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Original Research Article

Accuracy of foot length measurement for gestational age assessment in neonates: a prospective observational study in Central India

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ABSTRACT

Background: Gestational age (GA) is a critical-factors in the decision making and predicting mortality and morbidities of neonates. In low resource settings where affordability and availability of first trimester scan is limited, assessment is often done by postnatal methods like expanded new Ballard score (ENBS) which are often clinical skill dependent and complex. Hence, there is a need of a simple and cost-effective method which can be readily adopted by frontline health care workers at periphery. One such method is assessment of foot length (FL).
Methods: This prospective cross-sectional study was conducted in the level 3 NICU of Central India over a period of 18 months. Included neonates were assessed for GA by measuring FL by vernier calliper within 48 hours of birth and its validity was tested against ENBS as reference standard. Other anthropometric measurements like birth weight, head circumference and length were obtained within 48 hours of birth.
Results: Total 700 neonates were included in the study. For, determining preterm newborn, the potential cut-off of FL of ≤6.86 cm, with a sensitivity of 94.6% and specificity of 73.8%. The area under ROC (receiver operating characteristic) curve is 0.92.
Conclusions: FL measurement is a cost-effective and time-saving simple intervention that can facilitate early identification of preterm newborns as well as help in initiating timely interventions and hence improving neonatal outcomes in resource-poor settings.

Keywords: GA, Prematurity, ENBS, FL

INTRODUCTION

Preterm birth and its complications are the most common cause of neonatal mortality accounting for approximately 19% of all neonatal deaths in South Asia.[1] Approximately 13.4 million babies are born preterm annually, accounting for 10% of live births globally.[2] In India, recent data shows estimated 12% and 18% of children were low birth weight (LBW) and preterm birth, respectively.[3] Along with high case burden, prematurity is an independent risk factor for morbidity and mortality in neonatal period.[4] In 2019, UNICEF and WHO published survive and thrive which throws light on how countries can improve the care to support babies born too small or too soon.[5] Simple low-cost interventions like early feeding, kangaroo mother care and asepsis has the potential to reduce the complications of prematurity.[6]

Preterm neonates are defined as babies born at GA of less than 37 completed weeks. Early identification and classification of prematurity especially in rural areas of developing countries could aid in early interventions to

reduce global mortality from preterm birth and its related complications.[7] Birthweight cannot distinguish preterm gestation because of high incidence of small for gestational (SGA) age or intrauterine growth restriction (IUGR) in developing countries.[8] GA assessment is often challenging although methods both antenatal and postnatal are available for assessment like last menstrual period (LMP), fetal cardiac activity, symphysio-fundal height (SFH) and ultrasonography (USG). Antenatal first trimester USG (T1 scan) is the gold standard for GA assessment.[9]

Although in low resource settings, awareness, affordability as well as availability of T1 scan is limited and hence GA assessment is often done by postnatal methods like ENBS, Dubowitz score, anterior lens capsule vascularity.[10] ENBS is one of the commonly used assessment method and provides valid and reliable assessment until 7 days of life.[11] These methods are based of physical and neurological maturity assessment of the neonate, clinical skill dependent and complex and are, therefore, rarely used in primary care health facilities of low and middle-income countries (LMIC). Hence, there is a need of easy, reliable and affordable method for GA assessment.

The global action report on preterm birth, 'born too soon' emphasised on alternative methods such as FL for early identification of preterm newborns.[12] FL measurement is convenient method even for sick preterm and can be done by any healthcare staff as it is not skill dependent. The primary objective of the present study was to evaluate the diagnostic accuracy of FL in identifying preterm newborns in a level 3 NICU of central India with high case load of unbooked pregnancies and outborn neonates using ENBS performed within 7 days of birth as the reference standard.

METHODS

Study setting

This prospective cross-sectional study was conducted in the level 3 NICU of, Netaji Subhash Chandra Bose (NSCB) medical college, Jabalpur, Madhya Pradesh over a period of 18 months (March 2019 to August 2020) after obtaining approval from the institute ethics committee. A written informed consent in local language was taken from all parents before inclusion in the study. The annual admission rate of our unit is >3500 neonates/ year that is approximately 350 admissions per month and 10-12 admissions/day. Source of admission are babies born in the hospital (inborn) and babies referred from nearby district hospitals, civil hospitals, community health centres and primary health centres (outborn). Out of these admissions, 60% were inborn and 50% of the inborn admissions were preterm (born <37 weeks GA). About 65% of mothers does not have T1 scan on admission and lacks confirmed GA.

