ACCURACY OF FOOT-LENGTH IN DETERMINING GESTATIONAL AGE AND BIRTH WEIGHT OF NEWBORNS AT MOI TEACHING AND REFERRAL HOSPITAL

BY

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DECLARATION

Student's declaration

This research is my original work done and has not been presented for the award of any degree in any other university or institution. I attest to the best of my knowledge, it contains no material previously published by another person, except where due acknowledgment has been made in the text.

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ABBREVIATIONS AND ACRONYMS

FL	Foot length
GA	Gestational age
LMP	Last menstrual period
MTRH	Moi Teaching and Referral Hospital
NPV	Negative predictive value
PPV	Positive predictive value
PI	Principal Investigator
SSA	Sub Saharan Africa
WHO	World health organization
SGA	Small for gestational age
AGA	Appropriate for gestational age
LGA	Large for gestational age

DEFINITION OF TERMS

FOOT LENGTH	Length of the foot measured in a straight line from the posterior margin of heel to the tip of the longest toe
LOW BIRTH WEIGHT	Birth weight less than 2500grams
PREMATURITY	Gestational age < 37 weeks
GESTATIONAL AGE	The length of pregnancy counted from the first day of the last menstrual period (LMP) and expressed in weeks and days
NEONATAL MORTALITY	Death within the first 28 days of life
SENSITIVITY	The ability of a diagnostic test to correctly identify those who have the condition
SPECIFICITY	The ability of diagnostic test to correctly identify those without the condition
POSITIVE PREDICTIVE VALUE	The probability that a positive individual according to a test is actually positive
NEGATIVE PREDICTIVE VALUE	The probability that an individual who is negative is truly negative

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ABSTRACT

Background: Prematurity is a leading cause of neonatal morbidity and mortality. Early and accurate identification of newborns at risk and the institution of community-level interventions could reduce morbidity and mortality. Foot length measurement can be an essential tool to quickly assess and refer those requiring specialized care. However, there is a paucity of data assessing its accuracy in Kenya, especially at Moi Teaching and Referral Hospital (MTRH)

Objective: To determine the accuracy of foot length in determining the gestational age and birth weight of a newborn and to identify an operational cut-off foot length for preterm and low birth weight babies born at MTRH

Methods: A hospital-based cross-sectional study was conducted at the Riley Mother and Baby unit of MTRH. All babies born between 16th June 2021 and 30th June 2022 whose mothers had an obstetric ultrasound done between 6 to 23 weeks gestation had their foot length measured. A consecutive sampling method was used to select subjects. Ultrasound was used as the gold standard for determining gestational age. Foot length was measured within 24 hours of delivery using a digital vernier caliper and a hard plastic ruler. Birth weight was measured using a digital salter scale. Data was imported into STATA/MP Version 13, coded, cleaned, and analyzed. Receiver operating characteristic curves were used to identify optimal cut-off points for feet measurements that identify preterm and low birth weight neonates. Sensitivity, specificity, positive and negative predictive values were calculated for different cut-off points. The area under the curve (AUC) was used to describe the overall accuracy of foot length in diagnosing premature and low birth weight; A value of 0 was interpreted as perfectly inaccurate, while a value of 1 reflected a perfectly accurate foot length measurement in the ROC curve.

Results: A total of 414 neonates were recruited into the study. The males were 221(53.4%). 59(14.3%) were premature (<37 weeks) as determined by ultrasound. 59 (14. 3%) had a birth weight of less than 2500 grams with a mean of 3019 ± 625 grams. There were 10(2.4), 7(1.7%), and 397(95.8%) classified as Small, Large, and Appropriate for gestational age, respectively. The foot length cut off for identifying premature neonates by Vernier Calliper and the plastic ruler was 7.4 cm with a sensitivity of 83% and specificity of 86%. The area under the receiver operating characteristics curve (AUC) at cut-off by the vernier calliper was 0.9 with a positive and negative predictive value of 96.9% and 45.3%, respectively, while the AUC by the plastic ruler was 0.89 with a positive and negative predictive value of 96.3%and 44.7% respectively.

Conclusions: The operational cut-off foot length to identify preterm babies is 7.4 cm using a plastic ruler and digital vernier Calliper. The accuracy of foot length was good, depicted by a high sensitivity and specificity**.**

Recommendations: Foot length measurement by a plastic ruler or vernier Caliper can be used in resource-constrained regions to quickly assess the gestational age of a newborn and institute appropriate management.

CHAPTER ONE: INTRODUCTION

1.1 Introduction

Foot length of the new born measured from the posterior margin of the heel to the tip of the longest toe, is a good estimator of gestational age and birth weight. It has been noted to correlate well with gestational age, birth weight, and other anthropometric measurements like head circumference and chest circumference of the new-born. Foot length can be a simple and accurate way to determine the gestational age of the new-born(Gidi et al., 2019). Gestational age estimation remains a top priority in the management of new-borns. Inaccurate determination of gestational age could result in misclassification of babies as term or preterm, and consequently lead to wrong decision making and inappropriate treatment of these babies. This culminates in an increase in neonatal morbidity and mortality. Most at risk in this situation are preterm and low birth weight babies. Preterm birth is the leading cause of neonatal mortality and accounts for about 12% of live births in the US(Simhan, 2016). Globally, the average prevalence of preterm birth is about 5-18% , of which most occur in Sub-Saharan Africa and Asia(Wagura et al., 2018). An African preterm baby is 12 times more likely to die compared to a child born in Europe(Wagura et al., 2018). A hospital-based cross-sectional study done in Tanzania showed that, majority of admissions were preterm, and low-birth weight babies with an overall mortality rate of 19%; this mortality was linearly proportional to the gestational age(Marchant et al., 2012) Preterm deliveries are a common occurrence in Kenya. A study done at the Kenyatta National hospital found a prevalence of 18.3% of preterm birth(Wagura et al., 2018). Additionally, prematurity is the leading cause of neonatal mortality according to the UNICEF report, accounting for about 28% of deaths(Howson et al., 2013). Children faces the highest threat of dying in their first month of life at an

average world-wide rate of 17 deaths per 1,000 live births in 2020(UNICEF report 2021),In low resource settings, there are many missed opportunities to provide adequate care to premature or low birth weight babies born at home(Nabiwemba et al., 2012). Early and accurate identification of new-borns at risk, and institution of Community level interventions such as skin to skin contact, immediate and frequent breastfeeding, early escalation to hospital care could lead to reduction in neonatal mortality by about 40 %(Chawanpaiboon et al., 2019)

There are various methods that have been used to determine the gestational age, notably first trimester obstetric ultrasound scans, calculations from last menstrual period, various scoring methods like Ballard's score and most recently postnatal foot length. Ultrasound done during the first trimester has been shown to be accurate in determining the gestational age(Doubilet, 2013). However, this is unavailable in most of the rural areas worldwide. In a study done in India it was shown to be available in 10 -70% of patient(Rosenblum et al., 2012).The Last Menstrual Period (LMP) and the New Ballard Score have been shown to have various challenges in accuracy and systemic biases. LMP has been shown to be unreliable because the mothers tend to forget these dates, especially in the lower-income countries(Lecturer & Registrar, 1991). The new Ballard Score is technical and requires a qualified and experienced health worker to be able to carry it out with precision(J L Ballard et al., 1991). Due to these challenges, there is a need for an accurate yet simple method to estimate the gestational age of a new-born(Weinstein et al., 2018). This will lead to accurate identification of preterm and low birth weight neonates and thus, early initiation of proper treatments which eventually will reduce neonatal mortality and morbidity(Chawanpaiboon et al., 2019).

Foot length is a useful tool and has been used to identify preterm babies in need of urgent medical interventions(Nabiwemba et al., 2012). It is quick and easy to perform by health care workers of all cadres as well as other persons who may not necessarily be health care workers. Foot length has also been noted to be less disturbing to the very sick neonate unlike other postnatal methods that are time-consuming and involve significant manoeuvring of the neonate(James et al., 1979). A South African pilot study demonstrated that foot length measurements correlated well with Gestational Age, birth weight, and head circumference at a higher accuracy than the LMP and Ballard score(Wyk & Smith, 2016). It has a high sensitivity to identify babies who are premature and those with low birth weight; thus, it will help in shortening the time of referral and foster early institution of interventions for children who are born in the peripheral facilities or at home. Home delivery was reported to be as high as 23.68% in women in East Africa with factors such as increasing number of births, and ages between 20-34years found to be important determining factors for home delivery. Specifically in Kenya, Regassa et al showed that, the prevalence of home deliveries was 37.5%, and this is quite high(Regassa et al., 2022).

Babies require specialized care depending on their gestational age at their time of delivery; those who are born preterm have more needs than term babies. The preterm babies depending on their level of maturity will require different levels of care as well. All babies require warmth, but there are those who will require just kangaroo mother care (those who are stable but preterm and birth weight less than 2000grams), which can be done in the home setting with visits from the health care workers or in the hospital settings. Subsequently, there are those who have low birth weight (1500grams-2500grams) who may require warmth and feeding only, or very low birth weight (1000grams-1500grams) who may require kangaroo mother care or incubator

care or extremely low birth weight(less than 1000grams) who require more care like incubator care in the hospital setting. In terms of feeding, depending on the gestational age or birth weight the neonates require different needs as well, there are those who require intravenous fluids(like extreme preterm on day 1 of life), others require nasogastric feeds(birth weight less than 1550grams) while others require cup feeds(1550grams-1650grams) or just breastfeeding for stable late preterm or term babies. A cross-sectional study done in Bengaluru by Srinivasa et al with a foot length cut off of ≤7.4 cm had 98.81% sensitivity and 79.09% specificity and to identify the low birth weight babies with FL ≤ 7.4 cm had 97.03% sensitivity and 87.05% specificity. In Tanzania, Marchant et al were able to identify low birth weight/preterm babies with the sensitivity of foot length -of 75%, 87%, and 93% for Very low birth weight, Low birth weight, and for prematurity respectively. Their specificity was 99%, 60%, and 58%, respectively and the Positive predictive values were low (43%), but negative predictive values were high (96% for Low birth weight and 99% for Very low birth weight)

Currently, no study has been carried out in Kenya to determine the accuracy of foot length measurements in gestational age estimation; therefore, the current study aimed to provide pioneer data on the accuracy of foot length in Kenyan population.

1.2 Problem Statement

In low- and middle- income countries, Kenya included, many mothers deliver at home and are attended to by traditional birth attendants or other unskilled attendants, estimated at 37.5% in Kenya by Regassa and collaborates in their study (Regassa et al., 2022).Those who manage to get to a facility encounter challenges as some facilities have limited resources. Some health facilities lack basic equipment like a weighing machine, while other facilities lack experienced and qualified staff to be

able to carry out gestational scoring methods such as New ballard scores to estimate gestation age of new borns. Identification of preterm and low birth weight babies becomes a challenge, leading to delay in referral for urgent and appropriate new born care. Gestational age is crucial in managing these babies who are at risk dying from prematurity related complications. In the Nursery care settings, there are sick babies who require gestation age or frequent daily weight monitoring for treatment purposes, but often is not possible to obtain because they require little or no manipulation due to the severity of the illness; one is left in dilemma on how to give proper treatments without the crucial dates and weights. There are many methods that have been used to determine gestational age of newborns. Prenatal methods include obstetric ultrasound, LMP, measurement of the fundal height, and postnatal methods such as new Ballard Score, Dubowitz method, Eregie method, and anterior capsule measurements. However, each of these methods has various limitations; they require technical and skilled persons to be able to do it. Additionally, it has significant manipulation of the new-born and the exposure of the baby also interferes with the normal physiology of the baby, leading to neonatal hypothermia.

Given the suboptimal performance of these methods of determining gestational age, and the fact that obstetric ultrasounds are not readily affordable, there is a need for simple, novel methods to accurately determine gestational age and preterm birth in low and middle-income countries where the burden is greatest. This study therefore aimed to provide data on the accuracy of a simple, quick method of gestational age estimation which could be instrumental in neonatal critical care.

1.3 Justification

Gestational age estimation is essential in guiding the management of new-borns at birth and for epidemiological purposes. Inaccurate determination, wrong identification and misclassification of babies as term or preterm may lead to wrong decision making and inappropriate treatment given to these babies leading to increase in morbidity and mortality. Therefore, there is need for early and accurate identification of this babies. Most at risk in this situation are preterm and low birth weight babies.

Scientists and Public Health Practitioners have suggested that research on the early identification of babies with prematurity and low birth weight is key to decreasing the global mortality from prematurity and low birth weight(Marchant et al., 2014) A quick, simple, and low-cost methods that can help us identify these babies will be very critical in this effort

Foot length is a quick ,low cost ,simple tool that can be used in identifying this babies at risk(Marchant et al., 2010).Foot length has been noted to correlate well with gestational age(Wyk & Smith, 2016). It is easy to carry out and requires less time to perform. It requires less manipulation of the neonate and has been noted to reduce exposure of premature babies in the incubator to hypothermia(James et al., 1979). It also has high sensitivity to identify preterm and low birth weight babies(Nabiwemba et al., 2012). Additionally, in places or situations where the weight cannot be obtained , it can be used to estimate the weight and body surface area which can be used to calculate drug dosages or fluid requirements(Gohil et al., 1991)

There is currently no study that has been done in our setting to determine the utility of this method in determining the gestational age at birth and its sensitivity, specificity, positive and negative predictive values, in identifying the premature and low birth

weight babies in our settings. Studies done in other countries have shown different cut off points for foot length to identify preterm babies(Nabiwemba et al., 2012)(Srinivasa et al., 2017)(Gidi et al., 2019).If this study is not done, many high risk preterm and low birth weight babies are not going to be identified; and hence will be unable to get the timely critical interventions they may require; therefore contributing to the already high neonatal mortality and morbidity.

1.4 Research Question

What is the accuracy of foot length in determining the gestational age and birth weight of a new born in comparison to obstetric ultrasound in MTRH?

1.5 Objectives

1.5.1 Broad Objective

To determine the accuracy of foot length in determining the gestational age and birth weight of a new born in comparison to obstetric ultrasound at MTRH Eldoret .

1.5.2 Specific Objectives.

1. To identify an operational cut off foot length that can be used to identify premature and low birth weight babies in MTRH.
2. To determine the sensitivity, specificity, positive predictive value, and negative predictive values of foot length in determining gestational age and birth weight in comparison to obstetric ultrasound in MTRH.

CHAPTER TWO: LITERATURE REVIEW

Gestational age determination is essential in knowing the maturity status of a newborn. It is an essential component in perinatal practice. It can be determined in the prenatal period or in the postnatal period. Various methods are currently being used to determine the gestational age of newborns. These methods can be classified as prenatal and post-natal methods.

2.1 Prenatal Methods used to determine gestational age:

This are methods that are used to determine the gestational age before delivery of the baby. The following examples have largely been used in our settings:

2.1.1 The Last Menstrual Period (LMP)

Gestational age is estimated by applying the Naegele's rule which is done by subtracting three months from the LMP month and adding seven to the LMP date. Additonally, there are various electronic soft-wares and application which are available on the internet which can be used to calculate the gestation dates and expected date of delivery by entering the current dates and the date of the last menstrual period. This method, however, has several challenges and short comings that makes its implementation and utility difficult; just to list a few of them here; Firstly, there is an assumption in these method that there the ovulation occurs on the 14^{th} day of the month, which may not be the entirely true because the follicular phase varies from woman to woman(Johnson et al., 2009). Secondly, it has been demonstrated that the women who rely on memory to remember the dates rather than using a written method or electronic methods often have a preferred digit which they tend to remember and would likely use that instead of the date(Van Oppenraaij et al., 2015). Thirdly, most women in general both from the higher or lower and midle

income countries are often not sure of their exact dates when the monthly periods started and there are some conditions such as bleeding during the early stages of the pregnancy which may confuse the mother; as mother may not know if these are periods still or something else, unless they are examined by a qualified health worker and this may not be possible in many parts of the lower and middle income countries where women are busy and may just assume it to be the usual periods. There are a number of women who are on hormonal contraceptives and often this contraceptives causes amenorrhea , so these bring confusion to the mothers and they may not be able to tell when exactly the pregnancy started; other times their periods tend to irregular during this period after stopping the contraceptives. A number of studies have been done to compare ultrasound dating with LMP dates and in one of the studies it showed that Last menstrual period dating overestimated the gestational age by 3.1 days(Lecturer & Registrar, 1991). Another study done in South Africa by Macaulay et al showed that it overestimated the gestational age by 0.2 days and was also noted to be unreliable in estimating late-term neonates(Macaulay et al., 2018).

Lactation amenorrhea is as a result of prolactin suppression of ovulation. This period has particular characteristics such as absence of menses or sometimes can be irregular. This is challenging for the mother and often confuses the mother since mum is unable to tell the exact or near dates for return of fertility, making use of LMP in this situation to be very unreliable and unpredictable.

