FETAL BIOMETRIC MEASUREMENT RELIABILITY ON ESTIMATING GESTATION AGE AMONG NORMAL PREGNANT WOMEN ATTENDING ANTENATAL CLINIC AT MUHIMBILI NATIONAL HOSPITAL

By

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CERTIFICATION

The undersigned certifies that Dr. Kazema R.R has read and here by recommends for acceptance by Muhimbili University of Health and Allied Sciences (MUHAS) a dissertation entitled; Fetal biometric measurement reliability on estimating gestation age among normal pregnant women attending antenatal clinic at Muhimbili National Hospital (MNH) in partial fulfillment of the requirements for the degree of Master of Medicine in Radiology



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DECLARATION AND COPYRIGTH

I, Zuhura Nkrumbih declared that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature..... Date...25th NOVEMBER 2010

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DEDICATION

This dissertation is dedicated to Nkrumbih's family, Mr. and Mrs. Fadhili Nkrumbih with their beloved sons Abdulkarim Nkrumbih, Sadiq Nkrumbih, Eng Abdulswamad Fadhili and their lovely daughter Aisha Fadhili.

ABSTRACT

Objectives: To determine the internal reliability of fetal biometric measurements on estimating gestational age.

Methods: This was a cross sectional study, 250 pregnant mothers were recruited from antenatal clinic at MNH. Obstetric history obtained, standard obstetric ultrasound scanning was done and the biometrics recorded. Gestation ages from three variables (FL, BPD, and HC) were analyzed for their correlation to gestation age by LNMP as a gold standard.

Results: Correlation analysis between gestation age from LNMP and that from USS revels strong correlation with[r 0.95, t= 55 ,95%CI (0.94 – 1.01)],[t= 48.75,r= 0.92,95%CI (0.91 – 1.05)],[t= 24, r= 0.89, 95%CI(0.92-0.99)] for FL,HC and BPD respectively.
When combine three variables FL, HC and BPD r= 0.98, t= 58.46, 95%CI (0.98-1.02).

Conclusion: There is strong positive correlation between gestation age calculated from last normal menstrual period and that estimated by ultrasound with significant p value for each tested parameter.

ABREVIATIONS

1 .MNH	Muhimbili National Hospital
2. MUHAS	Muhimbili University of Health and Allied Sciences
3. FL	Femur Length
4. HC	Head Circumference
5. BPD	Biparietal diameter
6. USS	Ultrasound
7. LNMP	Last normal menstrual period
8. GA	Gestation age
9. ANC	Antenatal clinic

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INTRODUCTION

Among others, the most important aspect of pregnancy management is the assessment of gestation age (GA). Gestation is the period between conception and delivery. It is the time from the first day of the woman's last menstrual cycle to current date and is measured in weeks. A pregnancy of normal gestation is approximately 40 weeks, with a normal range of 38 to 42 weeks. Infants born before 37 weeks are considered premature while those who born after 42 considered being post mature/ post date.

It helps to know the progress of the pregnancy and any need of early intervention in case of abnormalities, for example anencephaly. The proper history of the last normal menstrual period can be used among several others for gestation age determination [1].

Real-time ultrasound is a very effective tool in the estimation of fetal age. Ultrasonography is so preferred since it is non invasive with no radiation[2], less expensive, widely available hence safe to both mother and child. Measurements are known as fetal biometric ,were by several parts of fetal anatomy and their growth are taken[3]. Fetal growth depends on the changes in body dimensions occurring throughout the pregnancy. The growth rate of different part is rapid especially in the 1st and 2nd trimesters and change significantly with the advancement of the pregnancy thus has to be evaluated against normal value at that age. There are various sonographic fetal biometric that can be used in determination of gestation age according to time of pregnancy. Late pregnancy age estimates are less accurate, but the use of multiple body measurements provides a composite age estimate generally accurate.[4]
The commonly use fetal measurements in estimating gestation age in second and third trimester are Femur length, head circumference, and Biparietal diameter.

Femur length accurately predict gestational age between 14 weeks and term, its accuracy is greatest in the second trimester and least near term. Biological and technical factors may lead to inaccuracies of FL measurements. Femur length may be over estimated particularly when the femur is in the far field of the image. But also if there is inclusion of distal epiphysis as the distal femoral epiphysis become echogenic in the third trimester.

