Development and initial validation of a simplified gestational age score in low birth weight newborns in India

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ABSTRACT

Background: Assessment of gestational age (GA) based on the last date of menstrual period is often inaccurate. Scores to predict GA of newborns are difficult to use particularly by health workers. An accurate, easy to use the method of assessing GA, particularly in low birth weight (LBW) babies, is needed to detect and link premature newborns to the appropriate level of care. **Objectives:** The objectives were (1) to develop a "simplified GA score" (SGAS) by selecting items from 3 standard GA scores that significantly predict the GA as measured by the best obstetric estimate (BOE), (2) to validate the accuracy of SGAS against the BOE, (3) to compare the accuracy of SGAS to assess the GA as compared to the accuracy of GA assessment by the New Ballard Score (NBS), and (4) to assess inter rater agreement of SGAS as compared to that of NBS. Materials and Methods: Both the development and validation studies were cross-sectional studies. In the development study, two neonatology residents trained in the use of the 3 scores assessed LBW (<2,500 g) newborns within 24 h of birth. The residents were blinded to each other's assessment and the BOE (GA obtained from last menstrual period [LMP] and confirmed by ultrasound (USG) to be within 2 weeks of the GA ascertained by LMP). Items significantly predictive of GA in multiple regressions were included in the SGAS. In the validation study, two different neonatology residents trained in the use of SGAS assessed the same LBW newborns within 24 h of birth, blinded to each other's assessment and the BOE. Results: In 171 LBW newborns enrolled in the development study, 4 items (Skin, breast, genitals, and posture) were selected for the SGAS. The prevalence of very preterm (<32 weeks) was similar to the actual prevalence. Agreement between the two ratters for SGAS (Cohen's kappa 0.825) was better than that for the NBS (Cohen's kappa 0.709). SGAS had higher positive predictive value for ≤ 32 weeks and for ≥ 32 weeks to ≤ 35 weeks as compared to the NBS. Conclusions: SGAS is a promising scale for assessment of GA. It needs further validation by public health nurses and community health workers of low resource settings.

Key words: Community, Gestational age, Newborns, Preterm neonates, Simplified gestational age score

Preterm birth (<37 weeks gestation) is responsible for an estimated 1 million deaths of children under age 5 globally [1]. In India, preterm gestation is responsible for 52% of the neonatal deaths and 19% of under 5 mortality. Preterm gestation may not be recognized at birth because of inaccurate estimation of gestational age (GA) from the reported date of last menstrual period (LMP) and lack of availability of ultrasonography. Preterm gestation cannot be assumed on the basis of low birth weight (LBW <2,500 g) because a large proportion of the 22% LBW babies born in India [2] are small for GA (SGA), not premature. Since 78.9% of Indian babies are born in facilities [3], mostly first-level facilities, it is important that preterm neonates are recognized and linked to appropriate care.

Before the availability of ultrasound (USG) for GA dating was widely available in high-income countries, newborn physical and neurologic maturity were used to estimate GA. The Dubowitz and Ballard (including the New Ballard) scores predict GA±14 days of LMP dating in high-income settings [4] where there are fewer SGA babies than in low and middle-income countries, and there is less uncertainty about the date of the LMP. These scores are complex to use, require expertise that frontline healthcare workers often do not have in low- and middle-income countries and may be inaccurate because neurologic examination may be influenced by birth asphyxia, congenital abnormalities and infection, etc [5-8].

Simplified methods have been developed in India [9-12], but they have not been adapted for use by community health workers to assess LBW babies. Therefore, our objectives were (1) to develop a simplified GA score (SGAS) by selecting items from 3 standard GA scores that significantly predict the GA as measured by the best obstetric estimate (BOE), (2) to validate the accuracy of SGAS against the BOE, (3) to compare the accuracy of SGAS to assess the GA as compared to the accuracy of GA assessment by the New Ballard Score (NBS), and (4) to assess inter rater agreement of SGAS as compared to that of NBS.

