ORIGINAL RESEARCH

Diagnostic Accuracy of Physical Assessment Techniques for Estimation of Gestational Age of Neonates- A Cross-sectional Study

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ABSTRACT

Background: Gestational Age (GA)estimation is one of the top priorities to improve clinical care for neonates and determine the burden due to prematurity. In Low and Middle Countries- lack of access of ultrasound during first trimester, late registration of pregnancy, and maternal illiteracy makes accurate estimation of neonate'sGA difficult. **Aim:** To estimate the gestational age of neonates using the New Ballard System and Parkin scoring system. **Material and Methods:** This was a single-centre, hospital-based, cross-sectional, observational study conducted over a period of 18 months by enrolling a total of 221 neonates born at Chirayu Medical College, Bhopal. The GA of all neonate was assessed using the New Ballard and Parkin scoring system. **Results:**Among 221 neonates enrolled in study, 149 (67.4%) were born full-term and remaining 72 (32.5%) neonates were born preterm.The mean gestational age calculated using LMP method was 37.6 weeks and New Ballard scoring system was 36.5 weeks and by Parkin system was 36.8 weeks. The sensitivity of NBS in identifying 'very pre-term' neonates was 75% (3 out of 4).The correlation co-efficient between the gestational age by LMP method, Sonography, and New Ballard scoring system was +0.81 and +0.75.The correlation co-efficient between the gestational age by LMP method, Sonography, and Parkin scoring system was +0.72 and +0.67.**Conclusion:** Parkin system can be used as a screening tool for all new-borns and NBS reserved for preterm or sick neonates.

INTRODUCTION

Globally, preterm birth affects more than one in ten births(1). It is the leading cause of death among new-borns and the second leading cause of death among children under the age of five(1). Many infants who survive preterm birth are at risk for lifelong disabilities such as cognitive impairment, poor motor skills, behavioural issues, hearing loss, chronic lung disease, and decreased economic productivity(1). More than 90% of the world's 15 million preterm births occur in low- and middle-income countries (LMICs), where preterm infants have a 7-fold higher risk of neonatal mortality and a 2.5-fold higher risk of post-neonatal mortality than their full-term counterparts(2–4). To identify preterm and small-for-gestational-age infants and provide them with effective interventions, an accurate GA is required(5–7). Therefore, prompt recognition of the preterm infant may facilitate the prompt administration of potentially life-saving interventions, such as continuous positive airway pressure or kangaroo mother care, to the new-born. In low- and middle-income countries (LMICs), the lack of available or accurate data on the gestational age (GA) of a pregnancy, and consequent misclassification of the infant as preterm or not, is a significant barrier to providing adequate care for these vulnerable infants and estimating the global burden of preterm birth(7,8). In LMICs, accurate and practical methods for determining gestational age (GA) are urgently required to facilitate the early identification and referral of premature infants and the delivery of potentially life-saving interventions(3).

The Every New-born Action plan launched in the year 2014, aimed to end preventable neonatal deaths and stillbirths by 2030(1). The New-born Action Plan has included improvement in GA estimation as one of the top priorities to improve clinical care for neonates and determine the exact disease burden due to prematurity(1). Ultrasound dating in early pregnancy is currently the most accurate method for determining gestational age (GA) and is the standard of care in

high-income nations(9–11). Clinical new-born assessment for GA dating has become less relevant in high-income settings, where early pregnancy ultrasound coverage is high and pregnancy dating uncertainty is less prevalent than in LMICs(12,13). Increasing access to ultrasound is a priority for both maternal and new-born health; however, given the limitations and challenges of ANC access, there is an urgent need for new strategies to date new-borns more precisely and identify preterm infants after birth.

In the majority of low- and middle-income countries (LMICs), determining gestational age at rupture of membranes and/or onset of labour is difficult, and postnatally, birthweight alone is too crude a measure to distinguish between growth-restricted and preterm infants(6,7,14). Secondary to the lack of access to early prenatal ultrasound, healthcare providers must rely on other methods to classify infant GA at delivery, such as last menstrual period (LMP), new-born assessment, or birth weight(11,15–17). Accurate menstrual dating requires maternal knowledge of the last menstrual period (LMP) and a regular 28-day cycle length and is considered to be accurate to within two weeks. In addition, the first presentation to antenatal care occurs late, on average at 3-4 months gestation(18).