Most antenatal clinics in Kenya and other countries in the region and outside have **obstetric gestational wheels**. These consist of an outer wheel in most of them that has markings for the calendar and an inner wheel, which is a sliding wheel with markings for weeks and the pregnancy gestation days. They help to facilitate the estimation of Gestation age and to calculate the expected date of delivery, depending

on the day of the last menstrual period. These wheels are of different qualities and different sizes as well, but in general, the larger wheels yield better results than the smaller ones. In well-resourced areas more accurate results can be arrived at by using electronic and computer softwares or web-based online calculators.

2.1.2 Obstetric Ultrasound

Ultrasound is often the gold standard and has been widely used as a prenatal method of determining the gestational age. The basic obstetric ultrasound examination provides an accurate estimation, safe and objective way to assess the gravid uterus throughout a woman's pregnancy term including determining the pregnancy location, demonstrating the number of embryos present, helping in the intrauterine diagnosis of fetal distress, abnormalities and anomalies; and in assessing the gestational age of the fetus. However, the accuracy is dependent on the timing when it is done, that is the trimester in which it is done; For instance, this has to be performed within the first trimester (13 weeks +6 days) to obtain more accurate dates, with 95% confidence interval of + or – 5 days, which is way better than 8 days error that is observed when done in the second trimester dating at 14-20 weeks (Doubilet, 2013).

Prenatal clinical assessment of gestational age using basic obstetric ultrasound scans should be done before 23 weeks of gestational age for better accuracy with the dates (Heine, 2017). Wyk & Smith et al in south Africa in their pilot study of using postnatal foot length to determine gestation age used obstetric ultrasounds performed before 23 weeks of age(Wyk & Smith, 2016). This is however a big challenge in the lower and middle income countries where resources are hard to come by and ultrasounds only is done by those who have access to it and those who can be able to pay for the services. For instance, a study carried out in India demonstrated that

ultrasound is rarely available in rural/low-income settings(Rosenblum et al., 2012).Closer home ,Wyk & Smith et al in south Africa found only a third of their study population in their pilot study of foot length measurement had early ultrasound done before 23 weeks gestation(Wyk & Smith, 2016). In kenya, there is no study that had looked at the use of obstetric ultrasound scans in the kenyan rural population setting. In addition to this majority of the women have their first antenatal care(ANC) visit late in to the pregnancy. In Kenya, only about 20 percent of women attend ANC before the 4th month(UNEP.IRD, 2012). So you may not be able to have the chance to perform the obstetric ultrasound early enough for dating purposes or rule out congenital anomalies.

The decision to use ultrasound as our gold standard was based on the fact that these is the gold standard for determining gestation age and is better compared to new ballard scores and other methods of determining the gestation age. We specifically chose 23 weeks gestation and below because of 3 reasons: 1. Practice guideline by society of obstetrics Canada published as guideline number 388 volume 41,issue no 10, P1497-1507, in october 2019 recommended that gestation age done at 23 and below is a good method to estimate gestation age and delivery date(Butt et al., 2014). 2. The pilot study that has been done in Africa to assess foot length in determining gestation age used ultrasounds who were 23 weeks gestation and below, so our study will be comparable to their study(Wyk & Smith, 2016). 3. Considering that according to KDHS 2014, only 23 percent of the women attend ANC before 4th month, we anticipated that there would be very few mothers with ultrasounds earlier than 23 weeks

2.2 Postnatal assessment of the gestational age

Postnatal gestational age is best determined within the first 24 hours of life. Various methods have been used to estimate gestational age in the postnatal period. Though, Some are not applicable on our settings. They are as follows;

1. Dubowitz method- The Dubowitz Score is a scoring method that was used widely for estimating the gestational age of babies. It was developed by a couple Lilly Dubowitz (Paediatrician/Neonatologist) and her husband Victor Dubowitz (a neurologist) in the 1970. The score proposed by Dubowitz et al assesses an infant for the apparent gestational age by putting into consideration both neurologic features and various external/physical features of development. The particular physical features assessed includes; presence of edema, texture of the skin, colour of the skin, the opacity of the skin, if lanugo is present, or presence of creases on the plantar surface, the nipple formation, the size of the breast ,how the ear has formed, ear firmness and the maturity of the genitalia, if complete or not .There are various neurological features which are assessed as well ,And this include the following; the posture of the newborn, the square window(on flexing the wrist), the ranges of ankle dorsiflexion, the arm recoil, and the leg recoil, the degree of popliteal angle, heel to ear with a range of 0-4, where score of 0 is the one that touches the ear and 4 is further away from the ear; (the lower the score the lower the gestation age), the scarf sign(performed by bringing one hand across the new born chest until you feel resistance), head lag(trying to asses the level at which the new born can support the neck when lift from the ground while lying on her back) , and ventral suspension(these is done by assessing the level at which the child coils/bends when held facing down in a raised position). This method was widely used in various countries in

the world in the 70s and 80s before the Ballard scores and other methods were validated. It had been adopted by many other countries; before other methods were developed. However, in a study carried out in south Africa with a study population of 110 preterm infants, this method of dubowitz overestimated the gestational age by 2.8 weeks (Allen et al., 1991). In a systemic review of different studies which have compared dubowitz cores with ultrasound, the Dubowitz score estimated more than 95% of pregnancies within ±2.6 weeks (n = 7 studies)(Lee et al., 2017a). It is also quite difficult to carry out in very sick infants requiring very little disturbance ,like those on the ventilator in the neonatal intensive unit or in those extremely preterm neonates and due to the fact that you have many features to perform then it also takes a lot of time to perform the full evaluation. In the same systematic review of various studies done to compare this method with Last menstrual period dates by Lee at al , they demonstrated that it date 95 % of the pregnancies within ± 2.9 weeks (n = 6 studies)(Lee et al., 2017a). This method is very subjective and skills intensive ,therefore one requires skilled personnel to carry it out.

2. New Ballard score- This is another method that uses scores to ascertain the gestational age of the new-born. It was developed by Jean Ballard to assess gestational age of the new born. Just like the Dubowitz score it combines both the physical features and neurological features. It comprises of six neurological features and another six physical features. The neurological features depends mainly on the muscle tone of the new-born. And the normal scenario is that we expect a neonate is who is premature to be more hypotonic than a term baby. The various neurological features include the posture of the new-born (while lying supine), the square window (wrist) on wrist flexion , the level of arm

recoil, popliteal angle, the scarf sign and the degree of heal to hear rotation. The physical maturity features usually rely on the anatomical maturation of the new-born and this includes; appearance of the skin with a score of -1 to 5(where -1 is friable and transparent skin and 5 is where we have a mature leathery or wrinkled skin), presence or absences and distribution of lanugo hair (fine, unpigmented hair in a new-born or foetus), appearance of the new-borns plantar surface(presence and distribution of creases on the plantar surface), the breast anatomy(whether it is appreciable or not and whether the areola is flat, marked,raised or full),the level of eye and ear maturity(eyelids if they are fused or open, and for the ears is the cartilage curvature and if it recoils or not), and the maturity of the genitalia(This varies depending on the sex of the baby; For instance in males the maturity of the scrotum in terms of the skin texture and contents is assessed and also the position of the testes, stage of descend) and for the females the maturity of the genitalia is based on the appearance and size of the clitoris and the labia minora. This method is considered to be an improved and a simplified one compared to Dubowitz method. Since, it has fewer physical and neurological features to asses compared to Dubowitz score ,it is expected that it takes a lesser time to perform all the features compared to Dubowitz method with maximum of 7 minutes(Jeanne L. Ballard et al., 1979). The new Ballard score method was an improvement of the initial Ballard score ,which was expanded to be able to assess the gestational age of those who are extremely preterm (J. L. Ballard et al., 1991). The New ballard scores in comparison with the Last Menstrual Period dating and the basic obstetric ultrasound dating, it was noted that it overestimated the estimated gestational age of the new-born by 0.15 and 0.32

weeks respectively((J. L. Ballard et al., 1991).In another systematic review of various studies done to compare this method with ultrasound by Lee at al , they demonstrated that the Ballard score miscalculated GA (0.4 weeks) and dated pregnancies within ±3.8 weeks (n = 9 studies). In the same systematic review of various studies done to compare this method with Last menstrual period dates by Lee at al , they demonstrated that the New Ballard score dated approximately 95% of the pregnancies within, ±4.2 weeks (n = 5 studies)(Lee et al., 2017a)

3. Other Rarely used neonatal assessment methods:

1. Farr method:

This is a neonatal assessment Scoring method similar to the other scoring methods such as new ballard scores. Which has 10 neuromuscular features, but no physical features. The neuromuscular features include the following : Spontaneous motor activity, reaction of pupils to light, the rate of sucking, the closure of mouth when sucking, stripping action of the tongue, resistance against passive movement, the recoil of forearms, the plantar grasp, pitch of babies cry, and the intensity of cry. The method was validated using last menstrual dates as the gold standard. The initial reported accuracy was dating 61 % of the pregnancies within ±1 week. This was first carried out in Scotland in 1968. The challenges with this method, is just like the other methods requires skilled persons to be able to carry out and also requires further validation in African population setting(Farr, 1968)

2. Capurro et al method:

This is also a neonatal assessment method that contains 7 physical and neuromuscular features. Which includes the following: the appearance of Skin texture, the level of nipple formation, how the ear form, size of the breast, appearance of plantar creases , the Scarf sign, presence or absence of head lag. This was validated in Uruguay using last menstrual period as the reference gold standard with a sample size of 115 neonates in the year 1978. It was noted to have a good correlation with gestation age. This method like the other assessment scoring methods requires skilled persons to be able to carry out and requires further validation on accuracy in African population setting(Konlchezky et al., 1978).

3. Tunçer et al:

This is an assessment method which was developed by Tuncer et al in Hacettepe University, Neonatal Intensive Care unit;in Ankara, Turkey. With a sample size of 100 neonates in 1981. The reference standard for gestation age used was last menstrual period. The correlation with gestation age was good, r=0.945.It comprises of 8 physical and neuromuscular features ,which are as follows: the Skin texture, the ear form, firmness, breast size and nipple formation, plantar creases, the facial appearance, Posture, arm recoil, and the scarf sign. Requires high skilled personell to carry out, and not been validated in our settings(Lee et al., 2017b)

4. Simplified Dubowitz

This is a neonatal scoring method validated by Allen at al in private hospitals, in the northern Territory of Australia, with a sample size of 98 neonates in 2009. The reference standard for gestation age was an obstetric ultrasound. The mean difference noted was 0.04 weeks. It also includes both physical and neurological features as in the original dubowitz score, but are much fewer, at only 6. It involves the following 6 features: The Breast size, skin texture, ear bending (substituted from ear firmness because some Aboriginal babies have less ear cartilage) the Square window, popliteal angle, and the scarf sign. These method maybe more specific to the native population on Australia, and may require further modifications if it is to be used in a different population. Especially like ours with diverse genetic differences.(Lee et al., 2017b)

5. **Bhagwat Method**:

This is one of the most recently validated method in the Medical College; Thiruvananthapuram, in Kerala, India, by bhagwat et al, with a sample size of 1000, and gestation range between 28 weeks and 37 weeks of age. The reference gold standard for gestation age was the last menstrual period. There was a good correlation with gestion age and LMP dates, r =0.91. There was a mean difference of -0.58 week. This method only considers 4 physical features and no neuromuscular features. The features are as follows : Skin texture, breast size, ear firmness, genitalia. This method is simpler compares to the other methods but requires further validation in different settings and in persons with different levels of skills.(Lee et al., 2017b).

6. Klimek et al Method:

This is another method introduced by klimek et al in a study of 800 new-borns in Tertiary hospitals in Poland, in the year 2000. The reference gold standard to determine gestation age used was new ballard neonatal assessment scores. There was a fair correlation with gestation age, with r=0.72. The method uses 3 physical features ; Lanugo, plantar creases, breast size and 3 neuromuscular features such as ; babies Posture, angle forearm to arm, pulling an elbow to the body. These is rarely used and not much validation has been done to compare with other methods. It requires highly skilled personel to carry out, and may not be applicable to persons in these community setting(Klimek & Klimek, 2000).

7. Finnstrom Method:

This a neonatal assessment method first studied in a university Hospital,Umea, in Sweden. With sample size of 174 neonates. The reference standard for gestation age used was last menstrual period. The correlation for 5 external characteristics was good, r=0.84. These methods contain 12 physical and there is no neuromuscular features. Which includes the following. physical features; the Breast size, nipple formation, skin opacity, scalp hair, hair-forehead border, eyebrows, ear cartilage, fingernails, xiphoid process, external genitalia, plantar skin creases, pupillary membrane. This is also rarely used and not much validation has been done to compare with other methods. It requires highly skilled personel to carry out, and may not be applicable to persons in the community settings such as in Kenya(Finnstrgm, 1972)

8. **Feresu et al Method:**

A neonatal assessment scoring method which was validated in Zimbabwe, with an African population in a maternity unit in Harare central hospital, in Harare. With a sample size of 364 neonates in 2002. The reference for gestational age was the last menstrual period dates as the gold standard. The method has 22 signs. both physical and neuromuscular. It has 11 physical signs such as: Edema, the skin texture, skin color, the skin opacity, presence of lanugo, plantar creases, nipple formation, breast size, ear form, ear firmness, and genitals. It also has 11 neuromuscular signs such as; Posture, square window, dorsiflexion of foot, the arm recoil, leg recoil, the popliteal angle, heel-to-ear, the scarf sign, head lag, and ventral suspension. In this study, birth weights of the neonates were compared with the dates obtained from this method of determining gestation age. Similarly, this method is complex and subjective, depending on the skills and experience of the person performing it. It requires well trained and skilled personnel to be able to carry it out. Since, validation has not been done in many settings, its application also may be challenging at this point in time (Lee et al., 2017b)

4 **Eye examination-** These is another post natal examination method that has been demonstrated to have the ability to estimate the gestation age of a neonate in the post natal period. The anterior capsule has been recognized to develop in correlation with gestational age. This has been noted precisely between 27 and 34 weeks gestation of age, therefore subsequent examinations of the eye with direct ophthalmoscope or an equivalent can be carried out to assess gestational age of the neonate. This method, however, has many challenges and short coming; For instance, this cannot be done before

27 weeks gestation because of the inability to see through the cornea, due to its opaque nature, which ultimately limits the visualization of the anterior capsule. Moreover, after 34 weeks gestation, this method cannot be performed due to the dissolution of vessels. Another disadvantage with this method is that ,this can only be carried out within the first 48 hours of life for it to be accurate (Sasivimolkul et al., 1986)

3. Electroencephalography – This is one of the methods that could be used in the post natal period to determine gestation age. This method attempts to look at the patterns of an electroencephalograph. The different patterns of EEG have been noted to correlate well with gestational age(Tharp, 1990). They increase with increasing gestational age. Some patterns are only seen at certain times of baby's development. However, this may be difficult to carry out since electroencephalography is not easily available in our most of the Kenyan hospitals, worse even in the rural areas. This is also a high resource intensive method, in terms of the human resources needed and also the capital resources and maintenance costs required. And it also requires highly skilled person to perform and also interpret it.

5 Eregie method- This is a simplified method of postnatal gestational age assessment which was validated in an African population setting in Nigeria. It has an accuracy which is close to Dubowitz maturation assessment method. This method has six features that are used to asses and score the baby soon after delivery. This features includes the following: the measurement of the head circumference, the measurement of mid-arm circumference, skin texture, level of ear formation, the size of the breast and maturity of the genitalia .This method, however, has the same challenges as the other post natal scoring

maturation assessment methods, For instance, it requires a lot of time and a well-trained or experienced person to be able to carry out (Eregie, 2000) .

These method has been used in some African studies as their gold standard in determining gestation age of a new-born, while measuring foot length; For instance, Gidi et al in Ethiopia, a side from using new ballard scores also used the Eregie method to determine in their study of 1486 new born with median gestation age of 39 weeks using new ballard scores and 40 using the Eregie method, there were less preterm identified with Eregie method compared to new ballard score , but prediction of prematurity estimated using the Eregie model had higher AUCs in all the measurements, AUC of 0.93 compared to AUC of 0.86 for the NBS, a conclusion was made that the Eregie method gave comparable results with that done using new ballard scores(Gidi et al., 2019). In a hospital based study carried out by Nabiwemba et al in Uganda to identify high risk neonates in the community with a study population of 711 used this method as the gold standard in determining the gestation of new-born(Nabiwemba et al., 2012).