Tangential section and artifuctual bowing of femur failing to visualize the entire length of the shaft, leads to underestimation[5, 6]

Biparietal diameter is used from 12^{th} week on ward; with appearance of the head it may be necessary to do correction in this parameter, and the measurement will be known as corrected biparietal diameter.

Head Circumference (HC): This parameter is used in the third trimester along with other parameters such as FL.[7]

LITERATURE REVIEW

It is generally accepted that the safe obstetric management depends on valid prediction of gestation age and term. Common methods used are estimation from last normal menstrual period using Naegele's rule, estimation by fundal height and ultrasound biometry.

The menstrual cycle is the series of changes a woman's body goes through to prepare for a pregnancy. The study done in Guatamala to determine which method provide the best estimate of gestational age showed that gestation age estimated by LNMP was within plus or minus fourteen days of the ultrasound estimate for 94% of the sample. Results of the study suggest that when trained field personnel assist women to recall their LNMP, this date provide the best estimate.[16].

Naegele's rule is the method that is nearly universally used. It is done by taking the first day of the last normal menstrual period and adds seven days to it, then subtracting three months and adds a year. This is assuming that the average length of the of menstrual cycle is 28 days.[17]. Mean length is recorded by 77% of menstruating women to compensate long or short cycles we add or subtract the days that circle differs from the standard 28 days.[18]

From the study ultrasound determinations of fetal biparietal diameter was a gold standard. Majority of deliveries occurred at or near term showed LNMP were valid within plus or minus seven days of the ultrasound estimate.[1]

Ultrasonographic fetal biometry is the most wide spread method used to establish gestation age, estimate fetal size and monitor its growth. Scan dating alone is significantly better in predicting the actual date of delivery than any of the dating methods taking menstrual dates alone or in combination with ultrasonography[19].

The study done at Department of radiology Harvard Medical School Brigham and Women's Hospital Boston showed that the accuracy of all predictors worsened progressively as pregnancy proceeded. In the second trimester, corrected biparietal diameter and head circumference were more accurate predictors of gestational age than were biparietal diameter, femoral length, and abdominal circumference (p less than .05). In the third trimester, the

corrected biparietal diameter, head circumference, and femoral length were the best predictors, significantly better than biparietal diameter and abdominal circumference (p less than .05). Prediction of gestational age that relies on a single sonographic measurement should be based on the head circumference or corrected biparietal diameter in the second trimester and on one of these two predictors or the femoral length in the third trimester.[20]

Biparietal diameter *(BPD):* This parameter is used in the second trimester, on ward. It measures the maximum distance between the two parietal bones taken from the leading edge of the skull to the leading edge i.e. outer to inner. It can also be measured from outer to outer table of the skull. This axial plane passes through the widest portion of skull where the continuous midline echo of falx cerebri is broken by cavum septum pellucidum with both the thalami enclosing the slit like opening of the 3rd ventricle of brain[21].
BPD in the second mid trimester is linear and rapid. The biological variation at each week of gestation is small. The mean weekly increase in the BPD between 13 and 30 weeks gestation is 4.9 mm/week, between 30 and 36 weeks, 3.3 mm/week and between 37 and 40 weeks, 17 mm/week.[22].

Taking technically adequate BPD image with accurate measurement , also eliminating pathological causes of variation in fetal head size (e.g. microcephaly, hydrocephaly, growth retardation), there remain two obvious reasons why women with the same last menstrual period may have fetuses with different BPD measurements which are genetic variations in head size in fetuses of the same conceptual age and differences in time of ovulation and fertilization with respect to the first day of the last menstrual period. Recent experience has suggested that variations in the shape of the fetal skull such as dolicocephaly and brachycephaly may also have a significant effect on BPD measurements. An investigation was therefore undertaken to determine the normal relation between the short and long axis of the fetal skull at the BPD plane, in hope of producing a simple method for detecting variations in the shape of the fetal skull, which may adversely affect the accuracy of the BPD measurement in predicting fetal gestational age[23] . The relationship is seen by calculating

cephalic index which is a measure of the shape of the human skull obtained by expressing the maximum breadth of the skull as a percentage of the maximum length measured from a point just below the eyebrow ridges. A figure below 75 is considered dolichocephalic between 75 and 80 is mesocephalic, and above 80 is brachycephalic.

