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A CO-RELATIONAL STUDY BETWEEN GESTATIONAL AGE ESTIMATION BY ULTRASOUND (GA USG) AND POST-NATAL FOOT-LENGTH

Paediatrics

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ABSTRACT

INTRODUCTION: Gestational age (GA) estimation, is a critical factor, in decision making in Pre-term care, Prognostication and Follow-up of the new-born. Unfortunately, in developing & resource restricted countries like, INDIA, in the absence of routine abdominal ultrasound, gestational age estimation is done by Ballard's score and Last menstrual period (LMP) dating, both of which are well predictive, but not accurate. In sick babies scoring becomes hazardous and difficult to estimate gestational age.

AIM: The aim of this Co-relational, Observational study, was to determine whether postnatal foot length measurement, compared with Ultrasound, Ballard's score, could accurately determine Gestational age in neonates studied at, Durgapur steel plant hospital, West-Bengal, India.

MATERIALS &METHODS: A VERNIER CALLIPER is used to accurately measure the foot-length (mid-point of heel to longest toe)

INCLUSION CRITERION- babies born <24 hours of life; AGA (Appropriate for gestational age);USG done <12 weeks.

EXCLUSION CRITERION- SGA(Small for gestational age);LGA(Large for gestational age); congenital anomalies,obvious disproportionate foot.

RESULTS: A foot length GA model (FL-model) has been constructed by Regression, and plotted on a graph, to independently predict Gestational age from Post-natal Foot length. The curve obtained, on regression was denoted by,

Gestational age in weeks = [(0.365 * Foot length in mm) +9.6]

A sample test value of size 20, who has been randomly selected from the master sheet, has been tested on this regression model (FL-model).

The Differential error between Foot-length predicted gestational age (Fl-model) and GA USG is 1.5%;

The Differential error between Foot-length predicted gestational age (Fl-model) and GALMP is 2.1%;

The Differential error between Foot-length predicted gestational age (Fl-model) and GA Ballard is 2.3%.

DISCUSSION AND CONCLUSION: This study was done at a hospital in Eastern India. The male: female ratio of the study population was 49:51 . This study was done in 200 newborns. If this study is done in a bigger sample size, it could lead to a Foot length model, that can be used with high accuracy to determine the Gestational age in a population, where there is poor utilization of antenatal ultrasound.

KEYWORDS

INTRODUCTION

Gestational age (GA) is a critical factor in the management, decision-making, prognostication and follow-up of newborn infants, especially low birth weight infants. An accurate GA is also essential with regard to research and epidemiology[1].

Low birth weight is a major problem in the developing world. Perinatal, neonatal and infant mortality as well as morbidity is associated with low birth weight (LBW).

The mis classification of infants as term, pre-term and post-term can lead to the inaccurate description of neonatal growth and jeopardize statistical analysis[2] thereby reducing important outcomes to mere observed associations or artifacts.[3,4]

Neonatal mortality is directly related to the birth weight and gestational age. In India (50 - 60%)[6] of all infant deaths occur in the first month of life. Of these more than half may die during the first week of birth, the greatest risk being during the first 24-48 hrs after birth. Over 70% of perinataldeaths[7],85% of neonatal deaths and 30% of infant death[8]occur among LBW babies.

Gestational age can be estimated from the last menstrual period (LMP), antenatal ultrasound or neonatal estimates. LMP dating is a simple and low-cost method, but assumes the menstrual cycle to be 28 days and does not take into consideration any delay of ovulation and may cause an inaccuracy of 1–4 weeks[9].

Ultrasound-based dating, if performed early in pregnancy (<12weeks GA), is considered the gold standard and most accurate. Ultrasound-based dating, if performed early in pregnancy (<20–22 weeks GA), is considered the gold standard, with random errors of ±10 days[10].