6 Anthropometric measurements:

These are non-invasive measurements of the different body parts and using them to estimate gestational age of the new born. These can be carried out in the post natal period and also in the prenatal period. There are various anthropometric measurements that have been used to estimate gestational age in the postnatal and in some cases using an ultrasound in the prenatal period. The prenatal obstetric ultrasounds relies heavily on the anthropometric measurements of the different body parts, such as head circumference and femur length to be able to estimate gestation age of the

foetus. Anthropometric measures such as Birth-weight of the new born, occipito-frontal circumference, mid-upper arm circumference, head circumference, chest circumference, baby's length and foot length have been noted to correlate well with gestational age(Thawani et al., 2013). This methods have been used to determine gestational age especially in the low resource setting. The birth weight , the measurements of mid upper arm circumference and measurement of the head circumference have reliably been used to estimate gestational age in the newborn(Thawani et al., 2013).The occipital-frontal diameter is also a reliable and accurate fetal parameter that has been shown correlate with gestational age and can thus be used to estimate gestational age(Isah et al., 2017). Measurements of the chest circumference using an elastic tape measure in the postnatal period has been shown to be a useful alternative in estimating the gestational age as well(Thi et al., 2015). Foot length has also been demonstrated that it could be a good predictor of gestational age(Srinivasa et al., 2017).Our study focused on determining the accuracy of foot length to determine the gestational age of a new born in the post natal period and also to attempt to obtain an operational cut off point that can be used to determine low birth weight and preterm babies(less than 37 weeks gestation).

2.3.1 Foot development

The development of the foot is influenced by both genetic and non-genetic factors. Just like growth and development of the human body, environmental factors like maternal diet play a great role in the maximum growth expected in the prenatal and postnatal foot development. Foot development does not occur in isolation but in proportion to the physical development of the foetus or baby. Some studies have

looked at estimations of mid-parental stature to calculate the expected stature or recumbent length of the child, with the recognition that there is a genetic parental contribution to the child stature or length(Himes et al., 2020).

In the early stage of foot development in the uterus, the foot grows in line with the position of the leg. At this first stage, for the reason that there is comparatively large growth of the fibula as likened to the tibia, in the subsequent stage the foot is displaced in inversion and dorsiflexion, consequentially leading to a physiological clubfoot (Also known as the 'fibular phase') ,which can be seen on a special obstetric ultrasound measurements probably in 3 dimensional version.The fibular phase is witnessed when the size of the embryo is like 21 mm to 30 mm, which is approximately corresponding to 8.5- to 10-week Gestational Age. In the third-stage of the foot growth, the growth spurt of the tibia makes the foot to achieve its normal position (also known as the 'tibial phase'). The foetal embryonic size is roughly 31–50 mm for the duration of these tibial phase, which is approximately corresponding to 10 to 11.5-week Gestation age of the foetus. At this early stage of pregnancy the length of the fibula and tibia is difficult to measure with an obstetric ultrasound in an accurate and reliable way because the bones are mainly made up of less echogenic cartilage rather than the bone itself. In the early foetal stage (approximately 30 to 60 mm size of the embryo), the average rate of foot growth is slower than the overall body (sitting height of) foetus. But when it reaches 70 mm of the embryonic size, until the baby is term, there is decelerating down in the growth of sitting height, while the foot continues with its development rate and shows some spurt of growth. This increase in foot length development is often slow from the 8th week to the 14th week, then the rate would increase until towards the 26th week of life, then it tends to become less rapid a little until baby is term. The ordinary change in the foot length

from the 14th week on is approximately 3 mm per week, with only minimal differences on the growth. When it reaches towards the end of the third month, the foot length measures on average approximately 0.8 cm and when the foetus is at term the average length is now nearly about 7.6 cm (with a range of maximum, 8.7 cm; and a minimum of 7.1 cm).The foot length often varies at different gestational ages and correlates well with the gestation age right from conception as also seen in this foot length model by merz et al(Merz et al., 2000).These dimensions in the foot length model were measured as a straight line from the posterior margin of the heel to the tip of the extended big toe(Table 1). Foot development is usually more rapid in the foetal period when the baby is still in the uterus, though there is a significant slowing down from the time of delivery to about when the child is about 5 years of age. About half of the adult foot length development is usually achieved within the first year of life after delivery. From approximately the age of 5 years until puberty, the foot length grows by about 0.9 cm per year. And by the age of about 10 years, girls reach approximately 90% of their adult foot size, whereas boys are usually slower as they reach 82% of their adult foot length at this age . The boys' feet tend to develop for an extended period of time and at a more quick rate after entering into puberty as equated with those of girls' feet. The ordinary man's foot is approximately 2.5 cm longer than the ordinary woman's foot in the older population (Bareither, 1995).

Foot length has been thought to vary according different races and some ethnic groups, though in a South African pilot study, they found no statistical difference between the different ethnic groups and that there was also no variations in sex and race(Wyk & Smith, 2016); In general, all anthropometrists who have measured foot length in the larger population studies have observed that Negroes have longer feet

compared to other populations of Asians and Caucasians. The average foot length measurement of the Negroes of the Soudan was 26.8 cm. The mean foot length of Negroes of French West Africa is approximately 23.5 to 30.6 cm; the average of all negroes thought to be about 27.0 cm. Subsequently, On the other hand, the short Indians of Middle America have shorter feet, with an average foot length of 23.0cm to 23.6 cm. While the the adult male pigmies of Giapanda have a mean foot length measurement of of approximately 22.2 cm.

Table 1: Model use to determine GA

GA(weeks)	Foot length (mm)
<24	<44
24	44.1–45.9
25	46–48.9
26	49–51.9
27	52–53.9
28	54–55.9
29	56–58.9
30	59–60.9
31	61–63.9
32	64–65.9
33	66–68.9
34	69–70.9
35	71–72.9
36	73–75.9
37	76–77.9
38	78–80.9
39	81–82.9
40	83–84.9
40+	>85

2.3.2 Foot Length.

The human foot length has been studied over the years. In a study of 106 human feet with gestational age ranging from 13 weeks to 26 weeks post conception, the length of the foot was compared with crown rump length and it showed that there was a positive correlation in the way they grow and in relation to gestational age and that

there was no significant statistical difference found between the length of the right and the left or between male and female fetuses(de Vasconcellos et al., 1992).

Streeter in 1920, did a study which was looking at post abortion pathologic specimens preserved with formalin, he was able to demonstrate the fact that development of the foot follows a normal growth curve and it has a direct correlation with gestational age(Mhaskar et al., 1989). Merz et al in a prospective study of 610 babies using early ultrasound(less than 23 weeks GA) as the gold standard was able to develop an age related reference range of foot length (Merz et al., 2000)

There are other studies that have been done to demonstrate the correlation of the foot and gestational age both in the antenatal period and also in the postnatal period. In the antenatal period, a comprehensive study done by Pandy et al in northern India showed that ultrasound is a reliable tool for assessing fetal foot length and that the foot length measurements correlates well with the gestational age(Pandey et al., 2016).

In the postnatal period, a study of 123 neonates by James et al in the UK found that foot length correlated well with gestational age and other anthropometric measurements, though there was a more pronounced correlation between foot length and birth weight, they concluded that foot length measurements are helpful in very ill patients in need of critical care where other anthropometric measurements are not possible to carry out and that it can easily be used to estimate the weight which can be used to calculate the required dosages of drugs ,intravenous fluids and also for feeding purposes(James et al., 1979). In a pilot study carried out in South Africa, they demonstrated that foot length correlated well with Gestational age, length, birth weight, and head circumference. The study had a significant correlation between foot length and GA of r= 0.887, and birth weight r=0.920, length r=0.906 and head circumference r= 0.903 (Wyk & Smith, 2016). Foot length has also been shown to be

a better indicator of birth weight than other anthropometric measurements(K. et al., 2018)

Foot length has been shown to be a sensitive tool in identifying patients who are premature and those that have low birth weight. In a Bengaluru study, the cut off foot length measurement of 7.4 cm was used to identify low birth weight babies and also the premature babies, with sensitivity of 97.03% and specificity of 87.05% in low birth weight and sensitivity of 98.81% and specificity of 79.09% for premature babies(Srinivasa et al., 2017). Singhal et al in a study of 1000 neonates between 28 and 42 weeks found a correlation coefficient of r=0.934, with foot length cut-offs of 7cm to identify babies less than 34 weeks with a sensitivity of 94.76%, and specificity of 94.30%, the positive predictive value of 81.55%, and negative predictive value of 98.54%(S. Singhal et al., 2014). Mukherjee et al in a hospital based study in Eastern India with a study population of 351 neonates, used a foot length of less than 7.75 cm with sensitivity of 92.3% and specificity of 86.3% to identify preterm neonates and for identification of low birth weight babies (<2500gm) a foot length less than 7.85 cm had a sensitivity of 100 % and a specificity of 95.3%,while, Foot length less than 6.85 cm had 100% sensitivity and 94.9% specificity for identification of VLBW babies (<1500 gm(Mukherjee et al., 2013)

Another study carried out in Nepal at a tertiary hospital which was looking at 811 neonates, which included 30 neonates with low birth weight and 54 preterm; using foot length cut off of 7.5 cm to identify low birth weight, had an average sensitivity and specificity of 84.0%, the positive predictive value of 17.03% and negative predictive value of 99.3 % ,with a cut off of 7.8% had sensitivity of 76.9% specificity of 53.9%, PPV of 10.6% and NPV of 97% to identify premature babies. (Ashish et al., 2015).

In a Tanzanian study, carried out on day 1 and day 5 of life . On day 1, foot length of less than 7cm had a sensitivity of 75%(CI 36-100) and specificity of 99%(CI 97-99) to identify birth weight <1500 grams, foot length of 8cm had a sensitivity of 87%(95% CI 79-94%) and specificity of 60%(95% CI 55-64) to identify birth weight <2500grams, and foot length of 8cm had a sensitivity of 93%(95% CI 82-99) and specificity of 58%(95% CI 53-62) to identify premature babies(Marchant et al., 2010). A similar study carried out in Uganda using an operational foot length cut off of 7.6 cm average of sensitivity and specificity was 83%, positive and negative likelihood ratios of 4.4 and 0.18. and to identify premature babies, an operational cut off measurements of 7.5cm had an average sensitivity and specificity of 88%, and positive and negative likely hood ratio of 6.56 and 0.11 respectively (Nabiwemba et al., 2012). In a hospital based cross sectional study of 1486 neonates with a community follow up done in Ethiopia using an operational cut off foot length of <7.5cm and using New ballard score to determine GA had sensitivity of 81.7% and specificity of 77% PPV of 28.6% and NNP of 97.4%. and using a cut-off point less than 7.7cm to identify low birth weight babies had sensitivity of 84.2 % , specificity of 73.9%,PPV of 35.4% and NPV of 96.5%(Gidi et al., 2019)

Foot length is a simple, low-cost method that can be used to determine gestational age. It has been shown to reduce the risk of exposure to hypothermia in extremely preterm babies in an incubator. It has also been shown to be useful in determining gestational age where other measurements cannot be applied such as hydrocephalus, short-limb dwarfism, and anencephaly(Mercer et al., 1987).The foot is easily available for measurement in patients who are undergoing intensive care treatment and those extreme low birth weight babies without interrupting the care(S. & V., 2017). Foot length measurement from foot print was used by Daga et al in India as a

substitute to birth weight and as an indicator for referral, with reduction in neonatal mortality(Daga et al., 1988). Hirve et al devised a tri-coloured tape for use at home by neonatal caretaker i.e mother of the neonate or Traditional birth attendant .

2.3.3 Measurement of Foot length.

There are various methods that have been used to measure the foot length, such as a plastic sliding vernier callipers, foot prints or special designed foot instruments and none can be said to be the ideal. The south African pilot study by wyk and smith et al measuring foot length on new-borns admitted to Tygerberg Children's Hospital neonatal units who were prospectively recruited between 2009 and 2010 ,they used a plastic sliding callipers to measure the foot and noted less intra observer and interobserver variability(Wyk & Smith, 2016). James et al in the UK in his study of 123 neonates between the ages of 26 weeks and 42 weeks who were measured when they were 12 hours upto 5 days old used a specially designed foot length gauge ; which was designed and constructed at St mary's hospital in Manchester city (James et al., 1979). In Tanzania, merchant et al in a hospital based study with a community follow up meant to measure newborn foot length to identify those in need of additional care in the hospital or within community set up used a transparent plastic ruler(Marchant et al., 2010). In uganda, Nabiwemba et al in a hospital based cross sectional study of 711 new borns with an aim to identify high risk new-born in the community setting, they used three different methods, a foot print on a piece of paper, transparent plastic ruler and tailor's tape measure(Nabiwemba et al., 2012).

Vernier callipers were invented by Pierre vernier (1580-1637), a French engineer and mathematician working in cartography and surveying. It is graduated in two scales. a fixed one and a sliding one. This dual-pitch scale enables readings to be made to a fraction of a division on the main scale. This tool has been known for its precision. It

comes in two forms a 15cm(6inch) and 30cm (12 inch). The digital caliper has an electronic display that displays measurements in millimetres or inches.

Table: 2: Summary of various studies with their sensitivity and specificity

a) Foot length measurement to identify premature babies

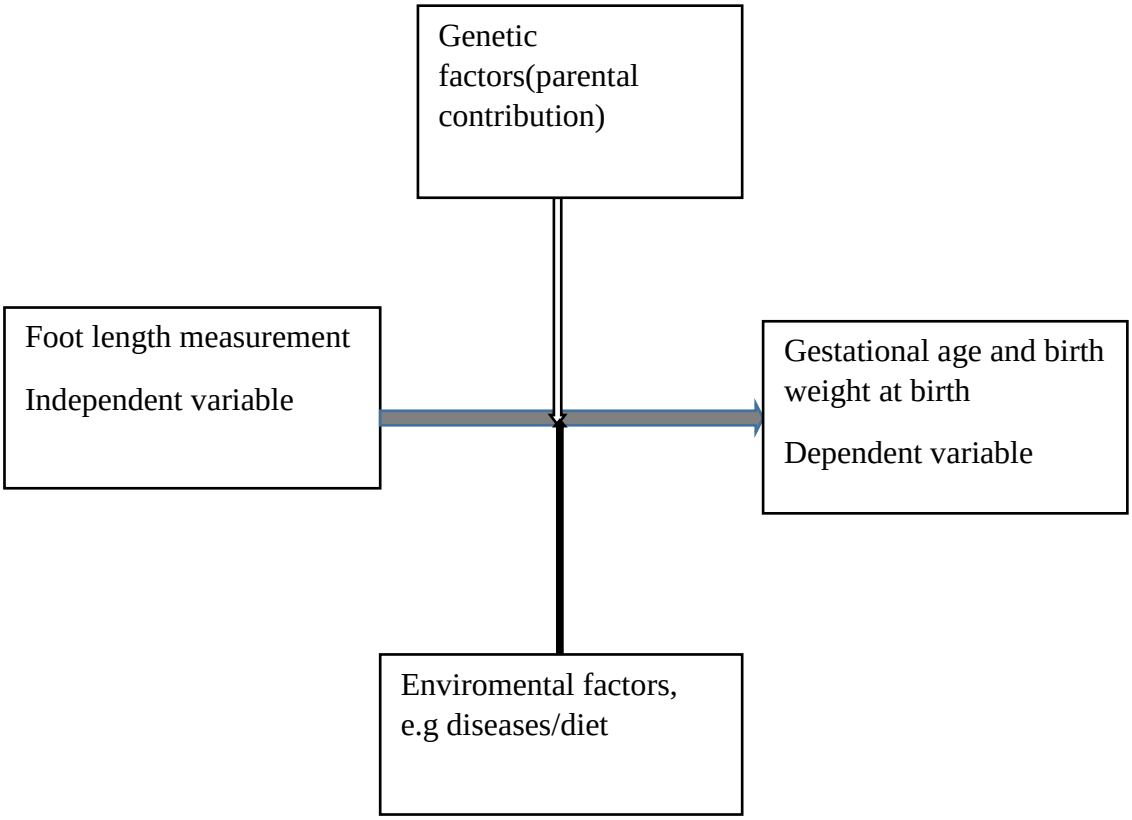
Study	Country/Setting	Study Population	Foot length cut off	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Measuring Tool
Srinivasa et al	Bengaluru/ Hospital	500	7.4cm(<37 weeks GA)	98.81 %	79.09%			Ruler
Singhal et al	Hospital based	1000	7cm(<34wks)	94.76 %	94.30%	81.55%	98.54%	Steel tape
Ashish et al	Nepal/hospital	811	7.8cm(<37 wks)	76.9%	53.9%	10.6%	97.0%	Measuring tape
Mukherjee et al	India/Hospital	351	7.75cm(<37 wks	92.3%	86.3%			Ruler
Nabiwemba et al	Uganda/Hospital	711	7.5cm(<37 wks)	88%	88%	6.56	0.11	Ruler
Marchant et al	Tanzania/ Hospital	529	8cm(<37wks)	93%	58%			Calibrated card
Gidi et al	Ethiopia/Hospital	1486	7.5cm(<37 wks	81.7%	77%	28.6%	98.4%	Ruler

b) Foot length measurement to identify low birth weight babies (<2500grams

Study	Country/setting	Study Population	Foot length cut off measurement	Sensitivity	specificity	PPV/likehood ratio	NPV/ likehood ratio
Srinivasa et al	Bengaluru/Hospital	500	7.4cm	97.0%	87.05		
Ashish et al	Hospital based	811	7.2 cm	75.9%	90.3%	27%	99%
Mukherjee et al	India/Hospital	351	7.85cm	100%	95.3%		
Nabiwemba et al	Uganda/Hospital	711	7.6cm	83%	83%	35.4%	96.5%
Marchant et al	Tanzania/Hospital	529	8cm	87%	60%		
Gidi et al	Ethiopia/Hospital	1486	7.7cm	84.2 %	73.9%		

2.3 CONCEPTUAL FRAMEWORK

The independent variable would be the foot length measurements and the dependent variable would be the gestational age as illustrated below. Foot length can be influenced by genetic factors and also parental genetics .Enviromental or geographical factors can also influence the foot length of a newborn. Maternal diseases such as anaemia, urinary tract infections, congenital intrauterine infections, can affect the growth of the baby, leading to slowing of the growth and resulting in growth restricted baby . Foot length is also dependent on the gestation age of the ne-born.For instance, a 28 week old new-born will have a shorter foot length compared with a 37 week or 40 week old new-born and vice versa.