Variations of head shape e.g. dolicephaly, brachycephaly have been shown to adversely affect the BPD. Due to variation in head shape, measurement of head circumference has become the integral part of assessing gestation age in second and third trimester[24-26].

Using the same image of BPD, fetal head circumference (HC) is obtained directly by measuring the outer perimeter of the head. The accuracy of HC measurement is comparable with that of BPD measurement in fetuses with abnormal head shape, either brachycephaly or dolicocephaly, HC may be a more accurate predictor of fetal age than BPD[24]

FL is an important as it gives information about the longitudinal growth of the fetus, measuring the FL has a very important function of excluding dwarfism in the fetus. [27]

By convention, measurement of the FL is considered accurate only when the image shows two blunted ends. The extension to the greater trochanter and the head of femur should not be included. The measurement is also considered inaccurate when the femur image is at an angle of over 30 degrees to the horizontal.

There was a study done determine the precise anatomic correlate for the end points of sonographic measurement of the fetal femur. A cadaveric fetal thigh was dissected in layers and correlated with sonographic images. The margins of the osseous portion of the femur were determined on sonograms. Potential for underestimating femur length (oblique images) and overestimating femur length (including nonosseous portions of the femur in measurement) can be eliminated by requiring a view of the femur with epiphyseal cartilages. In this way, the margins of the osseous portion may be accurately estimated, and there is assurance that the entire shaft has been visualized. Images of the dissected specimen indicate that the "distal femur point," which may cause confusion in measurement, is not a part of the osseous femur, but probably represents a specular reflection from the lateral surface of the distal epiphysis[5]. The measurements should be reported as they are. Do not take an average,

because you can always have a fetus with an average size head and a longer or shorter than average lower limb.

Different fetal biometric measurements have been reported from different population and these has show difference according to race, geographical location and even nutritional status of their mothers. So to avoid under estimation or over estimation of fetal age in their society. Various populations has tried to establish their own Fetal biometric and reference charts to be used locally [28-33]

PROBLEM STATEMENT

Perinatal mortality rate among African countries is high [8]. By knowing the gestation age it will be easy to follow the well being of the fetus that will help to improve obstetric management and hence reduce perinatal morbidity and mortality. This knowledge is required in the management of some obstetric condition like premature rupture of membrane, pre term labor, and post date. Identification of some complications like intrauterine growth retardation, macrosomnia, anencephaly and multiple pregnancies can also be done.

In our settings a number of pregnant women do not remember their last normal menstrual dates [9]. Gestation age estimation by ultrasound could be the best solution. Ultrasound at this stage forms the basis for growth assessment during the rest of the pregnancy and prediction of expected date of delivery.

RATIONALE

Prenatal measurement of fetal parameters and estimated size and weights vary among different populations. These variations depend upon race, geographical characteristics and nutrition status of the mother [10, 11]. Biometric curves for one population may over or under estimate the fetal age when used for another population with different demographic characteristics. Many existing references for biometric measurements has been reported by a number of Investigators with results that shows the uniqueness and specification to their settings[12-15]. To date the fetal biometric charts used at MNH are stipulated from a different geographical setting, race and nutritional status. It is therefore important to performed study to look on the reliability of the currently used references.

The result of this study will be used in creating a base line data on estimation of the gestation age at MNH.

OBJECTIVES

Broad objective

To determine the internal reliability of fetal biometrical measurements on estimating gestational age among pregnant women at their second and third trimester from June to December 2009

Specific objectives

1. To correlate gestation age estimated by femur length and by LNMP among pregnant women attending ANC at MNH during their second and third trimester, from June to Dec 2009
2. To correlate gestation age estimated by head circumference and by LNMP among pregnant women attending ANC at MNH during their second and third trimester, from June to Dec 2009
3. To correlate gestation age estimated by biparietal diameter and by LNMP among pregnant women attending ANC at MNH during their second and third trimester, from June to Dec 2009
4. To correlate gestation age estimated by composite of FL,BPD,HC and by LNMP among pregnant women attending ANC at MNH during their second and third trimester, from June to Dec 2009

HYPOTHESIS

Null Hypothesis:

There is no relationship between gestation age calculated from last normal menstrual period and that estimated by ultrasound

METHODOLOGY

STUDY DESIGN

This was a cross section observational study.