Study population

In this study based on GA, neonates can be broadly classified into preterm, term, and post term categories. Preterm are the neonates with GA of less than 37 completed weeks; GA between 37 weeks to 41 weeks 6 days are term and 42 weeks or more are post term neonates.

Both term and preterm neonates including SGA, appropriate for gestational age (AGA), and large for gestational age (LGA) were included in the study and assessed for GA using FL and ENBS within first 3 days of life. The study participants were selected using convenient sampling and total 700 consecutive neonates were included in the study. Still births, multiple pregnancies, gross congenital malformations such as neural tube defects, omphalocele, foot deformities such as clubfoot, children with clinical signs of chromosomal anomalies, outborn neonates admitting after 48 hours of life and failure to provide consent at the time of enrolment of the baby were excluded.

In all neonates fulfilling the inclusion criteria, FL was measured within 48 hours of admission by two health care workers. To enhance the accuracy of measurement vernier calliper was used instead of simple ruler. The right foot of the baby was selected for the FL measurement from the midpoint of the heel to the end of the longest to by a postgraduate resident. To minimize the effect of the plantar grasp reflex, examiner held the ankle with a finger placed on the dorsum of the foot to keep the foot straight. The final FL was an average of three readings. Other anthropometric parameters birth weight, length and occipitofrontal head circumference were also noted.

ENBS were obtained by the four post-graduate residents posted in NICU rotationally during the study period. Principal investigator (PI) did the ENBS for 50 neonates and team was taught using videos of assessment of physical maturity and neuromuscular maturity. Inter-observer variability measured by intra-class correlation coefficient (ICC) (95% CI) for the ENBS, calculated for consistency using the two-way random effect model, was 0.936 (0.888-0.966), suggesting good reliability.

Statistical analysis

Data were entered in MS excel sheet and analysis was done in SPSS version 22.0 (Armonk, NY: IBM Corp). Continuous variables were presented as mean and SD or median and interquartile range (IQR). Categorical variables were presented as proportions. Quantitative data with normal distribution were compared using independent samples t test. Normally distributed paired data were analyzed with paired t-test and data with skewed distribution were analyzed using Wilcoxon signed-rank test. Nonquantitative data were compared using Chi square or Fisher exact test as applicable. A

p<0.05 was considered statistically significant. Various FL cut-offs were calculated against ENBS estimated GA, considering sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), likelihood ratios (LR) and area under the curve (AUC).

RESULTS

A total of 746 newborns were screened for eligibility and 700 (93.8 %) were found to be eligible. The median age of enrolled newborns was 32 (IQR 19-44) hours. Total 312 (44.5%) were females and 388 (55.4%) males. A total of 476 (68%) were born inborn and 224 (32%) were born outside the health facility and referred within 48 hours of birth (Figure 1).

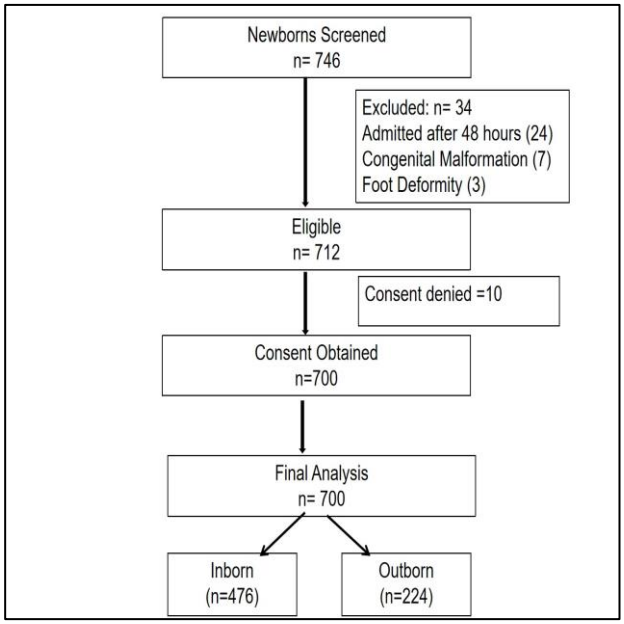

Figure 1: Study flow diagram.