CHAPTER THREE: METHODOLOGY

3.1 Study design

This was a hospital based cross-sectional study.

3.2 Study site

The study site was the Riley Mother and Baby Hospital at Moi Teaching and Referral Hospital (MTRH). MTRH is a level six hospital located at Eldoret town in Uasin Gishu County. It has a bed capacity of 1000 beds and offers inpatient and outpatient services as well as specialized healthcare services. Riley Mother and Baby Hospital houses neonatal unit and Maternity Unit, with over 10,000 deliveries annually. The hospital serves a population of about 24 million and includes patients from Western Kenya, Rift valley region, and parts of Eastern Uganda, and Southern Sudan.

3.3 Study Period

This study was carried out between June 16th 2021 and June 30th 2022

3.4 Target Population

All neonates who were delivered in MTRH in the study period

3.5 Study population

The following inclusion and exclusion criteria was used to select the study population

3.5.1 Eligibility Criteria

3.5.2 Inclusion Criteria

Babies whose mothers had an ultrasound performed before 23 weeks gestation; and age born less than 24 hours of life.

3.5.3 Exclusion criteria

Babies in severe respiratory distress, those with foot anomalies such as congenital vertical talus, talipes equinovarus,flat foot, metatarsus adductus, pes cavus and

multiple congenital anomalies such as in Edwards' syndrome(trisomy 18) and Patau syndromes (trisomy 13).

3.6 Sample size calculation

The Blume's formula for calculation of sample size using Area Under the Curve was used for sample size estimation (Dias, Vera Junn, Eunsung Mouradian, 2008). A study done in Ethiopia by Gidi, et al., (2019) found Area Under a ROC Curve (AUC) that gave out the highest sensitivity and specificity to be 86% (95% CI 84% – 88%). We projected that our findings would be almost similar to what was found by Gidi, et al., (2019). The minimum sample size required for this study was estimated as below;

$$n = 4(Z_{\alpha/2})^2 \frac{\theta(1-\theta)}{L^2}$$

Where

L= Margin of error of 5% from a 95% CI

θ=Estimated Area under a ROC Curve (AUC) of 84%

$Z_{\alpha/2}$= Standard normal critical value for two sided test at α type I error (α=0.05, z1-α/2= 1.96)

Using the above formula and the projected estimates, the minimum sample size required was 414.

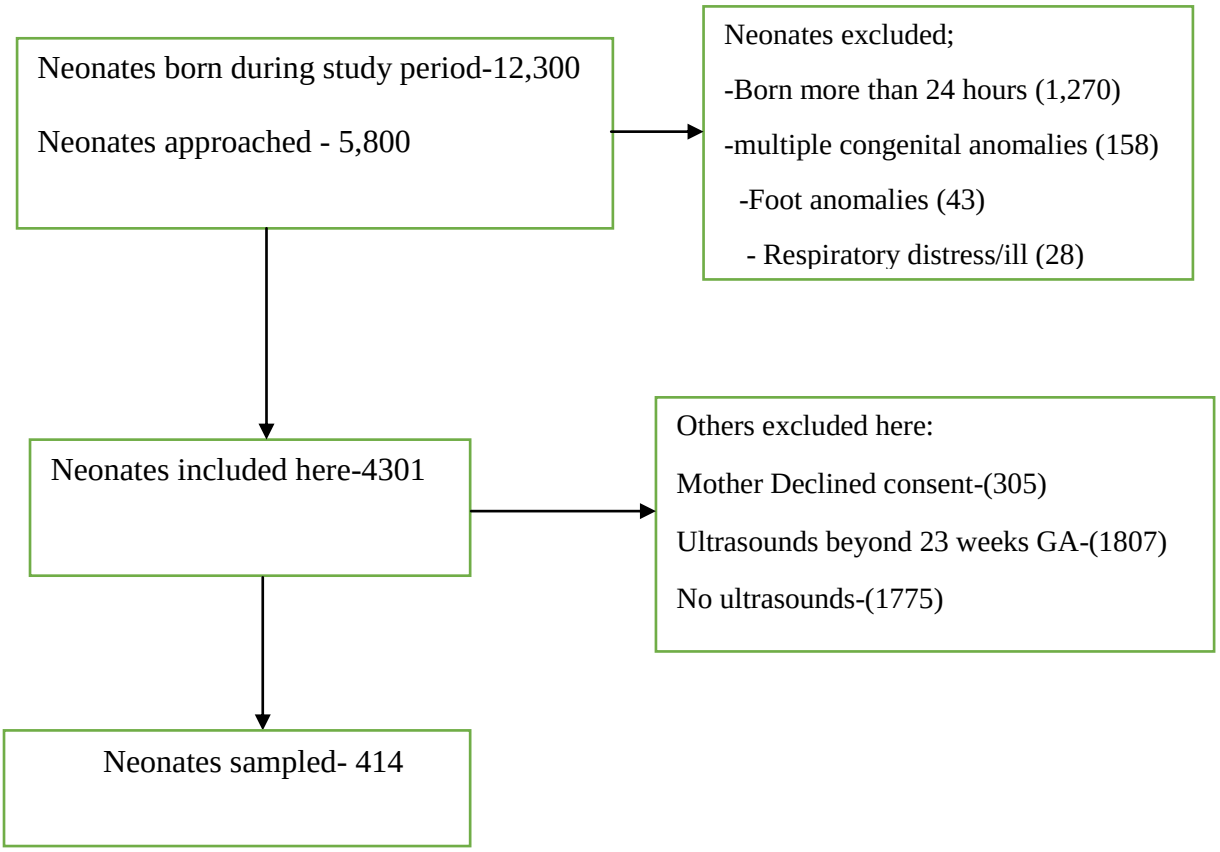
3.7 Sampling technique

About 700 preterm and 11,600 live term neonates were delivered in MTRH in 2020. Based on preliminary survey we noted that about 0-4 mothers are admitted daily with ultrasound performed before 23 weeks gestation. Since, the recruitment period was 12 months, for the 414 neonates we used consecutive sampling technique to obtain the neonates required for the study.

3.8 Recruitment schema:

We had a total of 12300 deliveries in the study period, we included babies who had been delivered within 24 hours, whose mothers have ultrasounds performed before 23 weeks. And excluded those who had multiple congenital anomalies (n=158), foot anomalies such as talipes equinovarus (n=43) , and those who had respiratory distress (n= 28). Also excluded those more than 24 hours of age (n= 1,270) ; Mothers who declined to consent (n=305), those who had ultrasounds but were beyond 23 weeks gestation (n= 1807), and those with no ultrasounds at all (n=1775). And ended up with our final sample size of 414 new-born.

The following recruitment schema was used followed to recruit neonates for the study



3.9 Study Execution Plan

The research study began with the principal investigator (P.I.) recruiting two research assistants who were qualified clinical officers that were trained on the research study. The research assistants were trained on the use of the measuring tools ,that is ; Digital vernier calliper, transparent plastic ruler and the digital salter scale, the criteria for choosing neonates, how to take consent from the mothers and on how to sample the neonates for the study. They were also trained on basic skills on how to examine the neonate and identify those with foot anomalies such congenital vertical talus, talipes equinovarus,flat foot, metatarsus, pes cavus and multiple congenital anomalies such as in Edwards' syndrome(trisomy 18) and Patau syndromes (trisomy 13) ,who tend to have foot anomalies such as rocker bottom feet, that may affect the outcomes of our measuremt. After training the research assistants, the Principal investigator then visited the post natal ward and the new born unit to introduce himself and the research assistants to the health care providers at the unit. This began with meeting the in charge of new born unit and also the in charge of mother and baby labour ward unit. The P.I. then sensitized the staff about the study to be conducted. This was done on one on one basis with the nurses and doctors covering the unit at each specific shift and within there working areas, in addition to that, the PI also placed a notice on the various notice boards within the unit showing the criteria for the study and this included the contacts of the PI as well.

Our recruitment was in the post natal ward and the mother and baby new born unit. We displayed notification asking the clinicians and nurses working in the various units to notify the principal investigator if there are any mothers who had done an ultrasound before 23 weeks gestation, and were being admitted or they had delivered in the last 24 hours. We then consented the mothers as follows.

The consenting process was carried out as follows:

- Mothers were approached by the principal investigator or the research assistant, then we introduced ourselves and what we were intending to do.
- Consent was always obtained before beginning or commencing any study-specific procedures.
- We ensured the mother was comfortable for the informed consent process at all times and that the mother was not in any danger. We also ensured that were not standing in the way of the nurses and doctors attending to her or preventing her from receiving the treatments that she needed at any particular time
- We then explained in details the consent process to the subject's parent, in this case the mother of the baby or both parents if both of them were by the bed side .
- We made certain that the parent understood that they had a choice,to either refuse or consent at any particular stage of the study and we informed them that they could contact the principal investigator if they feel uncomfortable proceeding or participating in the study
- We responded to all the questions and address all the concerns from the parent as much as possible before allowing them to sign the consent form.To the level possible, we made sure that the subject's parents understood enough details about the research study so as to give an informed consent.
- To the much of our ability, We made sure the subject's parent consent was at liberty from coercion or other undue influence and that their participation would not interfere with the care given to the mother or the baby in MTRH.

- Since the informed consent process continues throughout the subject's participation in the study, the consent was verbally confirmed on a continuing basis as the examination of the neonate and measurement of the foot was being done.

After the consent was fully obtained. We then obtained the obstetric ultrasound details and the last menstrual period dates from the mothers file; the gestation age was then calculated using the obstetric wheel or the online Medscape calculators for gestation age and recorded it on the data collection form. The Last Menstrual Period dates were also obtained from the file or from the mother; the gestation age was then calculated using the obstetric wheel or the online Medscape calculators for gestation age and recorded in the data collection form. The time of delivery was then obtained from the mothers file and calculated the age of the baby in hours from the time of delivery to the time of taking the foot length measurements, this was then entered on the data collection form. All mothers had delivered within the last 24 hours by the time consent was taken. The right foot length was held firmly in one position by the observer using the left hand then using the right hand to adjust the measuring tool then place it firmly but gently in between the Posterior margin of the heel to the tip of the longest toe. This was measured by either of the observers and recorded. This was done twice using the Silverline 6" inch digital callipers and the 150 mm hard transparent Pelican plastic ruler by one observer. Two measurements were taken on the right foot by one observer and recorded; if they differed by more than 2mm then we did a 3rd measurement. We then calculated an average of the three measurements taken and entered as one figure in centimetres on the data collection form.

In the study, foot length was measured within the first 24 hours using two different methods. The digital vernier caliper and the transparent plastic ruler were used to measure the foot length in the present study .The measurements from each tool were recorded separately in the data collection form.

3.8.1 Methods of measuring foot length

Digital Vernier callipers- There are different vernier callipers which are availale in the market. Some of them have digital readings and others are manually read. The pilot study done by Wyk J smith et al in South Africa used a plastic vernier calliper to measure the foot length. We used a Silverline 6 inch digital Vernier calliper (fig 1) to measure the gestational age of the newborn. Before using the tool. We turned on using the on and off button. We then brought the external jaws together then press the zero button. After this, the neonate's foot was then placed in the lateral position then held at the ankle; the foot was placed in between the external jaws of the Silverline 6 inch digital Vernier calliper (fig 1), the jaws were then adjusted carefully to fit from the posterior margin of the heel to the tip of the longest toe. The locking screw was then tightened so that the jaws do not move apart. Measurements were then read from the LCD display and recorded on the data collection form. Two measurements were taken on the right foot and recorded if they differ by more than 2mm then we repeated a 3rd measurement, We then calculated an average of the three measurements taken and entered as one figure in centimetres on the data collection form. The measurements were done by one observer. The measurements on the left foot were done only for babies who probably had an intravenous access on the right foot and therefore was not able to take the measurements on that foot. We then calculated an average of the measurements taken.

Figure 1: Digital vernier calliper

1. Transparent plastic ruler- The baby's foot was held firmly with the help of an assistant, the hard Pelican 6" plastic ruler was then pressed firmly on the plantar surface of the foot and measurements taken to read from the posterior margin of the heel to the tip of the longest toe. The measurements were repeated and recorded, then an average of the two measurements were taken . in the event the measurements differed by more than 2mm then a 3rd measurement was taken and an average of the three measurements were done and recorded on the data collection tool. The right foot was measured. The left foot was measured only if the right foot was not possible to measure, For example, if there is an intravenous access or exposed wound on that foot.

Figure 2: Transparent plastic ruler

The baby's weight was measured using a digital salter scale in grams(with resolution of 10 grams) and recorded in the data collection form. The baby clothes were entirely removed before taking the weights. Light linen was placed on the weighing scale to prevent hypothermia by conduction from the baby then calibrated each time before being used. Measurements were repeated twice to ensure that they were accurate.

3.8.2. Methods of determining gestation age of New-born:

Gestation age was determined using the gold standard of obstetric ultrasound; Which was performed before 23 weeks gestation. The decision to use ultrasound was based on the fact that these is the universally accepted gold standard for determining gestation age and is better compared to new ballard scores and other methods of determining the gestation age in terms of the accuracy as compared to other various methods. We specifically chose 23 weeks gestation and below because of 3 reasons: 1. Practice guideline by society of obstetrics Canada published as guideline number 388 volume 41,issue no 10, P1497-1507, in october 2019 recommended that gestation age done at 23 and below is a good method to estimate gestation age and delivery date(Butt et al., 2014). 2. The pilot study that has been done in Africa to assess foot length in determining gestation age used ultrasounds who were 23 weeks gestation and below, so our study will be comparable to their study(Wyk & Smith, 2016). 3. Considering that according to KDHS 2014,only 23 percent of the women attend ANC before 4^{th} month, we anticipated that there would be very few mothers with ultrasounds earlier than 23 weeks

The ultrasounds used in this study were performed by qualified Ultrasonographers, with a minimum qualification of diploma in radiology and imaging medical sciences. The gestation age was determined by measurements of crown-rump length, Biparietal diameter, head circumference, Abdominal circumference and Femur Length. Also, more than half of the ultrasounds done were reviewed by a qualified radiologist to ascertain the quality of the ultrasounds from the ultrasonographers

The Last menstrual period dates were also obtained from the mothers file and recorded on the data collection form

3.9 Data management, Analysis, and Presentation

Data was imported into STATA/MP Version 13, coded, cleaned, and analysed. Descriptive statistics were done to explore and summarized using graphs and means. Where numerical variable such age and foot measurement was summarized as means and their corresponding standard deviation while categorical data such as sex was summarised as frequency and percentage. The babies were categorized as 'small', 'large', and 'appropriate' for gestational age, using Fenton's reference charts. While weight obtained were categorised into categorical variables such (<2500grams and ≥2500grams). Also gestation age was categorised categorical variables such (<37weeks and ≥37weeks). Thereafter the categorised variables were summarised as frequency and their corresponding proportions. For the foot length measurements we used the mean calculated from the two observers. **To answer objective one**, Receiver operating characteristic curves was used to identify optimal cut-point for feet measurements that identify preterm and low birth weight neonates. This was done separately for both the Vernier Calliper and ruler foot measurements. The cut off was based on the Liu and Youden methods using roctab Stata command. In addition, *t*test was done to compare the mean foot length between binary categories of gestation age and birth weight, where a p-value of less than 0.05 was interpreted as statistically significant. **To answer objective two,** sensitivity, specificity and positive and negative predictive values were calculated for different cut-points. The area under the curve (AUC) was used to describe the overall accuracy of foot length measurements in diagnosing prematurity and underweight. Where a value of 0 was interpreted as perfectly inaccurate and a value of 1 reflects a perfectly accurate foot length measurement cut off for diagnosing underweight or preterm. An AUC of 0.5 would

suggest no discrimination, 0.7 to 0.8 was considered acceptable, 0.8 to 0.9 was considered excellent and more than 0.9 was considered outstanding.