Neonatal estimates of GA, including the Ballard (12 clinical factors) and Dubowitz (22 clinical factors) scores, are standardized postnatal scoring systems based on a variety of physical and neurological maturity factors. They are time-consuming and have been shown to be overestimating gestational age[11].Values are based on age-specific reference values but may be biased when symmetrically large or small fetuses are evaluated. Neonatal estimates of GA, including the Ballard[11] (12 clinical factors) and Dubowitz (22 clinical factors) scores, are standardized postnatal scoring systems based on a variety of physical and neurological maturity factors. They are time-consuming and have been shown to be highly inaccurate, overestimating GA by 1.3–11.9 weeks[12].

Foot length has been used in antenatal ultrasound examinations as an alternative marker for GA when other markers are unreliable, e.g. in the presence of hydrocephalus, anencephaly and limb dysplasia.[13]

Ultrasound-determined foot length remains operator dependant. In a developing country like India, especially in rural areas, access to proper health care facilities and trained medical professionals is limited. Various anthropometric alternatives to measure gestational age have been investigated in different settings to help identify LBW and Preterm babies. Some research studies have investigated newborn foot length (FL) as a screening tool for identification of preterm/LBW babies.[14-15]

The aim of this Co-relational, Observational study, was to determine whether postnatal foot length measurement, compared with Ultrasound, Ballard's score,could accurately determine Gestational

age in neonates studied at, Durgapur steel plant hospital, West-Bengal, India.

MATERIAL AND METHODS

Study Site:

- **Study area: In-patient labour room or post-natal ward** of, Durgapur steel plant hospital, Durgapur.

DATA COLLECTION TECHNIQUE AND TOOLS:

- **A Vernier calliper** is used to measure the foot length. The infant's foot was measured from the **midpoint of the heel** to the **longest toe**, ensuring that no pressure was exerted on the soft tissue. The foot was placed in a lateral position while the ankle was held and a finger placed on the foot dorsum so as not to elicit a grasp reflex, which would shorten the measurement.

Study Population: Term Neonates, less than 24 hours old, bornat Durgapur Steel Plant Hospital were included in this study.

Study Design: This is a Co-relational, Observational Study.

Time Frame To Address The Study:01-02-2018 to 01-02-2019

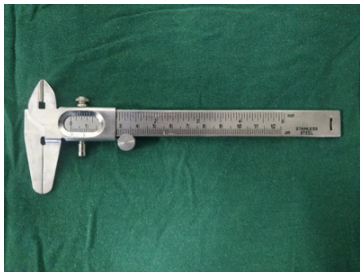
Method of measurement of outcome of interest:

1. The subjects fulfilling inclusion and exclusion criteria will be enrolled into the study after obtaining informed consent from the parent/ guardian.
2. The study subjects will be evaluated, and GESTATIONAL AGE calculated by-

2.1 USG (<12 weeks) + calculated till DOB (Date of Birth)

2.2. NEW BALLARD'S SCORE

2.3 The post-natal foot length will be taken with the help of a metallic Vernier calliper



Photograph-1: A metallic Vernier calliper

INCLUSION CRITERIA:

- All babies are **<24 hours** of life
- All babies are **AGA** (Appropriate for gestational age)
- **USG** done below <12 weeks of gestation.(1st trimester of gestation)

EXCLUSION CRITERIA:

- SGA (Small for gestational age)
- LGA (Large for gestational age)
- Congenital anomalies
- Obvious disproportionate foot
- Refusal of consent by parents

Method Of Collection Of Data:

Random sample of 200 Term neonates, from whom data were collected after clinical assessment, using a Proforma following written consent. The written consent was documented on the proforma following verbal permission from the parent to take an additional non-invasive measurement, post-natal foot-length, along with the head circumference and length, of the newborn. This is in addition to all other routine clinical measurements performed in routine neonatal care. Changes will be reported using proportions and percentages.

Anthropometric Measurements

Weight

Weight is measured and recorded within 72 hours of age and corrected to nearest 0.1 kg using an electronic weighing scale (<10kgs).

