;

22. Bahlmann F, Fittschen M, Reinhard I, et al. Reference values for blood flow velocity in the uterine artery in normal pregnancies from 18 weeks to 42 weeks of gestation calculated by automatic doppler waveform analysis. *Ultraschall der Medizin*. 2012;

23. Acharya G, Wilsgaard T, Berntsen GKR, et al. Reference ranges for serial measurements of umbilical artery Doppler indices in the second half of pregnancy. In: *American Journal of Obstetrics and Gynecology*. 2005

24. Bhide A, Acharya G, Bilardo CM, et al. ISUOG practice guidelines: Use of Doppler ultrasonography in obstetrics. *Ultrasound Obstet. Gynecol.* 2013;

25. J.B. G, V. L, S.H. L, et al. Plasmodium falciparum parasitaemia in the first half of pregnancy, uterine and umbilical artery blood flow, and foetal growth: A longitudinal Doppler ultrasound study. *Malar. J.* 2012;

26. Olatunji RB, Adekanmi AJ, Obajimi MO, et al. Normal ophthalmic artery doppler velocimetry in healthy pregnant women in Ibadan, South West Nigeria- A preliminary report. *West African J. Ultrasound*. 2015;

27. Wang Y ZS. No Title. In: *Placental blood circulation. Vascular Biology of the Placenta. Ch. 2. San Rafael, CA: Morgan and Claypool Life Sciences; 2010*. 2010

28. Sutton MSJ, Theard MA, Bhatia SJS, et al. Changes in placental blood flow in the normal human fetus with gestational age. In: *Pediatric Research*. 1990

29. Bower S, Schuchter K, Campbell S. Doppler ultrasound screening as part of routine antenatal scanning: prediction of pre- eclampsia and intrauterine growth retardation. *BJOG An Int. J. Obstet. Gynaecol.* 1993;

30. B.N. L. Doppler velocimetry of uterine and umbilical arteries during pregnancy. *Indian J. Radiol. Imaging*. 1999;

31. Oloyede OA, Iketubosin F. Uterine artery Doppler study in second trimester of pregnancy. *Pan Afr. Med. J.* 2013;

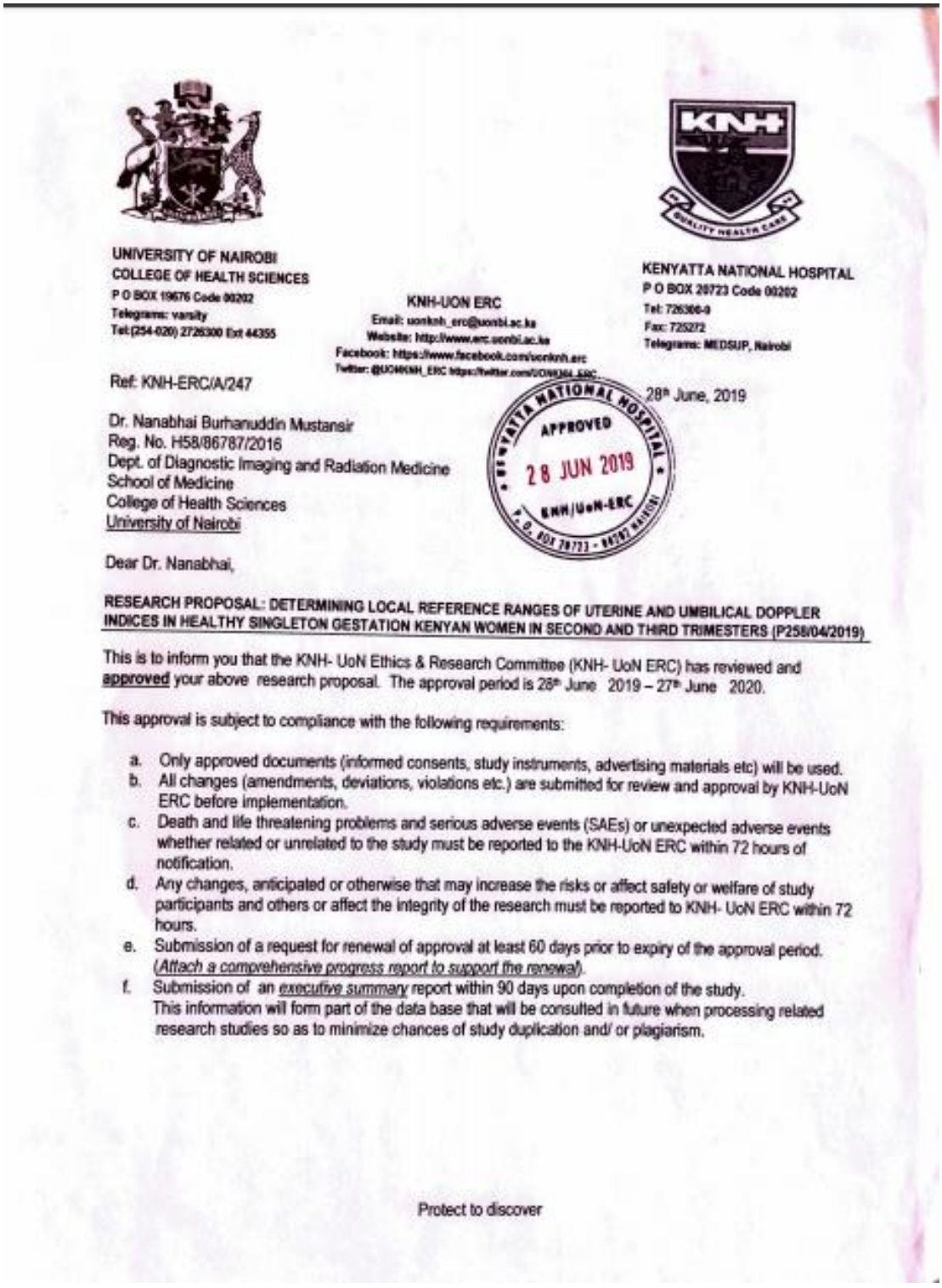
32. MD AC, MD TN, MD. DP. Relationship between Maternal Age and Uterine Artery Doppler Flow during Second Trimester. *Thai J. Obstet. Gynaecol.* 20:173–178.