3.10 Ethical considerations.

Approval from IREC and institutional approval from MTRH CEO were sought prior to commencing the study. Written Consent was taken from the participants (neonates)' parents. No incentives or coercion was done for one to participate in the study.

There was no cost implications for the subjects. The results of the study will be disseminated to the primary clinicians in the new born unit and other health care workers to improve patient care.

Confidentiality was maintained throughout the study. The findings of the study will be shared with the MTRH management, the primary clinicians of the patients, and the department of paediatrics.

I intend to publish the findings of my research for the benefit of the larger community.

CHAPTER FOUR: FINDINGS

4.0 Introduction

The results are based on 414 babies born between 1st June 2021 and 30th June 2022, who met the eligibility criteria. With an aim of determining the accuracy of foot length in determining the gestational age of a new born in comparison to the Gestation by ultrasound done at or before 23 weeks at MTRH Eldoret.

4.1 Demographic Characteristics

We recruited a total of 414 Neonates. On average the neonates were aged 12.5 ±6.4 hours at the time of data collection ranging from 1 hour to 23.9 hours.

Table 3: **Demographic Characteristics**

Variable	Category	Frequency	Percentage
Gender	Male	221	53.4
	Female	193	46.6
Birth Weight in grams	<1000	2	0.5
	1000 – 1499	13	3.1
	1500 - 2499	44	10.6
	≥2500	355	85.8
Gestation age (LMP) in weeks	≤32	17	4.1
	32 – 33	4	1
	34 - 36	35	8.4
	≥37	358	86.5
Gestation age (US) in weeks	≤32	15	3.6
	32 – 33	9	2.2
	34 - 36	35	8.4
	≥37	355	85.8

Males were at 53.4% (n=221) compared to females at 46.6% (n=193)(Table 3).

The mean birth weight was 3019.6 ±626.2 grams ranging from 840 grams to 4540 grams. A total of 59 (14.3%) newborns were below 2500 grams at birth, and the same proportion of 59 (14.3%) were premature (<37 weeks) as per the ultra sound gestation age. 26% of the neonates had prenatal ultrasounds done between 6 weeks and 13 weeks (plus 6 days), while the rest (74%) were done between 14 weeks and 23 weeks.

The number of those classified as premature (<37 weeks) through last menstrual period were 56(13.5%). However though these numbers seemed similar there was high level of individual misclassification.

We had two children who had extremely low birth weight (<1000 grams) consisting of 0.5 percent of the neonates, and thirteen who were between as very low birth weight (1000-1499grams), consisting of 3.1 percent and those classified as low birth weight(1500-2499) as 10.6 percent of the neonates. The children who were above 2500 grams, were 355 of the 414 neonates, consisting of 85.5 percent of the babies included in the study.

When we classified the m based on the Gestational age by last menstrual period. 17 of the neonates were less than 32 weeks gestation, which was 4.1 percent of the neonates, those who were between 32-33.9 weeks gestation were 4, which was 1 percent of the neonates, and those who were between 34 to 36 weeks were 35, consisting of 8.4 percent of the babies , the majority of them were classified as above 37 weeks gestation this was about 86.5 percent of the neonates(Table3).

Using our gold standard of gestation by ultrasound which was done before 23 weeks gestation. There were 15 babies who were less than 32 weeks in our study and this was about 3.6 percent. Another category of 32 to 33 weeks had 9 babies consisting of about 2.2 percent and the third category were those between 34 to 36 weeks, which was 35 babies, consisting of 8.4 percent, the last category were those above 37 weeks gestation. Which formed the majority at 355, consisting of 85.8 percent (Table 3)

Table 4: US GA by LMP GA and BWT

Variable	Category	US gestation age	
		< 37	**≥37**
Birth Weight in grams	<2500	37	22
	≥2500	22	333
Gestation age (LMP)	<37	44	12
in weeks	≥37	15	343

Out of the 414 neonates 27(6.5%) were classified differently in regards to being premature or not. In addition, 22 neonates were said to have birth weight of more than 2500 grams but had a gestation of more than 37 weeks (were mature)(Table 4)

Table 5: Weight for gestation age

WGA	Frequency	Percent
Appropriate for GA	397	95.9
Small for GA	10	2.4
Large for GA	7	1.7
Total	414	100

The 414 babies were classified based on the gold standard of ultrasound as those who are small, large or appropriate for gestation age, the definitions of each were based on the Fenton's weight percentile chart, where those less than 10 percentile weight for age are classified as small for gestational age and those who are more than 95% percentile weight for age are classified as large for gestational age. Based on Källén et al. (2012) who defined SGA defined as <2 SD from expected weight at the relevant gestational week and LGA as >2 SD from expected weight at the relevant gestational week.

10 children were small for gestational age, consisting of 2.4 percent, while 7 babies were classified as large for gestational age.which was 1.7% and the other 397 babies were appropriate for gestational age,which was 95.9 percent. All babies were included in the final analysis of the foot length (Table 5)

4.2. Foot Length Measurements using hard plastic ruler and digital callipers.

In the study, We used two different methods of measuring the foot length ; the Silverline digital vernier callipers with a range of 0 to 150mm and the Pelican hard plastic ruler with a range of 0 to 15cm and rounded to the nearest 0.01cm.

Table 6: Foot length by Birth weight

Variable	Category	Foot length in cm	
		Mean (SD)	Min – Max
	Vernier caliper		
Birth Weight in grams	<1000	5.12 (0.4)	4.8 – 5.4
	1000 – 1499	5.65 (0.42)	4.9 – 6.4
	1500 - 2499	6.87 (0.46)	5.6 – 7.7
	≥2500	7.75 (0.36)	6.6 – 8.8
	Ruler		
Birth Weight in grams	<1000	5.05 (0.49)	4.7 – 5.4
	1000 – 1499	5.55 (0.4)	4.7 – 6.2
	1500 - 2499	6.83 (0.46)	5.6 – 7.7
	≥2500	7.72 (0.37)	6.5 – 8.8

We calculated the means for the different categories of weights (extremely low birth weight(less than 1000 grams), very low birth weight(less than 1500 grams), low birth weight(less than 2500 grams), and normal birth weight(above 2500 grams) for each measurement of the foot length. While using the Silverline digital vernier calliper, the mean foot length for babies less than 1000 grams(extremely low birth weight) was 5.12 (0.4) cm with a range of 4.8 cm to 5.4 cm, and for the second category of very low birth weight babies(1000-1499 grams) the mean foot length was 5.65(and a

standard deviation of 0.42) and a range of 4.9 cm to 6.4 cm, the mean for the third category of low birth weight(1500-2499) was 6.87 cm (with standard 0.46 cm) and with a range of 5.6 cm to 7.7 cm. The last category of babies were those who had weights above 2500 grams, considered as normal weight babies, and in this group we had an average foot length of 7.75(0.36) cm with a range of 6.6 to 8.8 cm(Table 6)

Foot length measurements using the pelican hard plastic ruler showed the following measurements in the different weight categories ; for extremely low birth weight (less than 1000 grams) the mean foot length was 5.05 cm (with a standard deviation of 0.49) and a range of 4.7 cm to 5.4cm , for the second category of very low birth weight (1000 - 1499 grams) the mean foot length was 5.55 cm (with a standard deviation of 0.4 cm) and a range of 4.7 cm to 6.2 cm. and for those who had low birth weight (1500 to 2499) had a mean foot length of 6.83 cm (with a standard deviation of 0.46 cm) , then lastly the babies who had weight of 2500 kgs and above the mean foot length was 7.72 cm with a standard deviation of 0.37 cm and a range of 6.5 cm to 8.8 cm(Table 6).

In summary, the average foot length using Vernier caliper for those who had a birth weight of more than or equal to 2500 grams was 7.75 ±0.36 cm but slightly lower (7.72 ±0.37 cm) by 0.03 cm when measured using a ruler. And for those weighing less than 1000 grams had an average foot length of 5.12 ±0.4 and 5.05 ±0.5 when measured with Vernier caliper and ruler respectively (Table 6).

Gestation done by ultrasound was our gold standard. We classified based on gestation by obstetric ultrasound and this are the findings; Using vernier calliper as the tool of measuring the foot length. For those we classified using the obstetric ultrasound the mean foot length for less than 32 weeks was 5.72 cm with standard deviation of 0.56

cm and a range of 4.8 cm to 7.19 cm, and the mean foot length measurements for those between 32 weeks to 33 weeks gestation by ultrasound was 6.45 cm with a standard deviation of 0.71 cm and a range of 4.9 cm to 7.1 cm .The next category is for those who are between 34 weeks to 36 weeks gestation , their mean foot length measurement was 7.11 cm with a standard deviation of 0.51 cm and a range of 5.76 cm to 7.91 cm. Last category, for those who were 37 weeks gestation and above the mean foot length measurement was 7.73 cm with a standard deviation of 0.39 cm and a range of 6.2 cm to 8.81 cm.

Similarly. these were the findings when using the Pelican hard plastic ruler as the tool for measuring the foot length and using the gestation by obstetric ultrasound to determine the gestational age; for those who were less than 32 weeks the mean foot length was 5.65 cm with a standard deviation of 0.59 cm and a range of 4.7 cm to 7 cm. Secondly, those who had ultrasound gestation between 32 and 33 weeks the mean foot length was 6.34 cm with a standard deviation of 0.68 cm and a range of 5 cm to 7 cm Subsequently, those who had gestation by ultrasound at between 34 to 36 weeks the mean foot length was 7.09 cm with a standard deviation of 0.51 cm and a range of 5.7 cm to 8 cm. Lastly, the neonates classified as 37 weeks and above had a mean foot length of 7.7 cm with a standard deviation of 0.4 cm and a range of 6 cm to 8.8 cm

In summary, the average foot length using Vernier caliper for those who had an ultra sound gestation age of more than or equal to 37weeks was 7.73 ±0.39 cm but slightly lower (7.7 ±0.4 cm) when measured using a ruler. And for those with an ultra sound gestation of less than or equal to 32weeks had an average foot length of 5.72 ±0.56 and 5.65 ±0.59 when measured with Vernier caliper and ruler respectively.

The gestation age for the 414 neonates was estimated using the last menstrual period and the obstetric ultrasound. The gestation done by ultrasound was our gold standard for this study.

Table 6a: Foot length by US Gestation Age

Variable	Category	Foot length in cm	
		Mean (SD)	Min – Max
	Vanier caliper		
US GA in weeks	≤32	5.72(0.56)	4.8 – 7.19
	32 – 33	6.45(0.71)	4.9 – 7.1
	34 – 36	7.11(0.51)	5.76 – 7.91
	≥37	7.73(0.39)	6.2 – 8.81
	Ruler		
US GA in weeks	≤32	5.65(0.59)	4.7 – 7
	32 – 33	6.34(0.68)	5 – 7
	34 - 36	7.09(0.51)	5.7 – 8
	≥37	7.7(0.4)	6 – 8.8

We categorized the neonates based on the different ways of assessing the gestational age (that is by last menstrual period and by ultrasound). We begin with the gestation as classified by last menstrual period. Using vernier calliper as the tool of measuring the foot length. For those we classified using the last menstrual period the mean foot length for less than 32 weeks was 5.73 cm with standard deviation of 0.48 cm and a range of 4.8 cm to 6.74 cm, and the mean foot length measurements for those between 32 weeks to 33 weeks gestation was 6.52cm with a standard deviation of 1.11 cm and a range of 4.9 cm to 7.38 cm .Third category is for those who are between 34 weeks to 36 weeks gestation , their mean foot length measurement was 7.03 cm with a standard deviation of 0.54 cm and a range of 5.76 cm to 7.91 cm. Lastly, for those who were 37 weeks gestation and above the mean foot length measurement was 7.73 cm with a standard deviation of 0.38 cm and a range of 6.2 cm to 8.81 cm(Table 6a)

Table 7: Foot length by Gestation Age by LMP

Variable	Category	Foot length in cm	
		Mean (SD)	Min – Max
	Vernier calliper		
LMP GA in weeks	≤32	5.73(0.48)	4.8 – 6.74
	32 – 33	6.52(1.11)	4.9 – 7.38
	34 - 36	7.03 (0.54)	5.76 – 7.91
	≥37	7.73(0.38)	6.2 – 8.81
	Ruler		
LMP GA in weeks	≤32	5.65(0.51)	4.7 – 6.7
	32 – 33	6.39(0.99)	5 – 7.3
	34 - 36	6.99(0.53)	5.7 – 8
	≥37	7.7(0.39)	6 – 8.8

On the Other hand , these were the findings when we using the hard pastic ruler as the tool for measuring the foot length and using the gestation by last menstrual period to determine the gestational age; for those who were less than 32 weeks the mean foot length was 5.65 cm with a standard deviation of 0.51 cm and a range of 4.7 cm to 6.7 cm. Secondly, those who had LMP gestation between 32 and 33 weeks the mean foot length was 6.39 cm with a standard deviation of 0.99 cm and a range of 5 cm to 7.3 cm . Thirdly, those who had gestation by LMP at between 34 to 36 weeks the mean foot length was 6.99 cm with a standard deviation of 0.53 cm and a range of 5.7 cm to 8 cm. Fourth, the neonates classified as 37 weeks and above had a mean foot length of 7.7 cm with a standard deviation of 0.39 cm and a range of 6 cm to 8 cm.

In summary, the average foot length using Vernier calliper for those who had an LMP gestation age of more than or equal to 37weeks was 7.73 ±0.38 cm but slightly lower (7.7 ±0.39 cm) when measured using a ruler. And for those with an LMP gestation of less than or equal to 32weeks had an average foot length of 5.73 ±0.48 and 5.65 ±0.51 when measured with Vernier calliper and ruler respectively (Table 7)

4.2.1 Foot Length Measurement Cut off point to Identify Premature and Low Birth Weight Babies

To identify operational cut off foot length measurement that can be used to identify premature and low birth weight babies we used only those babies that were appropriate for age (n=397).

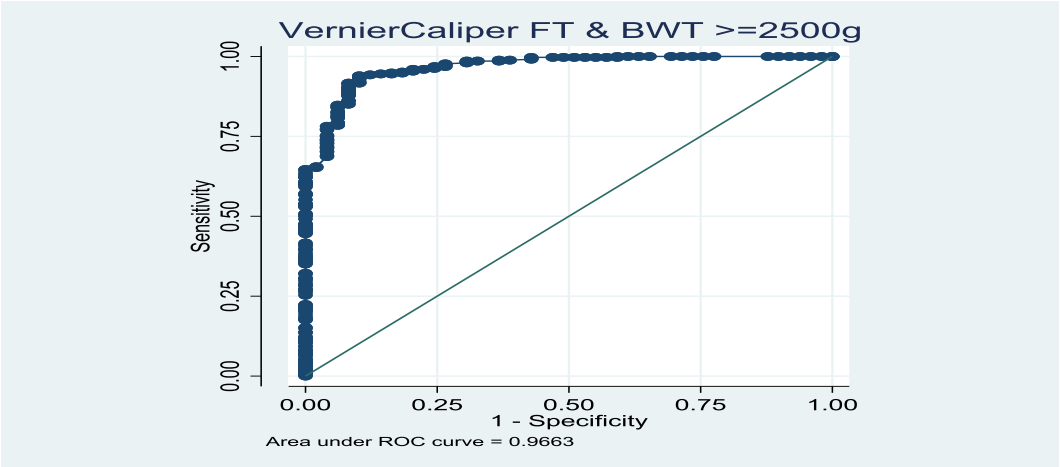


Figure 3: Predicting LBW (≥2500) using Vernier Caliper Foot length in cm

A Vernier caliper foot length of ≥7.19 cm is the best cut point to identify babies with a birth weight of ≥2500 grams.

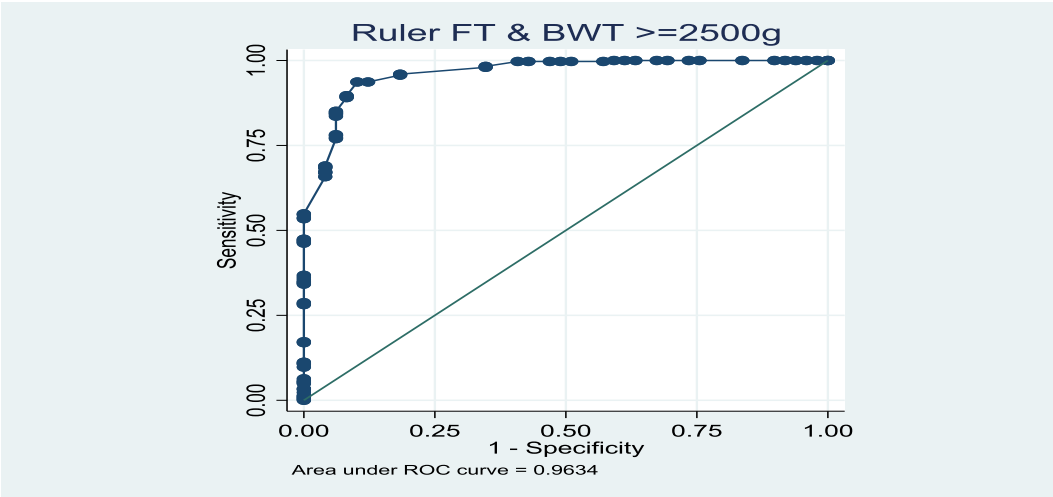


Figure 4: Predicting LBW (≥2500) using Ruler Foot length in cm

A ruler foot length of ≥7.14 cm is the best cut point to identify babies with a birth weight of ≥2500 grams (Fig 4).