In settings without widespread access to early ultrasound scan dating and where the accuracy of recalled LMPs is highly variable, clinical assessment of the new-born continues to be the most common method for determining GA. Clinical assessment of new-born maturity after birth has been used as a surrogate for estimating gestational age in new-borns for a very long time. Multiple scoring systems, ranging from four to twenty-three signs, have been described in the literature, with varying combinations of signs and measurements. However, the feasibility of implementation and expansion in LMICs with limited human resources is crucial. The Ballard test is one of the most frequently administered systems for GA assessment. This system was revised further (New Ballard Test) in the year 1991 to make it easier to apply and increase accuracy(19). Parkin has also proposed a method for evaluating GA. In addition, there are several other scoring systems and classifications. In South Asia, another challenge is the high prevalence of foetal growth restriction, which may influence the validity of the postnatal clinical maturity assessment. The overarching aim of this study was to compare the New Ballard Score and Parkin's Score in estimating the gestational age of neonates, to compare the New Ballard Score and Parkin's Score in comparison to gestational age estimated by Last Menstrual Period.

MATERIAL AND METHODS

STUDY DESIGN

This was a single-centre, hospital-based, cross-sectional, observational study.

STUDY SETTINGS

Department of Paediatrics, Chirayu Medical College and affiliated Hospitals, Bhopal. Itis a super speciality tertiary care institute.

STUDY DURATION

18 months

STUDY OUTCOMES

1. **New Ballard Scoring System:** The gestational age of the neonate was assessed using the New Ballard scoring system. The standard methodology of assessing the new-born was followed(19).
2. **Parkin Scoring System:**The gestational age of the neonate was also assessed using the Parkin scoring system. The standard methodology of assessing the new-born was followed(20).
3. **Independent variable:** Reports of the USG from the first trimester and the date of the first days of the last menstrual period as reported by the mother or available from the clinical records. **Sample Size Calculation:** Every neonate born at the study institute and referred to the department of paediatrics during the period of participant recruitment and who fulfilled the inclusion criteria was included in the study. Following this, a total of 221 participants were enrolled in the present study.**Participants recruitment:** The participants were recruited into the study after verifying that they fulfilled the following selection criteria.

INCLUSION CRITERIA

a. Neonate of all gender
b. Neonate of all gestational age (both term & preterm)
c. A neonate who was born <=72 hours ago from the time of assessment.
d. Neonates whose mother was aware of their date of last menstrual period or neonates whose mother had a report of first-trimester ultrasonography scan available.
e. Mother/guardian who consented to participate in the study.

EXCLUSION CRITERIA

a. Neonates with congenital malformations.
b. Neonates of postnatal age more than 72 hr.
c. Mother/guardian who did not consent to participate in the study.

SAMPLING METHODOLOGY

Non-probability, purposive, and convivence sampling methodology was employed to recruit participants for the present study. **Obtaining Informed Consent:** The consent form was given to all the mothers/guardian accompanying the neonate. Thereafter, the contents of the consent form were explained to them in their preferred language. Every question or query raised by

the participants related to the study was answered to the best of the principal's investigator knowledge. The participant's caretakers were explicitly informed that they have the right to withdraw from the study at any point in time. **Data Collection:** All the data were collected in a paper-based proforma. **Source of Data:** All the data for the present study were collected from the following two sources. The first source was the pregnancy reports, details of delivery, and laboratory reports. The second source of the data was findings of the clinical assessment of neonates using the New Ballard and Parkin scoring system.

PLAN AND PROCEDURE

a. At Chirayu Medical College, in addition to the routine new-born screening, all study participants were assessed for estimating the gestational age following the standard procedure. Time taken to complete the assessment using the two methods was recorded for each participant. All neonates were assessed for gestational age by the principal investigators.
b. The details of the pregnancy were collected after the neonatal assessment. The details of pregnancy were collected by the interns posted in the department. After the completion of the neonatal assessment, the details of the pregnancy and other relevant details were collected from the medical record. If any information or data was missing in the records only then the missing information was asked/confirmed by the mother/guardian.