33. Pirhonen J, Bergersen TK, Abdlenoor M, et al. Effect of maternal age on uterine flow impedance. *J. Clin. Ultrasound*. 2005;

34. Prefumo F, Bhide A, Sairam S, et al. Effect of parity on second-trimester uterine artery Doppler flow velocity and waveforms. *Ultrasound Obstet. Gynecol.* 2004;

APPENDICES

APPENDIX A: ERC APPROVAL FORM



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Ref: KNH-ERC/A/247

28th June, 2019

KENYATTA NATIONAL HOSPITAL APPROVED 28 JUN 2019 KNH/UoN-ERC P.O. BOX 20723 - 00202 NAIROBI

Dr. Nanabhai Burhanuddin Mustansir
Reg. No. H58/86787/2016
Dept. of Diagnostic Imaging and Radiation Medicine
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Nanabhai,

RESEARCH PROPOSAL: DETERMINING LOCAL REFERENCE RANGES OF UTERINE AND UMBILICAL DOPPLER INDICES IN HEALTHY SINGLETON GESTATION KENYAN WOMEN IN SECOND AND THIRD TRIMESTERS (P258/04/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 28th June 2019 – 27th June 2020.

This approval is subject to compliance with the following requirements:

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

Protect to discover

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

Yours sincerely,

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

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

Protect to discover

APPENDIX B : STUDY REGISTRATION CERTIFICATE-RADIOLOGY

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. NAMANGWA BURHANUDDIN MUSTAFA
2. Email address: drbm7786@gmail.com Tel No. 0722 280023
3. Contact person (if different from PI) —
4. Email address: — Tel No. —
5. Study Title
   DETERMINING LOCAL REFERENCE RANGES OF UTERINE AND UMBILICAL DOPPLER INDICES IN HEALTHY SINGLETON GESTATING KENYAN WOMEN IN SECOND AND THIRD TRIMESTER
6. Department where the study will be conducted KNH - ANC clinic & Department of radiology
   (Please attach copy of Abstract)
7. Endorsed by Research Coordinator of the KNH Department where the study will be conducted.
   Name: DR. S.C. RODRIGUES Signature [signature] Date 24/07/19
8. Endorsed by KNH Head of Department where study will be conducted.
   Name: DR. OTHIENO. P Signature [signature] Date 24.07.2019
9. KNH UoN Ethics Research Committee approved study number P258/04/2019
   (Please attach copy of ERC approval)
10. I NAMANGWA BURHANUDDIN MUSTAFA 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 19/7/2019
11. Study Registration number (Dept/Number/Year) Radiology / 19 / 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.