Table 8: Vernier and ruler foot length by BWT (≥2500gram)

Variable	Measure	<2500 grams	≥2500 grams	p-value
Vernier caliper FL	Mean (SD)	6.54(0.73)	7.75(0.36)	<0.001
	Minimum	4.8	6.58	
	Maximum	7.74	8.81	
Ruler FL	Mean (SD)	6.49(0.74)	7.72(0.37)	<0.001
	Minimum	4.7	6.5	
	Maximum	7.7	8.8	

On average babies weighing less than 2500 grams had a Vernier caliper foot length of 6.54 ±0.73 cm while those weighing more than or equal to 2500 grams had a Vernier caliper foot length of 7.75 ±0.36 cm and the difference in these two average was statistically significant (p<0.001)(Table 8).

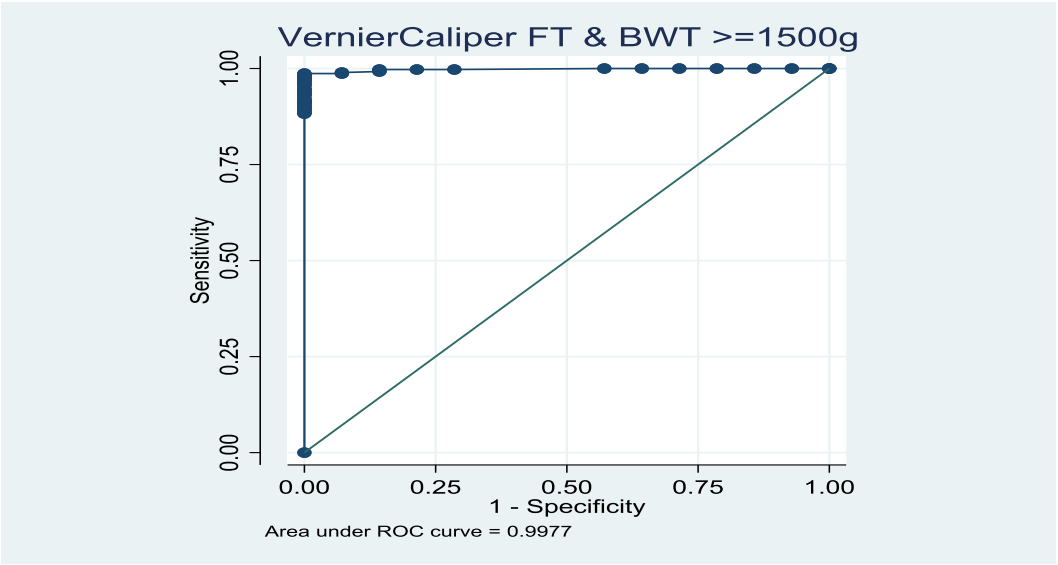


Figure 5: Predicting LBW (≥1500) using Vernier Caliper Foot length in cm

A Vernier caliper foot length of ≥6.3575 cm is the best cut point to identify babies with a birth weight of ≥1500 grams (fig 5).

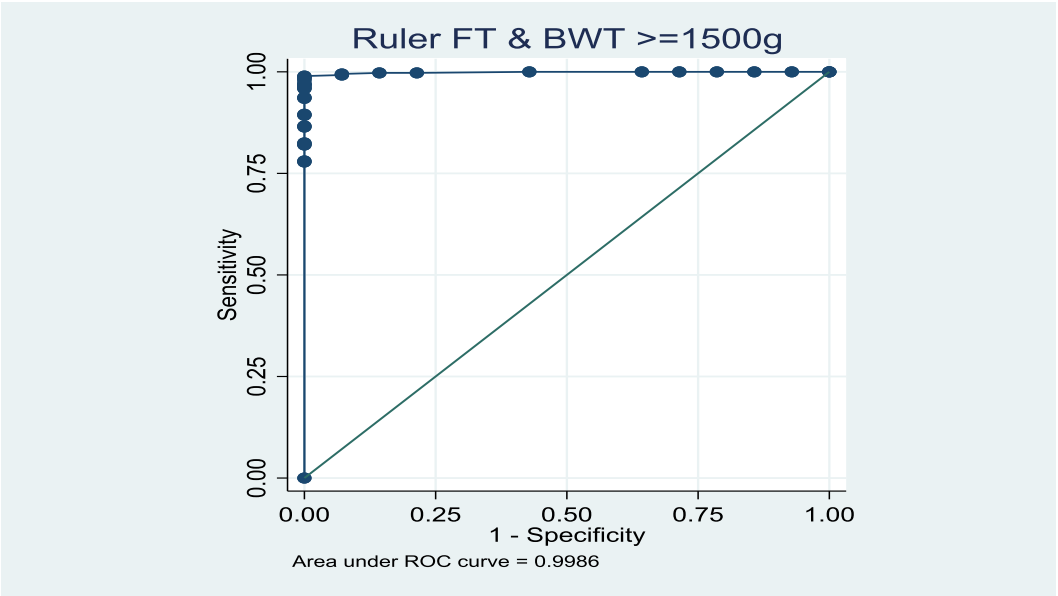


Figure 6: Predicting LBW (≥1500) using Ruler Foot length

A ruler foot length of ≥6.2 cm is the best cut point to identify babies with a birth weight of ≥1500 grams (Fig 6).

Table 9: Vernier and ruler foot length by BWT (≥1500gram)

Variable	Measure	<1500 grams	≥1500 grams	p-value
Vernier caliper FL	Mean (SD)	5.58(0.45)	7.65(0.46)	<0.001
	Minimum	4.8	5.6	
	Maximum	6.36	8.81	
Ruler FL	Mean (SD)	5.48(0.43)	7.62(0.47)	<0.001
	Minimum	4.7	5.6	
	Maximum	6.2	8.8	

On average babies weighing less than 1500 grams had a Vernier caliper foot length of 5.58 ±0.45 cm while those weighing more than or equal to 1500 grams had a Vernier caliper foot length of 7.65 ±0.46 cm and the difference in these two average was statistically significant (p<0.001)(Table 9).

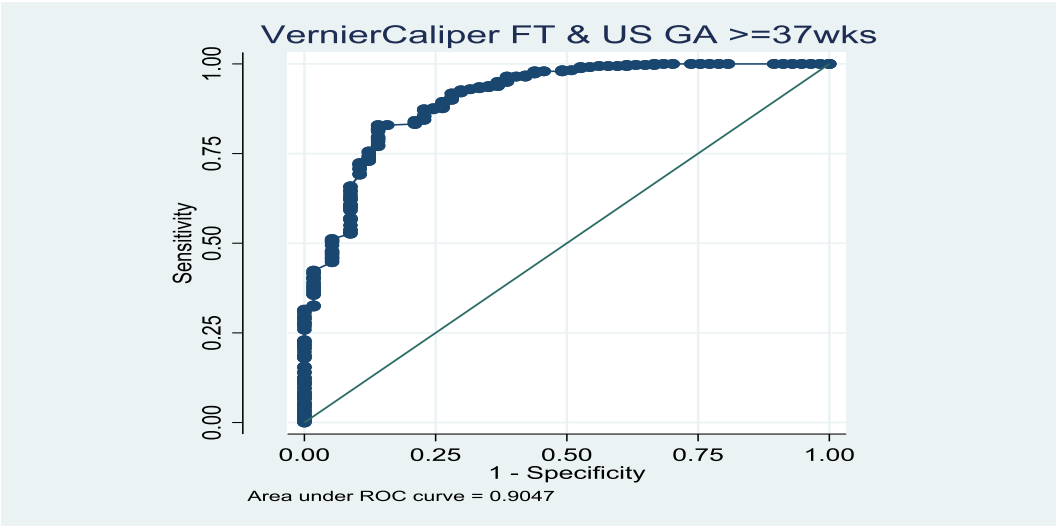


Figure 7: Predicting Premature (≥37 weeks) using Vernier Caliper Foot length in cm

A Vernier caliper foot length of ≥7.412 cm is the best cut point to identify babies with an ultra sound gestation age of ≥37 weeks(Fig7).

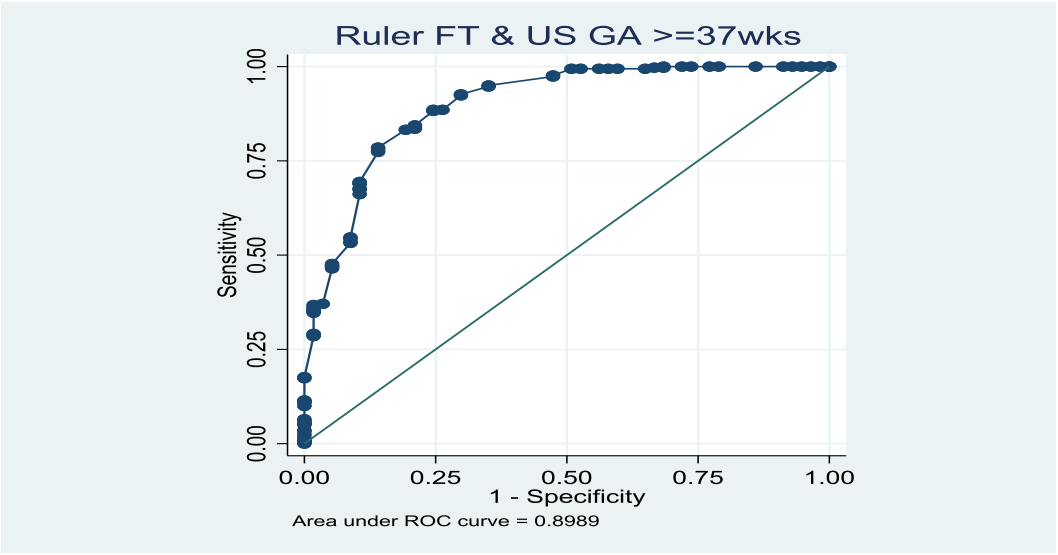


Figure 8: Predicting Premature (≥37 weeks) using Ruler Foot length in cm

A ruler foot length of ≥7.4 cm is the best cut point to identify babies with an ultra sound gestation age of ≥37 weeks (fig 8).

Table 10: Vernier and ruler foot length by gestation age (≥37weeks)

Variable	Measure	<37 weeks	≥37 weeks	p-value
Vernier caliper FL	Mean (SD)	6.65(0.81)	7.73(0.39)	<0.001
	Minimum	4.8	6.2	
	Maximum	7.91	8.81	
Ruler FL	Mean (SD)	6.61(0.83)	7.7(0.4)	<0.001
	Minimum	4.7	8	
	Maximum	6	8.8	

The mean digital vernier calliper foot length for babies less than 37 weeks gestation by ultrasound was 6.65 cm with a standard deviation of 0.81 cm and P value(<0.001) in the present study with a range of 4.8 cm to 7.91 cm. The mean Vernier foot length for babies more than 37 weeks gestation by ultrasound was 7.73 cm with a standard deviation of 0.39 cm, and a P value of (<0.01), and a range of 6.62 cm to 8.81 cm (Table 10)

While the mean hard plastic ruler foot length measurement for babies who were less than 37 weeks gestation (preterm) was 6.61 cm with a standard deviation of 0.83 cm and a range of 4.7 cm to 6 cm and p value of (<0.001). subsequently , for babies who were above 37 weeks (term) was 7.7 cm with standard deviation of 0.39 cm and a p value of (<0.001). (Table 10)

In summary, average babies with an ultra sound gestation age of less than 37 weeks had Vernier caliper foot length of 6.65 ±0.81 cm while those with an ultra sound gestation age of more than or equal to 37weeks had Vernier caliper foot length of 7.73 ±0.39 cm and the difference in these two average was statistically significant (p<0.001)(Table 10).

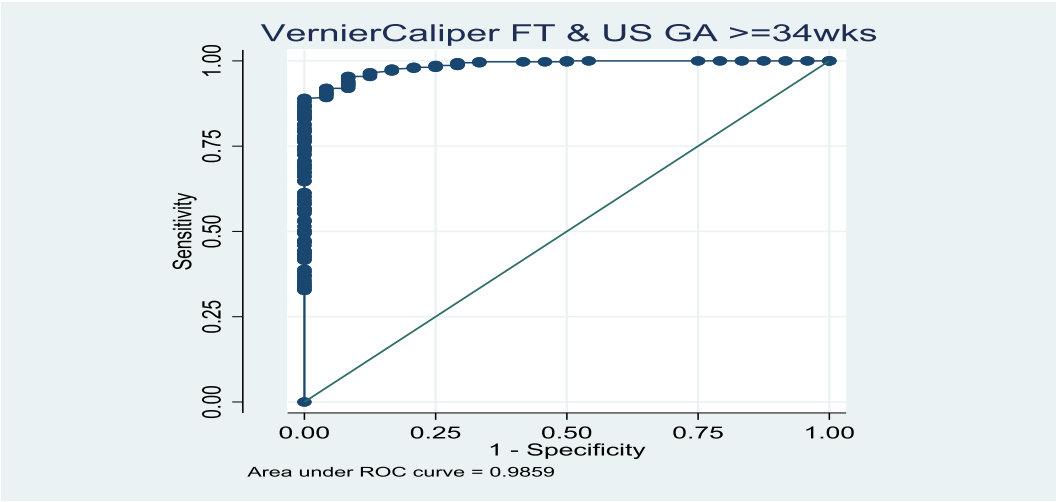


Figure 9: Predicting Premature (≥34 weeks) using vernier Foot length in cm

A Vernier caliper foot length of ≥7.19 cm is the best cut point to identify babies with an ultra sound gestation age of ≥34 weeks (Fig 9)

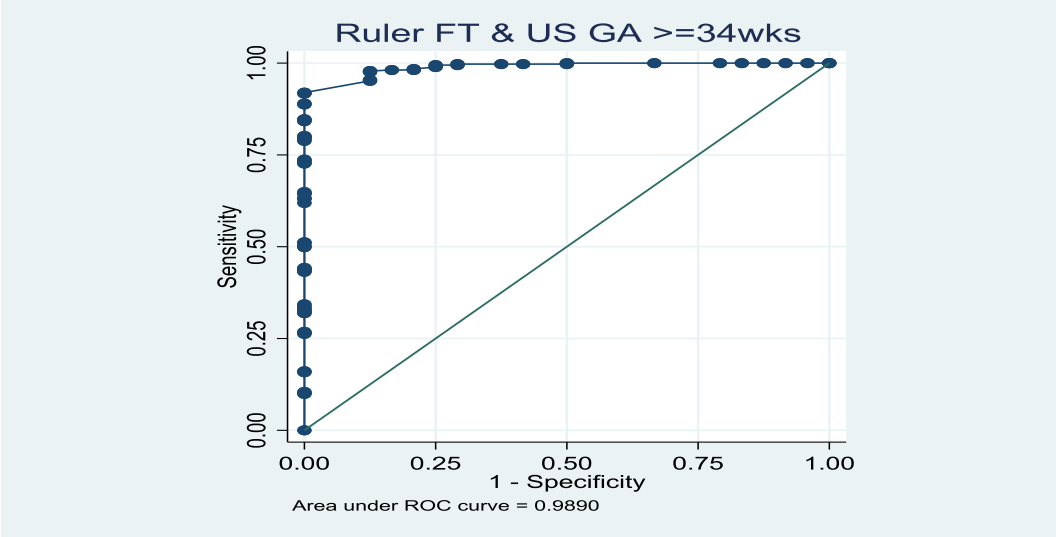


Figure 10: Predicting Premature (≥34 weeks) using Ruler Foot length in cm

A ruler foot length of ≥7 cm is the best cut point to identify babies with an ultra sound gestation age of ≥34 weeks (Fig 10).