STATISTICAL ANALYSIS PLAN

The primary outcome was the gestational age of the neonate as assessed by the New Ballard system and Parkin system. The secondary objective was to assess the degree of similarity between the gestational age calculated by the two methods. As mentioned previously, the data were collected in a paper-based data collection proforma. Thereafter, the data were coded and entered in Microsoft Excel. The coded data were imported into Stata 17.1 version for analysis. The comparison of continuous variables before and after following up was done using a student's t-test. Categorical variables were analysed using chi-square (χ^2) tests. A *P*-value < 0.05 was considered statistically significant(21,22). **Funding:** There was no external funding for this study. Participants were not paid any fee/incentive or given any gift to participate in the present study.

RESULTS

In the present study, 45% of women did not have a sonography conducted in first trimester. Moreover, 34 % of mother registered after the first trimester of pregnancy.In the present study, the average time taken to complete the GA by NBS method was 343 (±8.47) seconds ranging from a minimum of 293 seconds to 403 seconds. In comparison, the time to complete the GA assessment by PS was 97(±4.82) seconds ranging from a minimum of 82 seconds to a maximum of 127 seconds. In the present study, the GA assessment of all participants was completed with 48 hours, moreover, more than 80% of participants were assessed within 24 hours.

Table 1: Gestational age of the participants (n=221)

GA Category	n	%
30-32	6	2.7
33-34	29	13.1
35-36	37	16.7
37-38	44	19.9
>=39	105	47.5
Total	221	100.00
Mean(SD)	37.6 (2.73)	
Range	30.3 - 42.7	

The mean gestational age was 37.6 weeks, and the range of gestational age was from a minimum of 30.3 weeks to a maximum of 42.6 weeks. Among 221 neonates enrolled in study, 149 (67.4%) were born full-term and remaining 72 (32.5%) neonates were born preterm. In the present study, 43% neonate were born by normal vaginal delivery and remaining 57% had C-section. Among the 126 neonates born by C-section: 69.4% mothers had elective C-section and remaining 30.6% had elective C-section.Among the 221 neonates, 35% required admission to the NICU. The mean and the median birth weight of the participants was 2646 and 2721 grams, respectively. About 70 (31.67%) participants had low birth weight.

Table 2: Comparison of Gestational age by LMP and New Ballard Scoring System (n=221)

LMP	New Ballard Scoring System							
	30	32	34	36	38	40	42	Total
30	2	0	0	0	0	0	0	2
31	1	1	0	0	0	0	0	2
32	1	1	0	0	0	0	0	2

33	4	5	4	0	0	0	0	13
34	4	5	5	2	0	0	0	16
35	3	4	10	0	0	0	0	17
36	0	2	6	8	4	0	0	20
37	0	1	5	10	4	0	0	20
38	0	0	4	6	11	3	0	24
39	0	0	3	6	15	6	0	30
40	0	0	0	6	13	16	10	45
41	0	0	0	3	6	10	6	25
42	0	0	0	0	1	1	3	5
Total	15	19	37	41	54	36	19	221

Table 2 shows the distribution of gestational age calculated using the LMP method and the new Ballard Scoring system. The mean gestational age calculated using LMP method was 37.6 weeks and New Ballard scoring system was 36.5 weeks. The sensitivity of NBS in identifying 'very pre-term' neonates was 75% (3 out of 4).

Table 3: Comparison of Gestational age by LMP and Parkin Scoring System (n=221)

LMP	**Parkin Scoring**											
	30	**32**	**33**	**34**	**34.5**	**36**	**37**	**38.5**	**39.5**	**40**	**41**	**Total**
30	0	2	0	0	0	0	0	0	0	0	0	**2**
31	2	0	0	0	0	0	0	0	0	0	0	2
32	1	1	0	0	0	0	0	0	0	0	0	2
33	4	5	4	0	0	0	0	0	0	0	0	13
34	2	3	6	4	1	0	0	0	0	0	0	16
35	0	1	2	5	6	3	0	0	0	0	0	17
36	0	0	2	4	4	7	3	0	0	0	0	20
37	0	0	0	2	4	5	7	2	0	0	0	20
38	0	0	0	0	3	4	7	7	3	0	0	24
39	0	0	0	0	0	1	3	7	12	6	1	30
40	0	0	0	0	0	1	2	12	14	10	6	45
41	0	0	0	0	0	0	4	4	7	6	4	25
42	0	0	0	0	0	0	0	0	2	1	2	5
Total	9	12	14	15	18	21	26	32	38	23	13	221

The mean gestational age calculated using LMP method was 37.6 weeks and Parkin system was 36.8 weeks (Table 3).