STUDY AREA / STUDY PERIOD

The setting was Muhimbili national hospital antenatal clinic. Clinic runs for four days - Tuesday to Friday, for about five hours each day. Study was conducted from June to December 2009.

STUDY POPULATION

All pregnant women between 12wks and 40 wks of gestation age who attended antenatal clinic from June to December 2009.

EXCLUSION CRETARIA

Pregnant mothers with maternal disease known to affect fetal growth for example, Diabetes mellitus and chronic hypertension. Multiple pregnancy and fetuses with congenital anomalies were excluded in the study.

SAMPLE SIZE ESTIMATION

Considering the study power of 95%, a random error is estimated to be 0.5. Sample size of 245 pregnant mothers were estimated based on Cameroon study of the Fetal age assessment based on 2nd trimester ultrasound in Africa and the effect of ethnicity.[34](literature). The standard sample size estimation (**Kish & Leslie**) formula is: $\mathbf{N = z^2p\ (1\text{-}p) \div E^2}$ Where by: **Z-** is the point of normal distribution corresponding to the significance level 1.96; **p-** prevalence from Cameroon study 0.2; **E** -maximum likely error 0.05. From this formula the sample size was calculated as follows: $\mathbf{N = (1.96)^2\ X\ 0.2(1 - 0.2) \div (0.05)^2 \approx 245}$

SAMPLING TECHNIQUE

Pregnant mothers were selected using the random number tables according to the list, i.e. each study unit was obtained through three steps: Step one was to choose the direction (right, left, up or down) in which the number was read from the random table. Step two was to select a starting point by closing eyes and touches the random number table with a pointed object. Then eyes opened and the digit closest to the point touched the table was the starting point. Third step was to read the number of digits required (determined by the sampling range) in the direction chosen in steps one. Each day of the clinic ten mothers were selected until a sample size was obtained. Mothers requested to participate in the study and sign a consent form after detailed explanations and understanding of what was to be done.

DATA COLLECTION

Those who met the inclusion criteria for the study were enrolled; detailed history was taken to determine the certainty of the menstrual dates. Standard protocol for measuring BPD, HC, FL was used to obtain gestational age by the use of 3.5 HZ transducer.

BPD was measured in the axial plane at the point where continuous midline echo of falx cerebri is broken by cavum septum pellucidum. Measurements were made from outer to inner margins of the skull. Head circumference was measured at the same level of BPD but from outer margins of the skull table. Femur length was measured from the origin to the distal end of the shaft.

Estimated gestation age from BPD, HC was by Campbell charts while FL was from Hanssmann charts. The obtained data were stored as a summary showing the distance (cm) and age in (weeks). Gestation age from the last normal menstrual period was calculated by Naegele's rule.

Data was collected on a data collection sheet and it included the demographic information, like age and parity. Menstrual and contraceptive histories were also recorded.

DATA ANLYSIS

Data analysis plan was done and all the collected data was analysed by using Statistically Package for Social Sciences (SPSS) program.

ETHICAL CONSIDERATIONS

Ethical clearance was obtained from MUHAS - IRB (Institutional Review Board) and permission to conduct the study. Permission to use the antenatal clinic and imaging facilities was obtained from the Director of clinical services of MNH. An informed consent (verbal and written) was provided to patients. Confidentiality was observed when talking to mothers, and performing ultrasonography. Objectives and procedures to be done were clearly explained to all participants. A written consent was obtained.

RESULTS

Variables are continuous and normally distributed fulfilling requirements for correlation analysis. Pearson correlation coefficient (r) was used to measure their association as they showed linear relationship. Values obtained from last normal period correlate positively with values obtained by ultrasound.