Table 11: Vernier and ruler foot length by gestation age (≥34weeks)

Variable	Measure	<34 weeks	≥34 weeks	p-value
Vernier caliper FL	Mean (SD)	5.99(0.7)	7.68(0.44)	<0.001
	Minimum	4.8	7.19	
	Maximum	5.76	8.81	
Ruler FL	Mean (SD)	5.91(0.69)	7.64(0.45)	
	Minimum	4.7	7	
	Maximum	5.7	8.8	

On average babies with an ultra sound gestation age of less than 34 weeks had Vernier calliper foot length of 5.99 ±0.7 cm while those with an ultra sound gestation age of more than or equal to 34weeks had Vernier calliper foot length of 7.68 ±0.44 cm and the difference in these two average was statistically significant (p<0.001(Table 10).

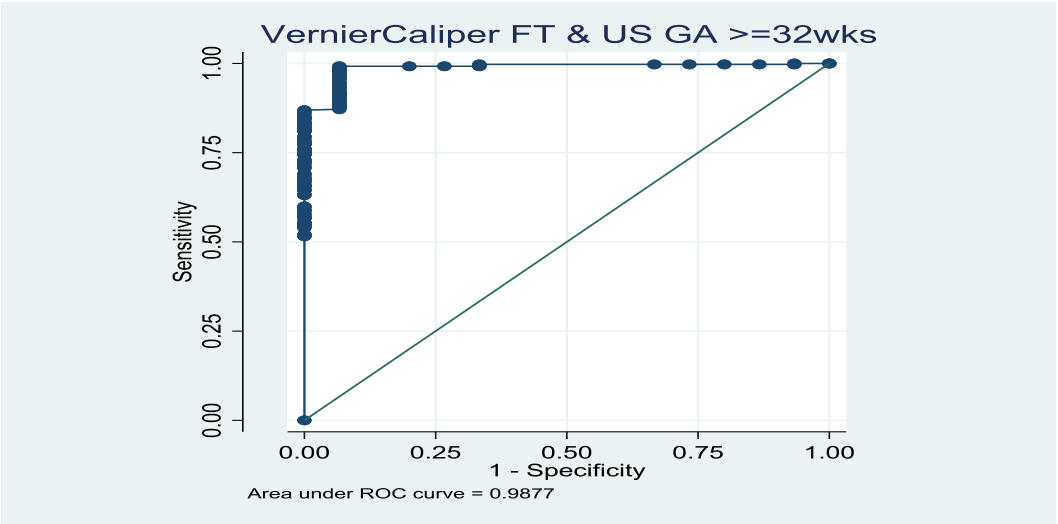


Figure 11: Predicting Premature (≥32 weeks) using Vernier Caliper Foot length i

A Vernier caliper foot length of ≥6.2 cm is the best cut point to identify babies with an ultra sound gestation age of ≥32 weeks (Fig 11)

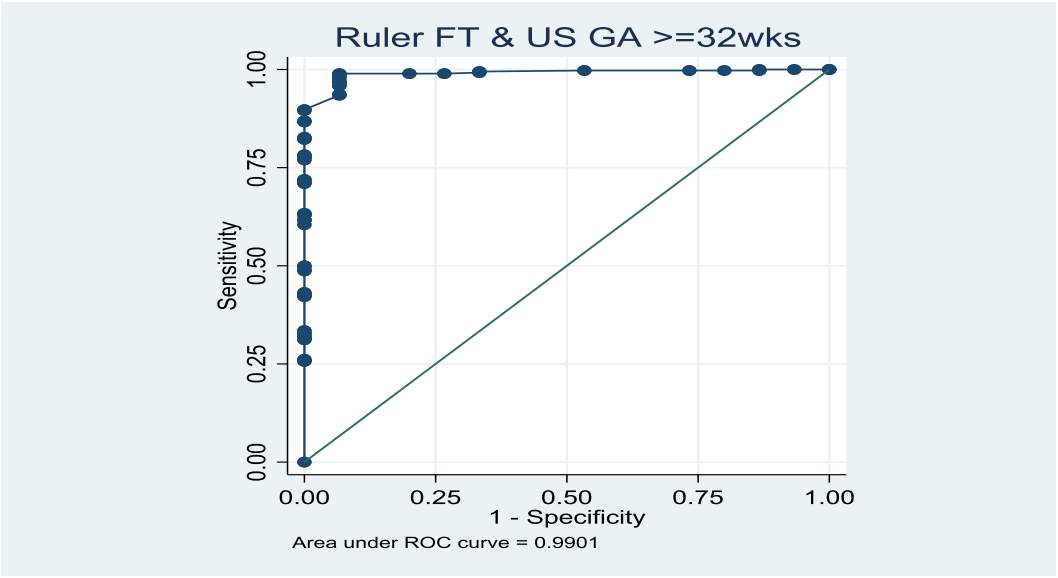


Figure 12: Predicting Premature (<32 weeks) using Ruler Foot length in cm

A ruler foot length of ≥6.2 cm is the best cut point to identify babies with an ultra sound gestation age of ≥32 weeks(Fig 12)

Table 12: Vernier and ruler foot length by gestation age (≥32weeks)

Variable	Measure	<32 weeks	≥32 weeks	p-value
Vernier caliper FL	Mean (SD)	5.72(0.56)	7.65(0.48)	<0.001
	Minimum	4.8	7.19	
	Maximum	4.9	8.81	
Ruler FL	Mean (SD)	5.66(0.59)	7.61(0.49)	<0.001
	Minimum	4.7	7	
	Maximum	5	8.8	

On average babies with an ultra sound gestation age of less than 32 weeks had Vernier caliper foot length of 5.72 ±0.56 cm while those with an ultra sound gestation age of more than or equal to 32weeks had Vernier caliper foot length of 7.65 ±0.48 cm and the difference in these two average was statistically significant (p<0.001)(Table12)

Objective Two:

To determine the sensitivity, specificity, positive predictive value, and negative predictive values of foot length measurements in determining gestational age.

Table 13: Sensitivity of Vernier caliper foot length measurement at 37 weeks

Vernier caliper foot length	Ultra sound gestation age		Total
	≥37 weeks	<37 weeks)	
≥7.412 cm	282	99	291
<7.412 cm	58	48	106
Total	340	57	397

A foot length of 7.412 cm cut off using Vernier caliper classifies 83.12% newborn correctly as term (≥37 weeks).

Sensitivity = 82.94%

Specificity = 84.21%

Positive predictive value = 96.91%

Negative predictive value = 45.28%

Table 14: Sensitivity of Vernier calliper foot length measurement at 34 weeks

Vernier caliper foot length	Ultra sound gestation age		Total
	≥34 weeks	<34 weeks	
≥7.19 cm	333	1	334
<7.19 cm	40	23	63
Total	373	24	397

A foot length of 7.19 cm cut off using Vernier caliper classifies 89.67% newborn correctly as ≥34 weeks.

Sensitivity = 89.28%

Specificity = 95.83%

Positive predictive value = 99.7%

Negative predictive value = 36.51%

Table 15: Sensitivity of Vernier caliper foot length measurement at 32 weeks

Vernier caliper foot length	Ultra sound gestation age		Total
	≥32 weeks	<32 weeks)	
≥6.2 cm	379	3	382
<6.2 cm	3	12	15
Total	382	15	397

A foot length of 6.2 cm cut off using Vernier caliper classifies 98.49% newborn correctly as ≥32 weeks.

Sensitivity = 99.21%

Specificity = 80%

Positive predictive value = 99.21%

Negative predictive value = 80%

Table 16: Sensitivity of ruler foot length measurement at 37 weeks

Ruler foot length	Ultra sound gestation age		Total
	≥37 weeks	<37 weeks)	
≥7.4 cm	283	11	294
<7.4 cm	57	46	103
Total	340	57	397

A foot length of 7.4 cm cut off using ruler classifies 82.87% newborn correctly as term (≥37 weeks).

Sensitivity = 83.24%

Specificity = 80.70%

Positive predictive value = 96.26%

Negative predictive value = 44.66%

Table 17: Sensitivity of ruler foot length measurement at 34 weeks

Ruler foot length	Ultra sound gestation age		Total
	≥34 weeks	<34 weeks	
≥7 cm	355	3	358
<7 cm	18	21	39
Total	373	24	397

A foot length of 7 cm cut off using ruler classifies 94.71% newborn correctly as ≥34 weeks.

Sensitivity = 95.17%

Specificity = 87.50%

Positive predictive value = 99.16%

Negative predictive value = 53.85%

Table 18: Sensitivity of ruler foot length measurement at 32 weeks

Ruler foot length	Ultra sound gestation age		Total
	≥32 weeks	<32 weeks)	
≥ 6.2 cm	378	3	381
< 6.2 cm	4	12	16
Total	382	15	397

A foot length of 6.2 cm cut off using ruler classifies 98.24% newborn correctly as ≥32 weeks.

Sensitivity of 98.95%

Specificity = 80%

Positive predictive value = 99.21%

Negative predictive value = 75%

CHAPTER FIVE: DISCUSSION

5.0 Introduction

This study was carried out to find an operational cut off foot length that can be used to identify premature and low birth weight babies and to find the Sensitivity ,Specificity, Positive and Negative predictive values in MTRH. High risk neonates are identified better with gestational age(Shetty et al., 2022).Many neonates face death and risk of dying the moment they are born, especially in lower and middle income countries like Kenya. Where resources are scarce in many occasions. We do not have the luxury of time to wait without any interventions when these precious but delicate new born are delivered. A method that can quickly and easily assess the preterm and low birth weight babies will be critical in efforts to save these babies from dying.

5.1 Demographic Characteristics

There were more males at 53.4 %(N=221) than females at 46.6%(N=193) which was similar to most of the studies done in Africa((Gidi et al., 2019)(Nabiwemba et al., 2012) and outside the region such as study done Singhal et at al in India, where they had more males than females in their studies(S. Singhal et al., 2014).

There is no scientific cut off time that has been universally recommended for measuring foot length. On average the neonates were aged 12.5 ±6.4 hours at the time of data collection ranging from 1 hour to 23.9 hours. Which was consistent with a study by gidi et al who also measured the neonates within 24 hours of life, but was different from another study done by Tergestina et all who were measuring foot length up to 48 hours(Tergestina et al., 2021), and another one by Nabiwemba et al who were measuring on day 1 and day 5 of life(Nabiwemba et al., 2012).The sensitivity of foot length when measured on day 1 by Nabiwemba et al had better sensitivity than when it was done on day 5 of life.

The mean birth weight was 3019.6 ±626.2 grams which was higher than the mean birth weight of 2627 ± 770 grams observed by Id et al in North-western Ethiopia (Id et al., 2020) but was close to what was found in Uganda by Nabiwemba and colleagues with birth weight mean of 3050 g (SD 0.53)(Nabiwemba et al., 2012).

In the study,14% (n=59) new-borns were below 2500 grams at birth, and also had fewer preterm; 14.3%(N=59) of the neonates were premature (<37 weeks) and 85.7 percent(n=355) term as per the ultra sound gestation age which is similar to 81.4% term and 18.6% preterm babies observed by Rakkapan et al(Rakkappan & Kuppusamy, 2016) and in contrast to 61% of preterms (<37weeks) and 39 per cent of terms charki et al had in there study(Charki et al., 2021) and that of James et al which showed females at 52 % and males at 48%(James et al., 1979).The differences in these could be due to sampling selection techniques applied in the various studies mentioned here and differences in the rates of preterm children among the different geographical region. Genetic differences in the various study populations could play a role as well

There were 10(2.4%) neonates who were classified as SGA and 7(1.7%) who were classified as LGA. And 95.9% were appropriate for gestation age(Table3), this findings were in line with the results of a study done by Hirve SS et al. (small for gestation, appropriate for gestation, and large for gestational age were 13.2%, 84.8%, and 2.1%, respectively) and what was found by Rakkappan et al as 85.1%, 14.3%, and 0.6% of appropriate for gestational age (AGA), small for gestational age (SGA), and large for gestational age (LGA) babies, respectively(B et al., 2018)(Rakkappan & Kuppusamy, 2016).The differences could be attributed to the genetic differences on the different populations studied by the researchers.

5.2. Foot Length Cut off points for different categories of gestational and birth weights

The average foot length using Vernier caliper for those who had a birth weight of more than or equal to 2500 grams was 7.75 ±0.36 cm but slightly lower (7.72 ±0.37 cm) by 0.03 cm when measured using a ruler, This was higher than foot length of 7.413±0.412 found by Charki et al(Charki et al., 2021) using vernier calipers in their study for the same category of babies with 2500 grams and above.The differences in the two measurements could be due the geographical and regional differences in their study population.

Neonates weighing less than 1000 grams had an average foot length of 5.12 ±0.4 and 5.05 ±0.5 when measured with Vernier caliper and ruler respectively. Which was close to a foot length measurement of 5.084±0.38 found by charki et al (Charki et al., 2021) The similarities could be as a result of using the same measuring tools ,that is the vernier calliper to measure foot length in the two studies.

The average foot length using Vernier caliper for those who had an ultra sound gestation age of more than or equal to 37weeks was 7.73 ±0.39 cm but slightly lower (7.7 ±0.4 cm) when measured using a ruler. This findings were higher than what was found by Kapoor et al at 7.30(+ 0.39SD),with a population of 514 neonates of which 71% were term(Kapoor & Soni, 2020) but close to 7.78 (0.46) cm with term neonates of 66.7 % Id et al found using a vernier caliper in Northwest Ethiopia, the similarities could be due to close similarity of the population included in the study.

To identify operational cut off foot length measurement that can be used to identify premature and low birth weight babies we used only those babies that were appropriate for age (n=397). A Vernier caliper foot length of ≥7.19 cm is the best cut point to identify babies with a birth weight of ≥2500 grams(figure 1) in the present

study, which slightly lower than foot length measurement of 7.35cm obtained by id et al in Ethiopia using a vernier caliper with a sample size of 205 neonates.The differences in the two studies were the use of new ballard in their study as the gold standard while in our study we used early ultrasound to determing gestation age.This findings were more similar to foot length of 7.0 cm which was obtained by Tergestina et all in their study(Tergestina et al., 2021) The similarities with the present study; the gold standard standard used ,in both studies obstetric ultrasound was used to determing gestation age and also the similarities in the tools used (i.e Vernier caliper) to measure the foot length in both studies; the differences could be that they measured the foot length in neonates who were upto 48 hrs old and ours were upto 24 hrs old. The above foot length was also in contrast to what was found by nabiwemba et al in uganda, with cut off foot length of 7.6 cm , differences could be the fact that they used eregie method to determine gestation age as the gold standard which may not be as accurate as the ultrasound that was used in the present study.

A ruler foot length of ≥7.14 cm is the best cut point to identify babies with a birth weight of ≥2500 grams.(Fig 4) which was close lower than 7.2 cm obtained by Ashish et al with a sample size of 811 neonates using a plastic hard ruler. However, the differences could be due to the fact that Ashish and colleagues used a cut off of 2000 grams for low birth weight while in these study we used a cut off of 2500 grams for low birth weight. This being the case; we expected to have a higher foot length cut off than Ashish et al

A Vernier caliper foot length of ≥6.3575 cm is the best cut point to identify babies with a birth weight of ≥1500 grams (Fig 5) which was slightly lower than what was obtained by Tergestina et al in the Neonatology unit of the Christian Medical College,

Vellore, India with their study of 520 neonates and using a vernier caliper(Tergestina et al., 2021).The differences in the studies is that; the measurements were done up to 48 hours in the Tergistina et al study but in our study we measured neonates who were less than 24 hours. In another study done by Nabiwemba et al they noted that the foot length significantly increased in size when measured on day 5 of life; this could imply that when foot length is measured in 24 hours and at 48 hours there could some differences when the measurements are compared with each other. The foot length cut off of 6.36 was similar to what was found by hirve at al at 6.3 cm, the similaries were than neonates were measured within 24 hours in both studies.

A ruler foot length of ≥6.2 cm is the best cut point to identify babies with a birth weight of ≥1500 grams(Fig 6). This was lower than what was found by mukhejee et al using a stiff transparent plastic ruler in a population of 351 neonates in India with 33.3 percent being very low birth weight, which was different from our study which had Very low birth weight babies of 3.6 % as with a population of 414 neonates.

A Vernier caliper foot length of ≥7.412 cm is the best cut point to identify babies with an ultra sound gestation age of ≥37 weeks.(Figure 7). Which was in contrast to foot a length of 7.0 cm that was found by Tergestina et al in their study(Tergestina et al., 2021) The differences could be due to the differences in their geographical population; where the Tergistina et al was done in India(Asian population) and the present study done in Kenya(African population). This was similar to what was found by Srinivasa et al with cut off point of 7.4 cm; the similarities in both studies were nearly similar proportion of preterm and term babies in their studies , Srinivisa et al had 16 % preterms and 83 % term neonates verses 14 % pretems and 85% term neonates in our study. But very close to 7.35 cm which was found by Dagnew et al in

North western Ethiopia using vernier calipers(Id et al., 2020)They both are east African nations(Kenya and Ethiopia) .