Post-natal foot-length

The new-born is comfortably made to lie on the mother's lap , with the foot end towards the doctor, who is measuring the foot-length accurately with a metallic Vernier calliper.

Head circumference

The Head circumference is measured in the newborn in dorsal decubitus. A tape is placed along the occipital-frontal circumference. Just over the eyebrows and the occiput in order to obtain the longest measurements.

Length:

Length is measured and recorded using an infantometer and corrected to the nearest 0.1cm.

Gestational age:

Gestational age of all the newborns were calculated by-

1. By adding the Ultrasound dating, done in the first trimester with the total duration of gestation, till the date of birth
2. Clinical assessment of gestational age using modified New Ballards scoring system.
3. From the first day of Last menstrual period

OBSERVATIONS AND RESULTS

Statistical Analysis:

The statistical Analysis was performed with the help of python code. Descriptive statistical analyses were performed to calculate the means with corresponding standard deviations (s.d.). Test of proportion was used to find the Standard Normal Deviate (Z) to compare the difference proportions. Pearson Correlation co-efficient had been calculated to find the correlation between variables. Regression analysis was done to find the regression co-efficient. t-test was used to compare the means of two groups. $p<0.05$ was taken to be significant.

It was found that the regression line to estimate the Gestational age (in weeks) of the newborns was found as; ($y= mx + c$), that is the equation of a straight line where m is the slope of the line and c is the intercept. In our situation "x" is foot-length and "y" is the gestational age.

Statistical analysis was performed using python. Numerical data were presented as the mean, standard deviation, percentages with 95% confidence intervals (95% Cis). There was significant correlation between post-natal foot length and gestational age, by ultrasound (GA USG), (r =0.9147)[Pearson's correlation coefficient], and its p-value was 0. 0002.Student t-test was done, and the t-statistics were = 101.7 and its p-value was 0.00002.

A foot length GA model (FL-model) has been constructed by Regression, and plotted on a graph, to independently predict Gestational agefrom Post-natal Foot length. The curve obtained, on regression was denoted by,

Gestational age in weeks = [(0.365 * Foot length in mm) +9.6]

A sample test value of size 20, who has been randomly selected from the master sheet, has been tested on this regression model (FL-model).

The Differential error between Foot-length predicted gestational age (Fl-model) and GA USG is 1.5%;

The Differential error between Foot-length predicted gestational age (Fl-model) and GALMP is 2.1%;

The Differential error between Foot-length predicted gestational age (Fl-model) and GA Ballard is 2.3%.

DISCUSSION

In this study, a good co-relation was found between gestational age by ultrasound (GA USG) and Post-Natal Foot length, satisfying primary objective.

A regression model has been constructed, and a formula has been derived from the curve obtained, thus aiding in finding out the gestational age in weeks from post-natal foot length in mm, satisfying our secondary objective. Foot length-derived GA was found to be more accurate than Ballard-determined GA.

In this study, we only included those women, whose ultrasound had been done in the first trimester, since GA-USG is considered gold standard, in my study. In an Indian study[16], it was found that antenatal ultrasound was available for 10–70% of women. Hence we can say, that if a foot length model is available, that could predict gestational age accurately, it could help the medical team or para-medical staff to get the right information about gestational age, in those poor patients, who did not have the privilege to an antenatal ultrasound.

Foot length was shown to correlate well with GA, birth weight, length and head circumference in the present study.

It was shown not to be influenced by sex or race.

In a comparison of GA determination methods in a low-resource setting[17], it was found that the Ballard score underestimated the GA, while the Dubowitz score overestimated the GA in a preterm infant population in Bangladesh. The clinical use of these neonatal scores is compromised by the need for sufficient training and clinical skills needed by the health care workers to accurately apply these scores. Foot length measurement with the Vernier'scalliper requires minimal training, is faster and can therefore be used by all levels of medical personnel. In contrast to the neonatal scores, foot length measurements also cause minimal disturbance to the neonate.