Gestation age calculated from the last normal menstrual period and those obtained by ultrasound, have mean raised from 26.94 to 28.22 with maximum range of 27 weeks as shown in Table 1. Total number of pregnant women was 250

Table 1: Descriptive statistics of Mean gestation age according to LNMP, FL, HC and BPD

GA in weeks	Mean ± SD	Range (weeks)
GA by LNMP	28.22 ± 7.25	13 – 39
GA by BPD	27.48 ± 7.32	13 - 39
GA by FL	27.46 ± 7.18	13 - 40
GA by HC	26.94 ± 6.86	13 - 39

Majority of women 53.3% fall in the age group of 28 – 37 years only 7.6% were above 37 years. Approximately two third of them were in third trimester 68%. Total number of women was 250. This is shown in Table 2.

TABLE 1: Characteristics of the study population of pregnant mothers attending ANC at MNH June- December, 2009

AGE GROUP (years)	Frequency	Percent (%)
18 - 27	98	39.2
28 -37	133	53.2
>37	19	7.6
TRIMISTER		
2	80	32
3	170	68

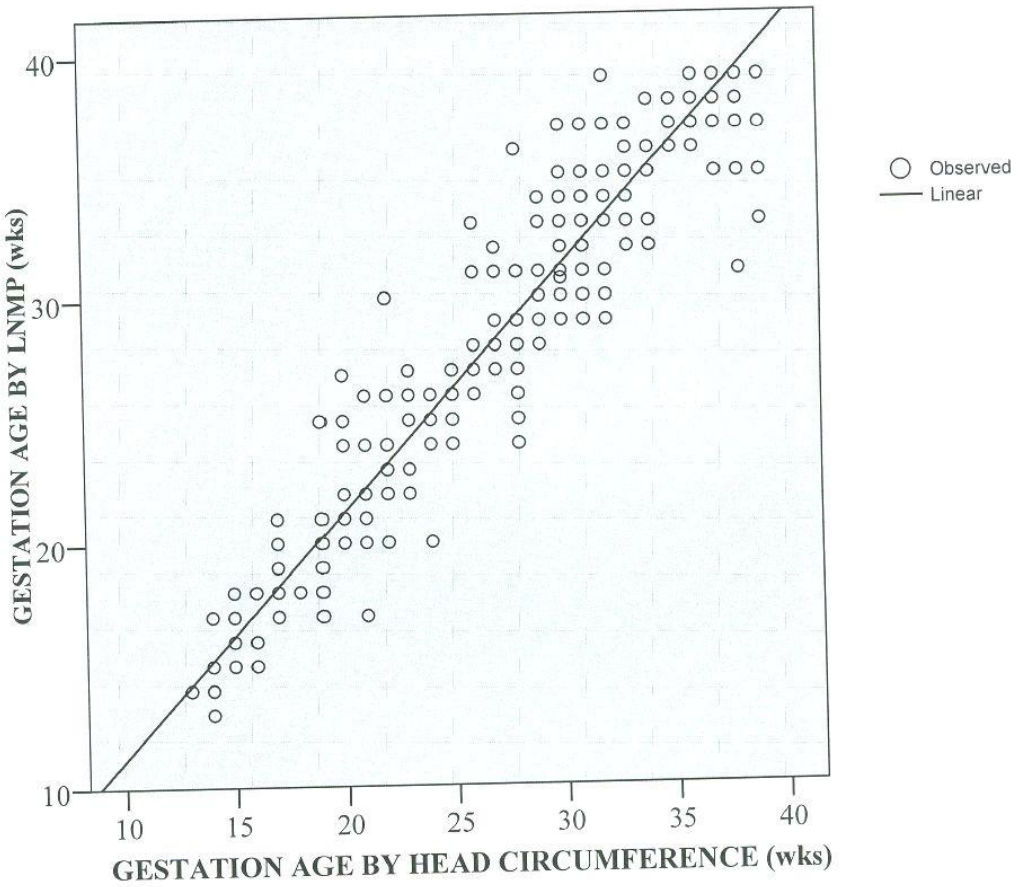
Analysis using Pearson correlation coefficient indicate a statistically significant linear relationship between FL and LNMP value for gestation age, r = 0.95. Test for null hypothesis of zero correlation 55, p value of less than 0.001 and 95%: CI (0.94-1.01) as shown in figure 1

Figure: 1. Correlation of fetal gestational age using femur length (FL)