A ruler foot length of ≥7.4 cm is the best cut point to identify babies with an ultra sound gestation age of ≥37 weeks(Figure 6).This is similar to what Gidi et al observed at 7.4cm in Ethiopia(Gidi et al., 2019), but was different from 7.75 cm observed by murkejee at al in india(Mukherjee et al., 2013).The differences could be due to racial or geographical dissimilarities.

A Vernier caliper foot length of ≥7.19 cm is the best cut point to identify babies with an ultra sound gestation age of ≥34 weeks(Figure 9) which is higher than 6.5cm obtained by Tergestina et al in india(Tergestina et al., 2021) using vernier calipers and their differences could be due to the differences in their geographical and genetics in their populations.

A ruler foot length of ≥7 cm is the best cut point to identify babies with an ultra sound gestation age of ≥34 weeks(Figure 10) which is similar to 7cm obtained by srinivasa et al in their study(Srinivasa et al., 2017) .The similarities could be due to the similarities in the measuring tools used in both studies, that is the ruler.

A ruler foot length of ≥6.2 cm is the best cut point to identify babies with an ultra sound gestation age of ≥32 weeks(Figure 12) which is close to 6.3 cm mehta et al obtained in their study(Mehta et al., 2020) The close similarities could also be due to the similarities in their use of ultrasound to determine gestation age as the gold standard in both studies and also due to the fact that they both used a ruler to measure their foot length.

5.3. The sensitivity, specificity, positive predictive value, and negative predictive values of foot length measurements in determining gestational age

A foot length of 7.412 cm cut off using Vernier caliper classifies 83.12% newborn correctly as term (≥37 weeks) had a Sensitivity of 82.94%, Specificity of 84.21%, Positive predictive value of 96.91%, Negative predictive value of 45.28% in the present study; The Sensitivity of 82.94 % was Similar to what was found by gidi at all at 81.7% , the similarities could due to the geographical similarities in their study population . This was dissimilar to a sensitivity of 94.57% found by Kapoor et al (Kapoor & Soni, 2020) using a digital vernier caliper. In the study by Kapoor et al , we note that they had more preterm babies at 28 % as compared to our study at 14 % , the other differences could genetic differences in the study populations. The Specificity of 84.21 % in the present study was similar to what was found by Mukherjee at al at 86.3% .The similarities noted were in the same study methods and used in both studies. This was dissimilar to a specificity of 41.99% found by Kapoor et al , the differences were in the cut off measurement used where as we used a cut of 7.41 cm , they used a cut off of 6.83 cm , which could have been due to genetic or geographical differences in the study population.

A foot length of 7.19 cm cut off using Vernier caliper classifies 89.67% newborn correctly as ≥34 weeks(Table 12),and had a Sensitivity of 89.28%, Specificity of 95.83%, Positive predictive value of 99.7%, Negative predictive value of 36.51% which was higher than 6.5 cm that was found by Tergestina et al using vernier calipers in Ethiopia(Tergestina et al., 2021);Though this was done within 48 hours as compared to 24 hours within our study.

A foot length of 7.4 cm cut off using ruler classifies 82.87% New born correctly as term (≥37 weeks), Sensitivity of 83.24%, Specificity of 80.70%,Positive predictive

value of 96.26%,Negative predictive value of 44.66% which is close to what gidi et al found using a cut off foot length of 7.4cm , had a sensitivity of 80.5 % , a specificity of 91.4 %, positive predictive value of 35.2% and Negative predictive 98.8%

In the present study,a foot length of 7 cm cut off using ruler classifies 94.71% newborn correctly as ≥34 weeks. With a Sensitivity of 95.17%, Specificity of 87.50%,Positive predictive value of 99.16%, Negative predictive value of 53.85%.The sensitivity of 94.71 % is similar to a study by singhal et al with a cut-off foot length of 7 cm with a sensitivity of 94.76%, for the prediction of gestational age below 34 weeks(R. Singhal et al., 2017) also comparable to a cut off foot length of 7.1 cm with a sensitivity of 95.83 % and specificity of 88.30 % obtained by Rajoriya et al(Rajoriya et al., 2020).The similarities could be due to the similar cut off points used in these studies. This was in contrast to a study done by. The specificity of 87.5% was similar to what was found by Rajoriya et al in 2020 with a specificity of 88.3 % .The similarities on this two studies is they same sample size population and they used similar measuring tools to measure the foot. The specificity was slightly lower than what was found by Singhal et al at 94.3 % . The differences could be geographical or genetic differences in their study populations

5.4 Limitations of the study

The study was done in one single centre therefore the results may not be easily generalizable into the population.

5.5 Strengths of the study

The study used a gold standard of ultrasound before 23 weeks gestation to determine the ultrasound dates, which is better than other methods such as new Ballard score, Dubowitz maturation assessment score, Last menstrual period dating and Eregie method used by other studies that have assessed the accuracy of foot length measurements in determining the gestation age of new-borns.

The study also used two different methods of measuring the foot length, the digital vernier callipers and a hard transparent plastic ruler. The vernier callipers was used because of its high accuracy in measuring even small diameters while the hard transparent plastic ruler was used because it is the method that is locally and easily available in low resource settings

CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

1. The operational cut off foot length to identify preterm babies in MTRH is 7. 4 cm using a digital vernier calliper and hard plastic ruler .
2. The accuracy of foot length measurement taken within 24 hours of birth to estimate gestational age in MTRH was good depicted by a high sensitivity and specificity to identify preterm new-borns.

6.2 Recommendations

1. We propose an operational cut off foot length of 7.4 cm be used to identify preterm babies in MTRH .
2. We recommend use of foot length measurement in a newborn within 24 hours of age to identify preterm babies in MTRH

   And additional studies are required to develop normo grams that can be used in our population

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APPENDICES

Appendix 1: Data Collection Form/Proforma

Demographic details

Case no:…… Hospital no:…….. Gender.....Age(hours)……..

Birth weight(grams)……..

GA ULTRASOUND: (I)Gestation when performed(weeks)……

(II)Current GA(weeks)……..

GA LMP(weeks)……..

Foot length measurement (cm)

1. First Observer:(i) Digital calliper measurement …….(cm) Repeat.....cm)

   Average……..

   (ii)Transparent ruler measurement …cm) Repeat…

   Average…....

2. 2nd Observer:(i) Digital calliper measurement …….(cm) Repeat.....cm)

   Average…..

   (ii)Transparent ruler measurement …cm) Repeat…

   Average….

Appendix 2: Consent Form

Name.…… Hospital No……

Study Title: Accuracy of Foot length measurements in determining the gestational age in New-borns at MTRH.

Investigator: Dr Erick Langat(Resident in Paediatrics and Child Health) Tel Number: - 0704366451

Supervisors: Professor Winstone Nyandiko

Professor Constance Tenge

Introduction: The aim of this study is to identify the accuracy of baby's foot length measurements in determining the gestational age and to identify the low birth weight babies and premature babies

The procedure to be undertaken in this study will be: Taking measurements of your baby's foot and also taking the birth weight.

Participation: Enrolment in the study will be on voluntary basis. There will be no financial rewards to you for participating in the study. One is free to participate or withdraw from the study at any point. Refusal to participate will not compromise your child's care in any way.

Risks: There will be a little discomfort to your child during the time of weighing since we will require that baby has very light or no clothing. When measuring the foot the baby could feel some pressure but there will be no pain. Refusal to participate will in no way interfere with the treatment of your child.

Confidentiality: The information obtained about you, your child and your family will be kept in strict confidence. No specific information regarding you, your child, or your family will be released to any person without your written permission. We will, however, discuss general overall findings regarding all children assessed but nothing

specific will be discussed regarding your child's condition. We will also, not reveal the identity of you or your child in these discussions.

Problems or Questions: If you have any questions about the study or the use of the results, contact the principal investigator, Dr. Erick Langat on Tel No.0704366451.

Questions about your rights as a research subject: You may contact the Institutional Review Ethics Committee (IREC) 053 33471 Ext.3008. IREC is a committee that reviews studies for safety and to protect the rights of study subjects.

I ……having received adequate information regarding the study research, risks hereby AGREE / DISAGREE (Cross out as appropriate) to participate/ for my child to participate in the study.

I understand that our participation is fully voluntary and that I am free to withdraw at any time. I have been given adequate opportunity to ask questions and seek clarification on the study and these have been addressed satisfactorily.

Participant /Guardian's Signature: …… Date…….

I ……declare that I have adequately explained to the above participant/ guardian, the study procedure, risk and given him /her time to ask questions and seek clarification regarding the study. I have answered all the questions raised to the best of my ability.

Investigators

Signature…… Date……...

Appendix 3: Fomu ya makubaliano ya kushiriki katika utafiti huu kwa washiriki walio chini ya umri wa miaka kumi na nane:

Mada ya Utafiti: Usahihi wa vipimo vya urefu wa Mguu katika kuamua umri wa ujauzito kwa watoto wachanga huko MTRH

Mtafiti: Daktari Erick Langat (mwanafunzi katika chuo kikuu cha Moi katika idara ya maabara na afya ya watoto). Nambari ya simu 0704366451

Wasimamizi: Profesa Winstone Nyandiko

Profesa constance Tenge

Utangulizi:

Kusudi la utafiti huu ni kubaini usahihi wa vipimo vya urefu wa mguu wa watoto katika kuamua umri wa ishara na kutambua watoto walio na uzani wa chini na watoto wachanga kabla

Utaratibu utakaofanywa katika utafiti huu itakuwa:

Kuchukua vipimo vya mguu wa watoto wako na pia kuchukua uzito wa kuzaliwa.

Ushiriki:

Uandikishaji wa kushiriki katika utafiti huu ni kwa hiari ya mshiriki pekee. Ana uhuru wa kushiriki au kujiondoa kutoka utafiti huu kwa wakati wowote katika uendeshaji wa utafiti huu. yote haya hayana madhara kwa mtoto wako.Kutoshiriki hautaathiri huduma kwa mtoto wako kwa njia yoyote.

Madhara ya kushiriki:

Kutakuwa na usumbufu mdogo kwa mtoto wako wakati wa kupima uzito, kwani tutahitaji mtoto mchanga awe na nguo nyepesi sana au hana nguo. Wakati wa kupima mguu mtoto anaweza kuhisi shinikizo fulani lakini hakutakuwa na maumivu. Kukataa kushiriki hakuhusiani na matibabu ya mtoto wako.Hakuna gharama yoyote

itakayotokana kwa ajili ya kushiriki katika utafiti huu. Hakuna malipo yoyote utakayopata katika kushiriki katika utafiti huu.

Siri:

habari zote za utafiti huu yatatunzwa kwa siri na kutumika katika utafiti tu. Utambulisho wako hautawekwa bayana katika makaratasi yoyote. Makaratasi yote yatawekwa katika kabati lililofungwa na kifunguu kuwekwa na mtafiti mkuu. Tarakilishi itatumika kuimarisha siri. Maswali ya dodoso yatajibiwa katika chumba ambacho kitakuwa kimetafutwa na mtafiti kwa usaidizi wa wahudumu wa afya kitachoshughulukia mambo ya siri. Majibu yako hayatapatiwa kwa mzazi/mlezi wako.

Lawama au maswali:

Iwapo utakuwa na swali lolote au lawamakuhusu utafiti huu, tafadhali wasiliana na, Daktari Erick Langat kupitia numbari ya simu ya rununu 0704366451.

Baada ya kusoma na kuelezwa kwa kina mambo yanayohusiana na utafiti huu;

Mimi……natoa idhini yangu kushiriki katika utafiti huu. Nafahamu kuwa naweza kusitisha kushiriki kwangu katika utafiti huu wakati wowote bila madhara yoyote.

Sahihi ya mshiriki……Tarehe……..

Sahihi ya mtafiti mkuu ……Tarehe…….

Appendix 4: Budget

ITEM	QUANTITY	UNIT COST (Ksh)	TOTAL (Ksh)
Photocopy papers (A4 box with 500 sheets)	4	500	2,000
Stationery (pencils, pens, and erasers)	20, 20, 5 respectively	20, 10, 10, respectively	650
Digital vernier caliper	2	5,000	10,000
Plastic rulers(transparent)	2	30	60
Research assistants	2	@ 4,500 per month	54,000
Photocopy charges	-	5,000	5,000
Biostatistician fee	-	50,000	50,000
Miscellaneous	-	30,000	30,000
		GRAND TOTAL = KSH 151,710	

Appendix 5: Time frame

ACTIVITY	**START**	**COMPLETE**
Proposal Concept Development	January 2020	February 2020
Proposal Writing	March 2020	Nov 2020
IREC approval	Nov 2020	Feb 2020
Preparation for Data Collection	April 2021	May 2021
Data Collection	June 2021	June2022
Data Analysis	July 2022	July 2022
Thesis Writing	July 2022	September 2022
Thesis Defense	October 2022	

Appendix 6: IREC Approvals

MTRH/MU-INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2020/265
Approval Number: 0003780

25th February, 2022

Dr. Erick Kiprotich Langat,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Langat,

RE: CONTINUING APPROVAL

The Moi Teaching and Referral Hospital/Moi University College of Health Sciences- Institutional Research and Ethics Committee has reviewed your request for continuing approval to your study titled:-

"Accuracy of Foot-Length in Determining Gestational Age of Newborns at Moi Teaching and Referral Hospital".

Your proposal has been granted a Continuing Approval with effect from 25th February, 2022. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 24th February, 2023. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
25 FEB 2022
APPROVED
P. O. Box 4606 - 30100 ELDORET

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc:	CEO	-	MTRH	Dean	-	SOD
	Principal	-	CHS	Dean	-	SPH
	Dean	-	SOM	Dean	-	SON

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2020/265
Approval Number: 0003780

25th February, 2021

Dr. Erick Kiprotich Langat,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Langat,

ACCURACY OF FOOT-LENGTH IN DETERMINING GESTATIONAL AGE OF NEWBORNS AT MOI TEACHING AND REFERRAL HOSPITAL

This is to inform you that ***MTRH/MU-IREC*** has reviewed and approved your above research proposal. Your application approval number is ***FAN: 0003780.*** The approval period is **25th February, *2021 – 24th February, 2022.***

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by ***MTRH/MU-IREC***.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to ***MTRH/MU-IREC*** within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to ***MTRH/MU-IREC*** within 72 hours.
v. Clearance for export of biological specimens must be obtained from ***MTRH/MU-IREC*** for each batch of shipment.
vi. 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.
vii. Submission of an executive summary report within 90 days upon completion of the study to ***MTRH/MU-IREC.***

Prior to commencing your study; you will be required to obtain a research license from the National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and other relevant clearances. Further, a written approval from the CEO-MTRH is mandatory for studies to be undertaken within the jurisdiction of Moi Teaching & Referral Hospital (MTRH), which includes 22 Counties in the Western half of Kenya.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
25 FEB 2021
APPROVED
P. O. Box 4606 - 30100 ELDORET

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc CEO - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

Appendix 7: Hospital Approvals (MTRH)

An ISO 9001:2015 Certified Hospital

MOI TEACHING AND REFERRAL HOSPITAL

Telephone :(+254)053-2033471/2/3/4
Mobile: 722-201277/0722-209795/0734-600461/0734-683361
Fax: 053-2061749
Email: ceo@mtrh.go.ke/directorsofficemtrh@gmail.com

Nandi Road
P.O. Box 3 – 30100
ELDORET, KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010

1st March, 2021

Dr. Erick Kiprotich Langat
Moi University
School of Medicine
P.O. Box 4606-30100
ELDORET-KENYA

ACCURACY OF FOOT-LENGTH IN DETERMINING GESTATIONAL AGE OF NEWBORNS AT MOI TEACHING AND REFERRAL HOSPITAL

In order to conduct research within the jurisdiction of Moi Teaching and Referral Hospital (MTRH) which includes 22 counties in the Western half of Kenya. You are required to strictly adhere to the regulations stated below in order to safeguard the safety and well-being of staff and patients seen at MTRH involved research studies.

1. The study shall be under Moi Teaching and Referral Hospital regulation.
2. A copy of MU/MTRH-IREC approval shall be provided.
3. Studies dealing with collection, storage and transportation of Human Biological Material (HBM) will not be allowed to export the HBM outside the jurisdiction of **MTRH.**
4. For those tests which are unavailable locally the PI is tasked to ensure sourcing of equipment and subsequent training of staff to build their capacity.
5. No data collection will be allowed without an approved consent form(s) to participants to sign.
6. Take note that **data** collected must be treated with due confidentiality and anonymity.

Permission to conduct research shall only be provided once all the requirements stated above have been met.

MOI TEACHING AND REFERRAL HOSPITAL
C.E.O
APPROVED
01 MAR 2021
SIGN.....
P.O.Box 3 - 30100, ELDORET

01/03/2021

DR. WILSON K. ARUASA, *EBS*
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

c.c. - Senior Director, Clinical Services
- Director of Nursing Services
- HOD, HRISM