Table 4: Correlation coefficient

Scoring System	**LMP**	**USG**
New Ballard Scoring System	+ 0.81	**+ 0.75**
Parkin Scoring	+ 0.72	**+ 0.67**

The correlation co-efficient between the gestational age by LMP method, Sonography, and New Ballard scoring system was +0.81 and +0.75.The correlation co-efficient between the gestational age by LMP method, Sonography, and Parkin scoring system was +0.72 and +0.67.

DISCUSSION

Accurate GA determination is a public health goal in LMIC settings when early ultrasound dating is not widely available and accurate LMP recollection is extremely variable to lower preterm birth-related morbidity and death. There are several ways to evaluate GA at the bedside utilising physical and neurological parameters. These techniques either make use of a set of physical or external criteria, neurological criteria, or both. Nineteen distinct new-born evaluations or scoring methods for GA determination were published between 1966 and 2022(6). A total of 12 GA scoring systems were first developed in high-income environments, and 7 in LMIC (4 in Africa, 2 in Asia, 1 in other). To provide a more straightforward score for evaluating the Gestational Age of the new-born, Ballard et al. updated the Dubowitz scoring system in 1979(23). The original Ballard score was upgraded to New Ballard Score (NBS) in 1991 and expanded to account for severely preterm infants(19). A GA score was created by Parkin et al. based on four external factors (skin colour, ear firmness, skin texture and breast size). This scoring system is simple, takes less time and has strong inter-observer reliability(20). Less research has been done on these metrics' concordance with the Indian population. With LMP GA serving as the benchmark, our goal was to examine the applicability of two scores, ENBS and PS among

children born at our institute. We enrolled a total of 221 neonates in the present study.

In the present study, the mean gestational age calculated using LMP methods was 37.6 weeks, and the range of gestational age was from a minimum of 30.3 weeks to a maximum of 42.6 weeks. We found 30 papers that examined the Original (n=25) and/or New Ballard Score (n=13) for validity. In the present study, residents and a specialist from the paediatrics department assessed GA. In comparison among the 30 reviewed studies, the NBS GA evaluations were carried out by Healthcare workers in the majority of the studies (physicians, nurses, or research assistants) and two studies by community health workers after training. The Original Ballard Score was utilised in 14 research from the LMIC, and the New Ballard Score was used in 7.

The mean gestational age in the current research was 36.5 weeks using the New Ballard Scoring system and 37.6 weeks using the LMP technique. Between the NBS and LMP methods, there was an average discrepancy of (±)1.1 weeks. Furthermore, the NBS and LMP techniques' correlation coefficient (r) was +0.81. The correlation coefficients of Ballard GA and LMP GA across the studies examined varied from 0.66 to 0.96 (median=0.85; n=13). Thus, the findings of the present study were comparable to other studies comparing the NBS and LMP GA assessments. In the present study, the NBS scoring system accurately predicted the GA in more than 75% of cases, predicted it accuracy of ±1.5 weeks in more than 88% of cases, and ±2 weeks in more than 93% of participants. According to a systematic review by Lee AC et al., GA fell within 1 week of LMP GA in 43.9% (95% CI: 23.9% - 66.1%; n=3) of new-borns and within 2 weeks of LMP in 75.4% (95% CI: 70.3% - 79.8%; n=9) of new-borns(6).

In the present study, NBS was more accurate in identifying ‘very preterm’ neonates and ‘full-term’ in comparison to ‘moderate’ & ‘late’ preterm. The NBS correctly identified 3 out of 4 ‘very preterm neonates’ in the present study. Baumann et al. reported that the correlation of Ballard with GA was lower among SGA infants compared to those AGA. Grey AR et al. showed that for SGA babies, the bias for GA dating was 1-1.5 weeks lower than for non-SGA infants(24).The majority of individual physical and neurologic signs that have been used in NBS had a moderate to excellent correlation with GA, with a median correlation coefficient of 0.8. A critical consideration in LMIC is the validity of the assessment in populations with high rates of foetal growth restriction, or SGA. Distinguishing whether a small baby is preterm, SGA, or both, is a challenge in these settings. Most neonatal assessments were designed to measure infant maturity, as opposed to gestational length. SGA infants may act less mature during a neonatal clinical assessment. Three studies have shown that among growth-restricted infants (SGA), neonatal clinical exams tend to systematically underestimate GA. Thus, improving the validity of the neonatal assessment to estimate GA in growth-restricted populations is a critical research need in LMIC.