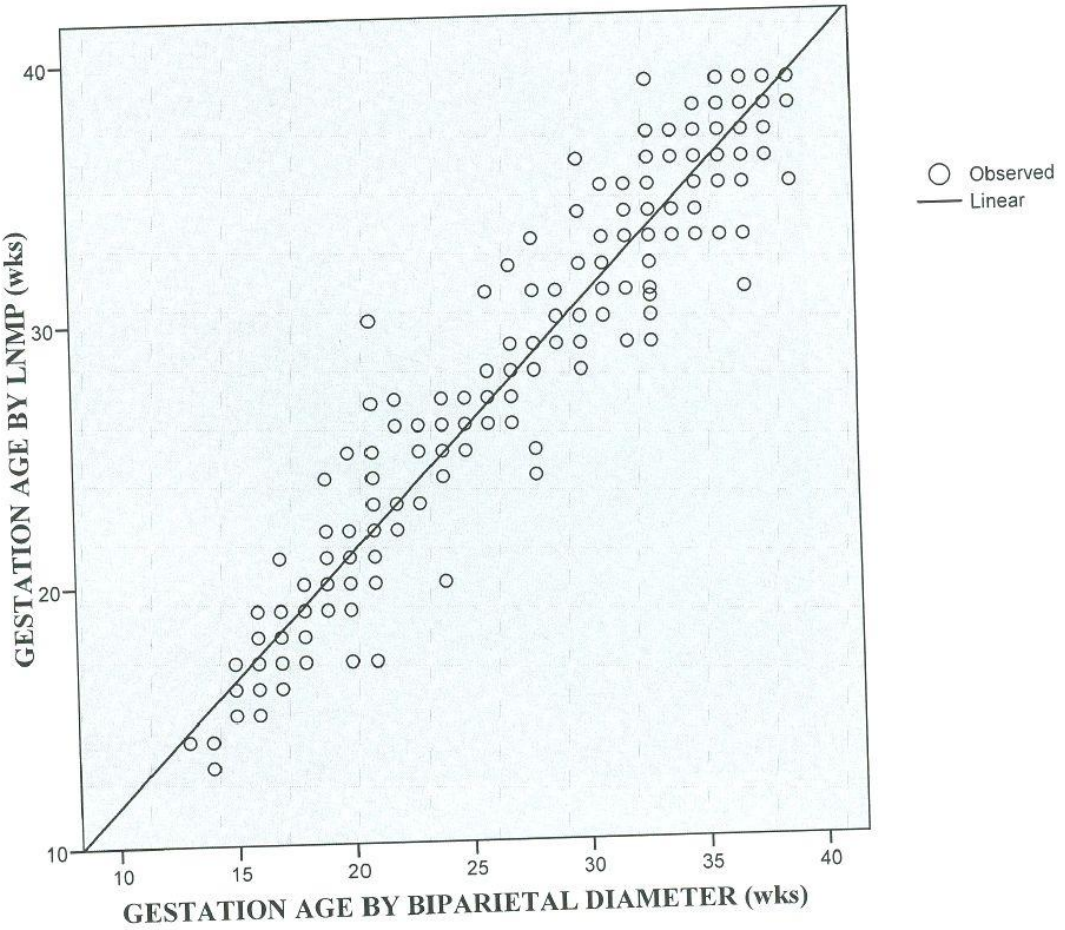
Correlation coefficient for gestation age from LNMP and by head circumference is 0.92 as shown in figure 2. t = 48.75; 95% CI (0.91 – 1.05), p value less than 0.001.

Figure: 2 Correlation of fetal gestational age by head circumference (HC)