Version 2: August, 2014

APPENDIX C: STUDY REGISTRATION CERTIFICATE- OBSTETRICS AND GYNAECOLOGY

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: [illegible]rch@gmail.com

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
   DR. NAWABHAI - BURHANUDDIN MUSTANSIR
2. Email address: drburh786@gmail.com   Tel No. 0722230023
3. Contact person (if different from PI) —
4. Email address: —   Tel No. —
5. Study Title
   DETERMINING LOCAL REFERENCE RANGES OF UTERINE AND UMBILICAL DOPPLER INDICES IN HEALTHY SINGLETON GESTATION KENYAN WOMEN IN SECOND AND THIRD TRIMESTER
6. Department where the study will be conducted KNH- ANC Clinic & Department of radiology
   (Please attach copy of Abstract)
7. Endorsed by Research Coordinator of the KNH Department where the study will be conducted.
   Name: DR. KOL ADUNIAD   Signature [signature]   Date 30/07/19.
8. Endorsed by KNH Head of Department where study will be conducted.
   Name: Dr M. Qureshi   Signature [signature]   Date 31/07/19
9. KNH UoN Ethics Research Committee approved study number P258/04/2019
   (Please attach copy of ERC approval)
10. I NAWABHAI BURHANUDDIN MUSTANSIR 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 29/7/2019
11. Study Registration number (Dept/Number/Year) Obs & Gynae / 326 / 2019
    (To be completed by Research and Programs Department)
12. Research and Program Stamp [stamp: KENYATTA NATIONAL HOSPITAL ... 2019]

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.

Version 2: August 2014

APPENDIX D: DATA COLLECTION TOOL

Patient characteristics	
Age	
Gestational Age	
Parity	
Blood pressure(mmHg)	
Umbilical Artery Doppler Parameters	RI- PI-
Right Uterine Artery Doppler Parameters	RI- PI-
Left Uterine Artery Doppler Parameters	RI- PI-

APPENDIX E: CONSENT FORM TO PARTICIPATE IN RESEARCH STUDY.

This consent form has three parts:

- Information sheet
- Consent certificate
- Statement by the researcher/research assistant

Information sheet

Investigator's statement.
I am Dr. Nanabhai Burhanuddin Mustansir, a postgraduate student at the University of Nairobi, department of diagnostic imaging and radiation medicine. I am conducting a study on Normal second and third trimester uterine and umbilical doppler indices in healthy singleton gestation kenyan women. Ultrasound will be used for the study. There are no radiations with ultrasound. You will be required to lie supine (on your back). 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.

Background

In pregnancy Doppler ultrasound of the Uterine and Umbilical artery is a safe and important tool in analysis of utero-placental and feto-placental blood flow. The information obtained from this non invasive procedure is invaluable in helping patient management

Study purpose

To evaluate the uterine and umbilical artery Doppler indices in healthy singleton Kenyan women which will serve as baseline values in our country and help in predicting impaired blood flow velocimetry in hypertensive disorders of pregnancy which lead to serious maternal and foetal health compromise.

Risks and benefits

There is no risk of complications occurring during and after this procedure. The procedure will be carried out under supervision of experienced practitioners and in the occurrence of any adverse effects you will be promptly managed by the KNH emergency protocol. There is no

additional harm or risk to you for participating in this study. No additional tests will be requested other than routine for management of your condition. There will be no extra cost to you for participating in the study.

Voluntariness of participation

Participation in this study is voluntary and you will not be denied medical care in case you refuse to participate. You may withdraw from participating in the study at any time with no consequence whatsoever.

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 his supervisors where relevant to the study.

No records of names of the patients/ relatives will be kept in the data collection.

Compensation

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

Contact information

Shall you need any further clarification regarding this study please feel free to contact the principal researcher

Dr. Nanabhai Burhanuddin Mustansir (MBCHB)

UoN Postgraduate radiology resident

Cell phone number 0722230023.

Supervisor:

Dr Angeline Aywak

DDIRM (UON).

Box 19676-00202 Nairobi

Nairobi.

aaywakke@yahoo.com

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

KNH-UoN Ethics and Research Committee

Box 19676-00202 Nairobi

Or

Box 20723-00202 Nairobi

uonknh_erc@uonbi.ac.ke.

Consent certificate

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 his 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 Name .....

Respondent's Signature ……..…..……..

Date ……

Statement by the 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 ……..

APPENDIX F: FOMU YA IDHINI YA KUSHIRIKI KATIKA UTAFITI

Fomu hili lina sehemu tatu

- Maelezo kwa ufupi kuhusu utafiti
- Fomu ya idhini ili kushiriki katika utafiti
- Dhibitisho la mtafiti/mtafiti msaidizi

Maelezo kwa ufupi kuhusu utafiti

Kauli Ya Mtafiti.