In the present study, 45% of women did not have sonography conducted in the first trimester. Moreover, 34 % of mothers registered after the first trimester of pregnancy. These results highlight the need of using GA evaluation at birth rather than USG. Raj M et al. found that 47% of the women did not receive early trimester USG, which supports the selection of an appropriate postnatal GA evaluation approach and is consistent with our findings(8). According to Raj M. et al., both the NBS and PS scoring systems overestimated the GA, albeit only by one week when compared to LMP. In this investigation, ENBS had the best validity at low GA, but PS exhibited substantial validity at higher GA. This bias variance was highly significant (p 0.001). According to Sreekumar, et al., who compared ENBS with Parkin, Parkin demonstrated greater accuracy within 12 days, especially in ill and premature new-borns(25). According to Sunjoh, et al findings's(26), ES had the lowest MD between method and by dates and was the most accurate score. Between Farr, Dubowitz, ENBS, and ES with LMP, they made comparisons. In a similar vein, research comparing ENBS and Parkin scores revealed a mean difference of 3.75 days. According to studies from Bangladesh and Zimbabwe, relying solely on the physical parameters of the Ballard score proved reliable in low-resource environments(14,27). Given the low prevalence of early trimester USG and the high rate of preterm delivery in LMICs, predicting GA using scores based solely on physical criteria should give crucial GA evaluation to seek appropriate care and improve outcomes. Due to the scarcity of medical professionals with the necessary training and clinical expertise, their viability for usage in low-resource settings is significantly hampered.

Both the New Ballard score and the Parkin score used to estimate gestational age in the current investigation indicated a significant positive connection. Sreekumar K et al., and Ambey R et al. made comparable findings (63,71). In the present study, GA assessment by NBS was found to be more accurate than PS. Similar findings were also reported by Sreekumar K et al., Ambey R et al., Sarkar K et al., and Raj M et al(8,25,28). Another study done by Erman, et al. also found NBS more accurate compared to the Dubowitz score(14). Parkin score gestational age had a good correlation with LMP-GA in healthy new-borns, however, it was less precise than NBS. NBS did not significantly correlate (p-value>0.05) with the Parkin score and with the gestational age determined by LMPGA in unwell neonates who had morbidities of HIE-3 and RDS, but the Parkin score did. This conclusion is comparable to that shown by Indra et al.

In the present study, the average duration to complete the GA by NBS method was 343 (±8.47) seconds in

comparison to the time to complete the GA assessment by PS was 97(±4.82) seconds. In comparison, Ambey R et al., reported that the mean time to complete GA by NBS and PS was 324 and 89 seconds respectively(28). Feasibility and scalability are critical factors in considering the use of the new-born assessment for GA dating in LMIC. There is a positive correlation between the number of parameters and the accuracy of a GA assessment. Yet, there is likely to be a negative correlation between the number of parameters (especially neurological) and the feasibility of use. While the Dubowitz assessment had the best accuracy of the new-born clinical assessments, the assessment is complex (21 signs), may take 15-20 minutes to complete, and includes more difficult-to-train neurologic criteria. The handling of sick neonates, particularly those with prematurity and perinatal asphyxia, is advised to be as gentle as possible because vigorous handling increases the risk of intraventricular haemorrhage in preterm low-birth weight neonates. All new-borns, healthy or unwell, run the danger of developing sepsis if handled needlessly for a long time. Neonates were more uncomfortable as a result of the new Ballard score than they were as a result of the Parkin score, as seen by the considerably more crying bouts and extended examination times. Raj M. et al., Sreekumar et al., AmbeR. et al., and Sarkar K. et al. all made similar observations(8,25,28).

CONCLUSION

The overarching aim of GA is to determine if the new-born requires any intervention to improve the outcome. Towards this aim, factors other than the accuracy of the method are critical for wide-scale implementation and adaptation by healthcare workers. For the clinician, the primary objective is to identify preterm infants requiring special care. A measurement tool with high sensitivity is desired to identify all preterm infants, perhaps at the expense of specificity. Although the NBS system was more accurate and correlated better with LMP GA, the feasibility of its widescale adaptation is limited by the complexity of the assessment. The parking system is simple with a fair degree of accuracy. Therefore, the Parking system can be used as a screening tool for all new-borns and NBS reserved for preterm or sick neonates.

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