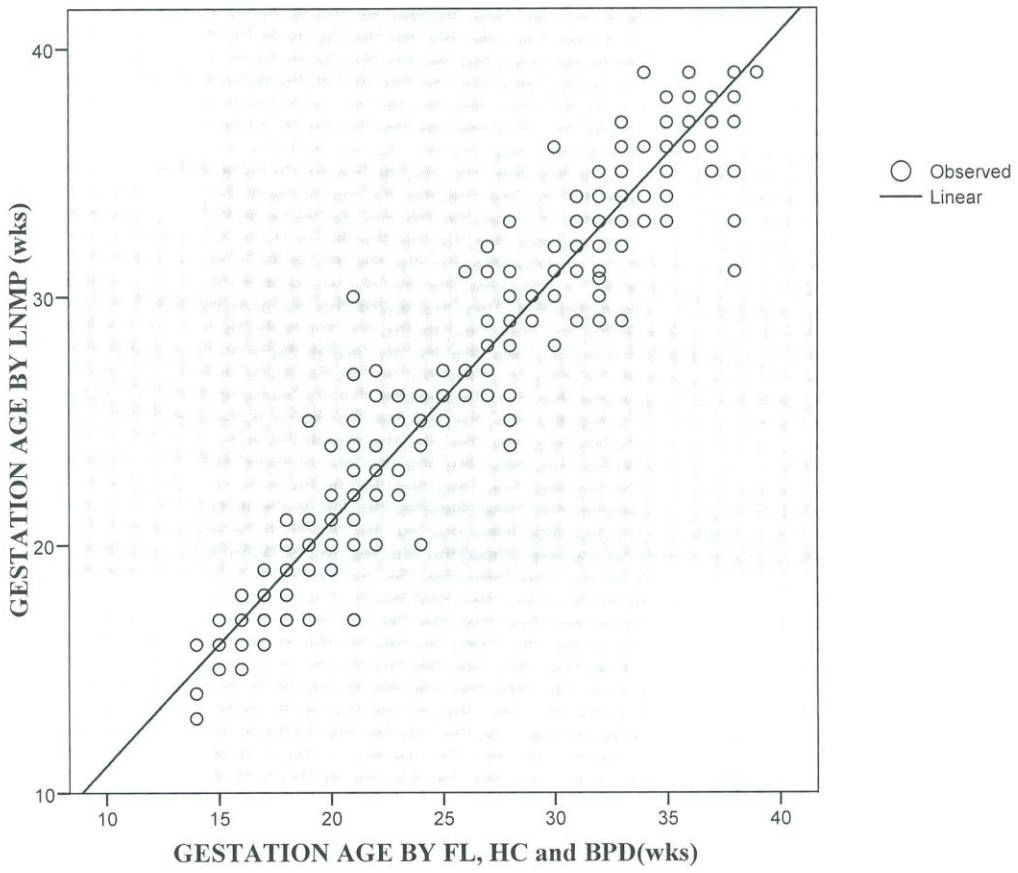
Pearson correlation coefficient for gestation age by LNMP and by biparietal diameter as shown in figure 3, r = 0.89, statistical test for null hypothesis of zero correlation of 24.90, 95%CI (0.92 – 0.99) and p<0.001

Figure: 3. Correlation of fetal gestational age by biparietal diameter (BPD)



The graph shows strong association between gestation age from LNMP and the gestation age calculated as the average FL, HC and BPD. The average value is calculated by the USS machine. Correlation coefficient r = 0.98; p<0.001 and t = 58.46 with 95% CI (0.98 – 1.02)

Figure: 4. Correlation of fetal gestational age by composite of FL, HC and BPD



DISCUSSION

From the study sample, women attending the antenatal clinic during the study period were between 18 – 40 years that represent the reproductive age [35], whereby 53.2% were in the age group of 28- 37years.

According to the results, majority of women were in third trimester representing 68% of the study sample. Their mean gestation age by LNMP was 28.22 ± 7.25 weeks. Mean gestation age by femur length, head circumference and biparietal diameter were 27.46 ± 7.18, 26.94 ± 6 .86, 27.48±7.32 respectively.

Normally but unfortunately the overwhelming majority of women in developing countries book beyond the first trimester[9]. This has been unsolved missed opportunity to mothers since earlier in pregnancy an ultrasound examination is performed, the more accurate it is. Changing behavior of late booking can be quite expensive, therefore obstetricians depend on later ultrasound to determine the due date of their pregnant mothers.
Beyond 13 weeks, measurement of fetal biparietal diameter (BPD) is used in conjunction with the femur length (FL) and head circumference (HC) to assess an interval fetal growth [31].