Jina langu ni Dr. Nanabhai Burhanuddin Mustansir , mwanafunzi wa uzamili katika Chuo Kikuu cha Nairobi idara ya radiologia na dawa mionzi .Ninafanya utafiti wa kupata vipimo za umbilical na uterine indices kwa mama wajawazito wenye afya nzuri .

Ultrasound itatumika katika utafiti. Hakuna mionzi wakati ultrasound inatumika.Utapaswa kulala kwa mgongo (kulala chali).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 hili utafiti.

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

Utangulizi

Katika Mimba,uterine na umbilical doppler ultrasound ni chombo salama na muhimu katika uchambuzi wa damu kati ya mama na mtoto. Habari zitakazopatikana kutoka hii utafiti ni muhimu sana katika kusaidia udhibiti wa mgonjwa

Madhumuni ya utafiti

Lengo la utafiti huu ni kupata vipimo za umbilical na uterine indices kwa mama wajawazito wenye afya nzuri ambayo hutumika kama msingi maadili katika nchi yetu na kusaidia katika kutabiri matatizo ya shinikizo ya damu kwa mama ambayo husababisha maelewano makubwa ya afya ya uzazi na mtoto.

Madhara na faida

Napenda kuwahakikishia kuwa hakuna madhara au hatari utakayopata kwa ajili ya ushiriki wako katika utafiti huu. Hakuna vipimo vya ziada utakavyoomba kufanya zaidi ya mara kwa

ajili ya uchunguzi wa hali yako. Hakutakuwa na gharama za ziada kwa ajili ya kushiriki katika utafiti huu.

Hiari ya ushiriki

Kushiriki katika utafiti huu ni wa hiari na huwezi kuwa kukataliwa huduma ya matibabu katika kesi kukataa kushiriki . Unaweza kuondoa kujitoa katika ushiriki wa utafiti wakati wowote na bila kuadhiri huduma za matibabu yako.

Usiri

Taarifa zote matibabu yako zitakuwa siri na taarifa yoyote muhimu matibabu kuhusu matokeo na takwimu zilizokusanywa itakuwa kupatikana kwa mtafiti. Habari inaweza kuangaliwa na wasimamizi wake ambapo husika na utafiti.Taarifa zote zitazokusanywa ziharibiwa mwishoni mwa utafiti .

Hakuna rekodi ya majina ya wagonjwa / jamaa yatawekwa katika ukusanyaji wa takwimu .

Fidia

Hakutakuwa na fidia ya kifedha au vinginevyo kwa washiriki , hakuna upendeleo , zawadi au malipo, kwa washiriki zitatolewa wakati wa utafiti huu.

Ukihitaji ufafanuzi zaidi kuhusu utafiti huu tafadhali jisikie huru kuwasiliana mtafiti mkuu

Dk Nanabhai Burhanuddin Mustansir (MBCHB) Chuo Kikuu cha Nairobi

Namba ya simu 0722230023 .

DDIRM .

Chuo Kikuu cha Nairobi

Msimamizi:

Dk Angeline Aywak

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Nairobi.

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Au

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Au

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Fomu ya idhini ili kushiriki katika utafiti

Mimi nathibitisha kwamba daktari amelielezea kuhusu utafiti na mimi kuelewa kikamilifu. Nimepewa nafasi ya kuuliza maswali na ametoa majibu yakutosha Ninaelewa kwamba ushiriki wangu katika utafiti huu ni kwa hiari yangu mwenyewe sijalazimishwa.

Ninaelewa kwamba sitapokea fidia yoyote iwe fedha au vinginevyo wala sitapokea matibabu yoyote ya upendeleo, takrima au tuzo kwa ajili ya ushiriki wangu katika utafiti huu.

Naelewa kwamba taarifa zangu binafsi zitakuwa siri. Hata hivyo taarifa kuhusu matokeo ya chunguzi zitakazokusanywa wakati wa utafiti zitaangaliwa na kuchambuliwa na mtafiti mkuu na hata wasimamizi wake pindi itakavyohitajika. Mimi natoa ridhaa ya upatikanaji wa habari hii na natoa idhini ya kushiriki katika utafiti huu.

Ninatoa idhini yangu kushiriki katika utafiti huu.

Jina la Mshiriki .....

Sahihi ya Mshiriki ……..

Tarehe …..……....

Dhibitisho la mtafiti/mtafiti msaidizi

Ninadhibitisha ya kwamba nimemwelezea mshiriki mambo yafuatayo kuhusu utafiti huu

- Kwamba kushiriki ni kwa hiari yake
- Hatapokea fidia yoyote kwa ajili ya kushiriki katika utafiti.
- Anaweza kubadili nia ya kushiriki wakati wowote bila kuathiri haki yake ya huduma zake za kiafya.