The median GA at birth was 38.2 (IQR 37.0-39.3) weeks, 123 (17.6%) preterm, 524 (74.8%) term and 53 (7.6%) post term. Out of total, 605 (86.4%) were AGA, 76 (10.8%) were SGA and 19 (0.02%) LGA. Overall, the median FL was 7.49 (IQR 7.6-8.1) cm. The median FL for preterm and term births was 7.3 (IQR 6.7-7.5) and 7.9 (IQR 7.8-8.2) cm, respectively (Table 1).

For determining preterm newborn, the potential cut-off of FL of ≤6.86 cm was identified using Youden index, with a sensitivity of 94.6% and specificity of 73.8% to predict a preterm baby; with a positive predictive value of 94.4% and a negative predictive value of 72%. The area under ROC curve is 0.92 (Figure 2).

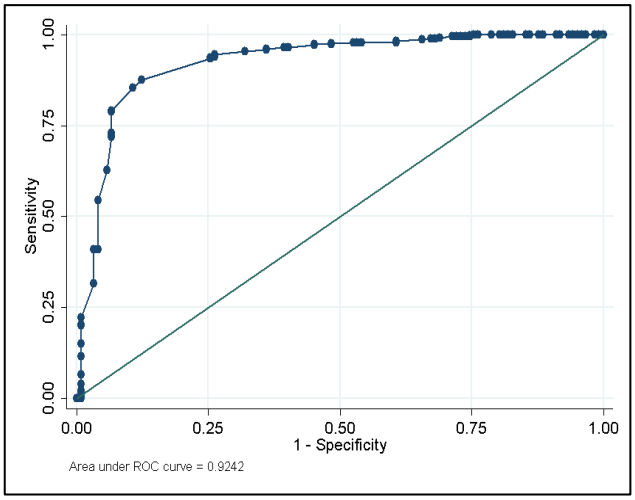

Figure 2: ROC curve.

The correlation coefficient (r) of FL with GA, birth weight, crown-heel length and head circumference are 0.41, 0.38, 0.51 and 0.25 respectively. All the variables are correlated significantly with FL having the p<0.0001 (Table 2). The correlation of FL with GA estimated via Ballard's score has the correlation coefficient of 0.77 (p<0.0001) (Figure 3).

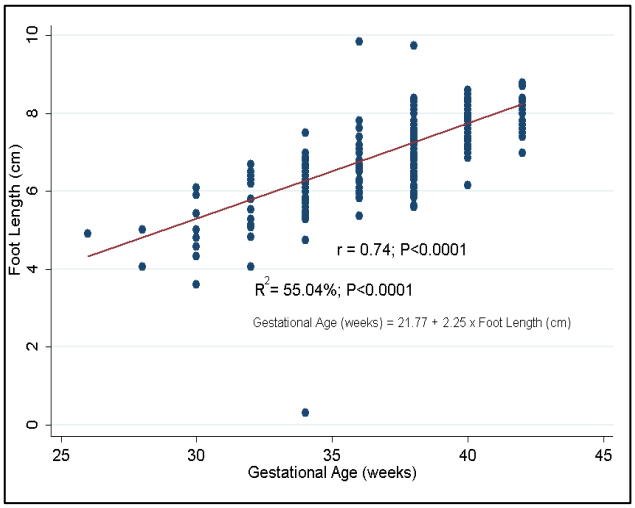

Figure 3: Diagnostic performance of FL (cm) at cut-off 6.858 to predict preterm neonate.

Table 1: Distribution of subjects by their foot length and their gestational maturity.

Gestational maturity	Foot length (cm)							
	≤6.9 cm		7-7.8 cm		>7.8 cm		Total	
	N	%	N	%	N	%	N	%
Preterm	108	15.4	14	2	1	0.1	123	17.5
Term	67	9.5	361	51.5	96	13.7	524	74.8
Post term	4	0.5	17	2.4	32	4.5	53	7.5

Table 2: Regression model to predict the gestational age with FL, crown-heel length, birth weight, Ballard's score and head circumference.