A simple linear correlation was performed to determine if there is a considerable relationship between femur lengths estimated gestational age and mother estimated gestational age from LNMP. Correlation coefficient for this variable was 0.95 that is relatively high compared to individual tested variables (BPD and HC), lying within 95% confidence interval of (0.94 – 1.01). This may be due to linear growth of the femur from second trimester through out the pregnancy and proper measurement of the diaphysis. P value of less than 0.001.This is supported by a study on fetal femur length as predictor of menstrual age measured sonographically. Where by variability assaciated with predicting menstrual age form femur length was +/_ 9 to 22 days fro 12 to40 weeks[27].

The head circumference (HC) showed stronger correlation relatively to the BPD despite of all being measuring the same fetal organ that has non linear growth, the head. Correlation coefficient 0.92with limited variability 95% CI (0.91 – 1.05), p value less 0.001. The results therefore show convincing evidence to reject the null hypothesis. Its measurement technique contributes in error reduction that reduces inaccuracy in case of head variation. This may contribute to difference of coefficient obtained from head circumference and biparietal diameter. This is supported with the study done to correlate fetal head circumference with gestation age. Analysis of the data demonstrated that the head circumference growth curve is nonlinear, similar to biparietal diameter growth curve. [24]

The biparietal diameter (BPD) as independent to last normal menstrual period showed correlation coeffient r = 0.89. The correlation is relatively low compared to the correlation value obtained by other tested variables, femur length and head circumference. This may be due to non linear growth of fetal head, error when taking the measurement as only minimal pressure with the real time transducer is frequently sufficient to change obliquely oriented fetal head to an occiput transverse position. Slightly excess pressure may lead to inaccuracy. Scanning at various angles through the fetal head in the midline also contribute to variation of biparietal diameters obtained. The study results are against that study done to compare femur length and biparietal diameter in the third trimester looking at the effects of gestation and growth variation. The results suggested that the biparietal diameter and femur length are equal estimator of gestation age in late pregnancy [38].

All fetal biometric parameters discussed above correlate closely with gestational age estimated from last normal menstrual period. A composite assessment of gestation age using all parameter (FL, HC, and BPD) gives a lower systemic random error than any single parameter. Calculated gestation age from the average of the three parameters done by ultrasound showed relative strongest correlation compared to the correlation from individual parameter r =0.98, 95% CI (0.98 – 1.02). Combining two or more variable maintain the closest correlation with gestation age estimated by LNMP[40]. This is supported by the study done by Hadlock and his fellows on estimation of fetal age A number of combinations of

parameters including combination of head circumference and femur length provided age estimate that were significantly better ($p = 0.05$) than those using single parameter alone[39].

Various constrain has been encounter during study performance, it was difficult to obtain sample size: Most of our women do not remember their normal menstrual period. They have little knowledge about ultrasound that gives them hesitance to participate; I had to spend a quite enough time for explanation and answering their questions to clear doubts.

It was difficult to obtain the original currently used charts from Hardlock and Hansman only modified versions were used.

The analysis used (correlation) does not show how best the biometric methods can predict the gestation age. From the study, values of gestation age calculated from last normal menstrual period showed strong positive linear correlation with the gestation age values obtained by the use of ultrasound fetal biometry. Based on literatures, experience and the observed results these two methods seem to agree with one another in estimation of gestation age at MNH.

CONCLUSION

This study showed that, although we don't have our own fetal biometric measurements charts at MNH, the measurements (FL,HCand BPD) which we have adopted from else where correlates very well with gestation age derived fro last normal menstrual period of our pregnant mothers.(P values obtained from each tested parameter confirm this significantly)

While waiting to formulate our own fetal biometric measurements we can continue to use currently adopted charts as they show correlation with gestation age derived from last normal menstrual period with an assumption of agreement of the two methods.

RECOMMENDATION

1. Ultrasound facility should be available in all Government district hospitals in Tanzania including all the newly formed districts and Health centers. This facility should be used in antenatal clinics for pregnant ladies to ensure perinatal mortality is lowered in Tanzania.
2. At the district level antenatal clinics, all pregnant ladies, especially those at risk should have at least one ultrasound scan during second trimester. Facilities should also be available for re - scanning on Medical request.
3. The currently used fetal biometric measurements charts can be used for estimation of gestation age, because the study has shown the strong correlation with gestation age estimated from our ladies Last normal menstrual period(LNMP)

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