A commercially available metallic sliding Verniere's calliper was used in this study. Different measurement techniques have been used to measure the fetal/infant foot sonar[18,19-20],callipers[21,9], , footprints[23] or specifically designed instruments[24], thereby not allowing a single method of measurement to stand out as the ideal. Present study showed a high degree of intra-observer agreement, making this method of measurement easy to apply and rapid to perform, and comfortable for the babies.

Satarupa M et al[25] , concluded from their study that foot length of less than 68.5 mm has 100% sensitivity and 94.9 % specificity for identification of VLBW babies. Similar results were shown by **Mukherjee et al**[26]

In this study, there were 5 Extremely low birth weight (ELBW) babies; 13 Very low birth weight (VLBW) babies and 52 Low birth weight babies (LBW). By statistical analysis, it was found that the average foot length of the ELBW babies was 51.62 mm ; and the average foot length of the VLBW babies were 64.12 mm. It was found that 64.12 mm has 100 % sensitivity and 92% specificity in identification of VLBW babies.

Daga et al[27], through their study suggested that foot length measurement of 6.5 cm be made cut off for identifying a newborn at risk of being born within 34 weeks, where as in this study, we found that 66.2 mm is the cut off for identifying a newborn at risk of being born within 34 weeks.

Kulkarni et al[28],studied eight hundred and seventeen newborns and concluded that mean foot length at 28 weeks and 41 weeks were 5.6 cm and 7.5 cm respectively. From this study , mean foot lengths at 28 and 41 weeks were 5.7 cm and 8.4 cm respectively.

LMP and ultrasound comparisons[17]of GA determination have shown ethnical discrepancies, with more non-Caucasians being falsely identified as preterm. The effect of ethnicity on foot length also varies in published literature. **Munsnick et al**[29]however, found no ethnical differences. In our study, we could not find any effect of ethnicity on foot length.

Previous studies have shown a 4–8% difference in foot lengths in SGA infants[13]. The effects of fetal growth can be expected to affect foot length measurements, as foot measurements incorporate bone and soft tissue. Soft tissue stores of subcutaneous fat are decreased in SGA infants and may be increased in LGA infants[30]. This may affect the accuracy of foot length measurements in these populations. SGA and LGA babies were excluded from our study, hence the effect of SGA or LGA on the foot length could not be predicted.

Genetic and anatomical abnormal infants were excluded from this study. Sherwood et al[31]showed that foot length estimations caused a bias of 2–3 weeks in GA in various genetic and chromosomal abnormalities (trisomy 18 and 21, Turner syndrome, anencephaly, spina bifida and renal agenesis)

We acknowledge various weaknesses of present study. There is a lack of ethnical representivity, and a larger study is required to establish a foot length model for eastern Indian population. This study's sample size precluded further analyses to define the effect of antenatal steroids and SGA/LGA on foot length. Training for foot length measurements was not undertaken, and further research is required to determine the applicability of this measurement in areas with less-skilled medical staff.

Despite the weaknesses of the study, there are obvious advantages. The method of measurement is easy to teach and uses a cheap and easily acquired piece of equipment, making it applicable for a low-resource setting.

It can be used in NICU setups too, as it can be easily inserted through incubator port holes, thereby requiring less manipulation and causing less distress to premature or sick neonates.

This study was done in 200 newborns. If this study is done in a bigger sample size, it could lead to a Foot length model of eastern India, that can be used with high accuracy to determine the Gestational age in a population where there is poor utilization of antenatal ultrasound.

CONCLUSION

This study was done at a hospital in Eastern India. The male: female ratio of the study population was 49:51 . This study was done in 200 newborns. If this study is done in a bigger sample size, it could lead to a Foot length model, that can be used with high accuracy to determine the Gestational age in a population, where there is poor utilization of antenatal ultrasound.

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