Gestational age	Foot length (cm)		Birth weight (gm)		Crown-heel length (cm)		Head circumference (cm)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
<37 weeks (preterm)	6.2	1.1	1853.7	551.2	41.7	3.5	30.0	2.2
37-41 weeks (term)	7.5	0.5	2784.0	399.3	47.2	2.0	33.1	1.1
>41 weeks (post term)	8.0	0.4	3202.8	426.0	48.8	1.9	34.0	1.4
Gestational age (weeks)	21.77±2.25, foot length		29.09±0.03, birth weight		11.66±0.57, baby length		5.66±1.0, head circumference	
R2	0.55		0.66		0.55		0.57	
P value	<0.0001		<0.0001		<0.0001		<0.0001	

DISCUSSION

This prospective study was done in high caseload tertiary care unit of central India and included 700 neonates for FL measurement and ENBS score was done within 48 hours of life. Other anthropometric parameters i.e., head circumference, birth weight and crown-heel length were also analysed with the GA. An FL of ≤6.86 demonstrated high sensitivity and specificity, and correctly identified 94.6% of preterm newborns. Conversely, it correctly ruled out preterm newborns in 73.8% of cases. This highlights its proficiency as a simple screening tool for low resource healthcare providers in identifying preterm infants. The high sensitivity facilitates early identification of preterm newborn, which is a crucial factor for timely interventions and improved outcomes.

Stevenson et al done a similar study in South Africa on 106 newborns using T-1 scan as well as ENBS as reference standard and FL ability to discriminate between preterm and term infants gave an area under ROC curve of 0.95 which is higher than our study. This can be explained on the basis of small sample size.[13] Another study done in 260 Nigerian neonates showed a high level of intra-GA reliability between calliper measurements and GA estimation by ENBS.[14] Thi et all studied 485 neonates within 24 h of birth and found good predictability of FL (AUC 0.94, 95% CI 0.92-0.96) similar to present study. The optimal cut-points for measurement in this study was ≤7.4 cm for FL.[15] In present study, 51.5% (361) neonates the FL between 7.0-7.8 cm and 15.4% (108) PT has FL of ≤6.9 cm. This is comparable to the study done by Rakkappan et al in which the FL ranges between 4.5-9.9 cm with the mean FL of 6.91cm in term new-borns and the mean FL of 5.94 cm in preterm new-borns.[16] Three studies using T1 scan as a reference standard reported an FL cut-off of ≤7.5 cm. reported a sensitivity of 95.4% to 98.9%, while our study observed a sensitivity of 94.6%.[17-19]

Strength of the study is firstly; it was conducted in a tertiary care centre with high case load of unbooked mothers and outborns babies whose first trimester scans are often not available. Because of the high case burden immediate identification of the neonate based on gestational age was sometimes delayed as ENBS examination is time consuming and skill dependent. Second, excellent inter-rater reliability and inter-rater agreement improves internal validity of the study. Third, to improve the measurement accuracy, vernier calliper was used whereas other studies have used simple ruler. The optimal cut-off was obtained from receiver operator curve, balancing sensitivity and specificity effectively.

Major limitations of this study were diagnostic accuracy was not validated against first trimester T1 scan which is gold-standard for GA estimation. Secondly, it was single centre study, potentially limiting external validity and challenging generalisation to a broader population. Additionally, impact of classification on complications and clinical outcomes neonates is not observed, it can provide a better perspective of utility of FL measurement.

Present study obtained a of optimal FL cut-off values, specifically ≤6.86 cm presents a quick, and accessible tool for clinicians and frontline healthcare providers in resource-limited settings where availability of T-1 scan may be limited. The simplicity and low cost of measuring FL make it a reliable option for early detection of preterm newborns. To ensure the usability of FL in day-to-day practice, it can be integrated in the training programmes to educate healthcare workers on accurate measurement techniques and interpretation of FL.

CONCLUSION

FL measurement is a cost-effective and time-saving simple intervention that can facilitate early identification of preterm newborns as well as help in initiating timely interventions and hence improving neonatal outcomes in resource-poor settings. It is especially useful when T-1 scans are unavailable and healthcare workers are not skilled in doing EBNS. Further research is essential to validate and generalize these findings in diverse populations as a GA assessment screening tool.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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