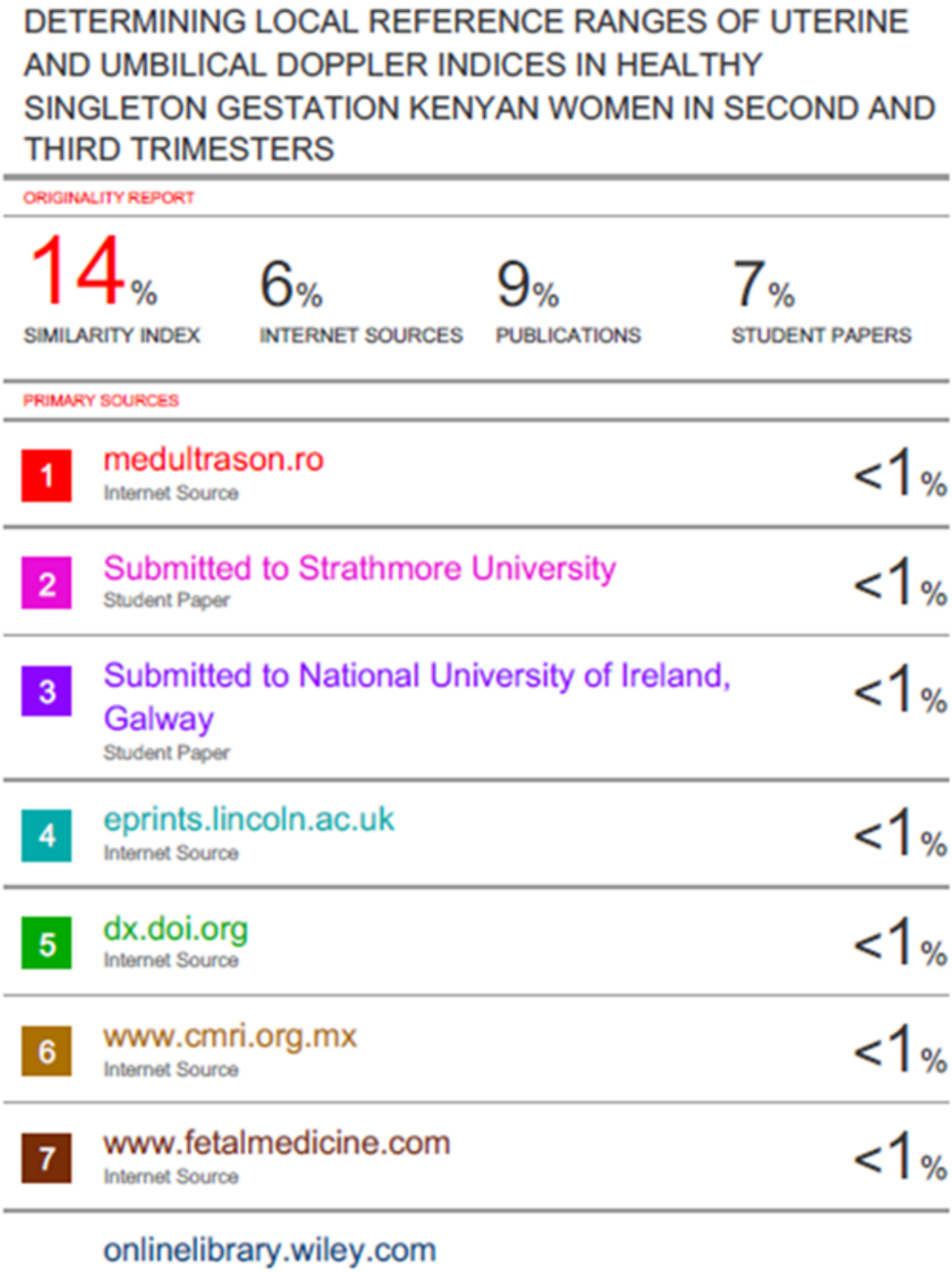
- Haki zake zitalindwa na habari atakakazotoa au ile itakayopatikana kumhusu itawekwa katika hali ya siri wakati wote na itatumika kwa ajili ya utafiti pekee yake.

Jina……

Sahihi ……

Tarehe ……

APPENDIX G: TURNIT IN ORIGINALITY REPORT



DETERMINING LOCAL REFERENCE RANGES OF UTERINE AND UMBILICAL DOPPLER INDICES IN HEALTHY SINGLETON GESTATION KENYAN WOMEN IN SECOND AND THIRD TRIMESTERS

ORIGINALITY REPORT

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