MATERIALS AND METHODS

The Phase I was the development of the score and Phase II was the validation. Both studies were conducted in a tertiary care teaching hospital of the central India. Both were observational cross-sectional studies, which the latter was a diagnostic validation study. Both were of 20 months duration from February 2007–October 2008 and January 2011–September 2012 respectively. Ethical approval was received from the IGGMC IRB.

Phase I (Development Study)

Study subjects and procedures

All mothers of LBW neonates were screened for eligibility criteria.

Inclusion Criteria

Singleton LBW baby born alive in the hospital and available for assessment within 24 h of birth; GA available both by LMP and USG obtained in pregnancy with the difference between the two being <2 weeks.

Exclusion Criteria

Neonates with twin gestation, perinatal asphyxia, congenital anomalies, neurological depression, shock, or major illness like respiratory distress, intracranial hemorrhage, and sepsis were excluded. After written informed consent was obtained, a neonatology resident, trained in the use of the NBS [13], the Dubowitz score (DWS) [14], and the Meharban Singh score (MS) [15] assessed the GA of each neonate using the 3 scores. He was blinded to LMP, USG, and mother's obstetric history [16]. The residents examined the undressed babies in a relaxed position in diffuse light separately on two different occasions but within 24 h of birth in the postnatal ward or Neonatal Intensive Care Unit or Premature Baby Unit, wherever the baby was shifted after birth. The BOE was the GA obtained from USG during pregnancy (any trimester), corresponding to LMP within 2 weeks, by a different observer.

Statistical Analysis

As a development study, the sample size for this study was empiric and included only LBW babies equitably distributed across the GA categories. We assessed the correlation of the 3 total scores and each item in the 3 scores with the BOE (gold standard). Predictive power of each item in single score was estimated and compared with others and was used to select the items in SGAS as described in the results section. We also decided to divide the total SGAS into four GA categories (<32 weeks; 32-<35 weeks; 35-<37 weeks; and 37 weeks and greater) to correspond closely to levels of recommended care and need for referral/urgent treatment and simplify decision making by frontline healthcare workers in the future [16]. Statistical analysis was done using STATA 10/IC software.

Phase II (Validation Study)

Study subjects and procedures

The validation study consecutively enrolled 179 infants. The screening procedures were the same as for the development study. Two different neonatology residents (R1 and R2) were trained in the use of the NBS and the SGAS. They obtained the scores on NBS (NBS1 and NBS2) and SGAs (SGAs 1 and SGAs 2) of the newborns enrolled in the study within 24 h of birth. As in the Development Phase, they were blinded to LMP, USG, and mother's obstetric history and were blinded from each other's assessment.

Statistical Analysis

The sample size for the validation study was also empiric and similar to the sample size for the development study. The power calculations for different prevalence in the four categories of GA suggests adequacy of sample size. We compared frequency distribution of neonates in four GA categories based on proportion of babies identified by both observers using NBS and SGAS versus the BOE. We also evaluated following agreements (1) inter- observer between NBS 1 and NBS 2, (2) inter-observer between SGAS 1 and SGAS 2, using Cohen's Kappa. Statistical analysis was performed in R-statistical package. We assessed the sensitivity, specificity, likelihood ratios and positive and negative predictive values of SGAS and NBS of both the first and second observers to allow comparisons of the test qualities between the two methods.

RESULTS

Development Study

We screened 850 mothers of LBW infants and enrolled 171 eligible neonates (91 females and 80 males). Among NBS items, the highest correlation with the BOE was with the following items: Breast, posture, genitals, plantar surface, heel to ear, arm recoil and ear, in that order. The DWS items best correlated with BOE were: Posture, popliteal angle, heel to ear, skin color, skin opacity, plantar creases, nipple formation, breast size, and ear firmness; and the items in MS correlating with BOA were: Posture, ear firmness, plantar crease, and lanugo showed correlation. We then derived three reduced models from three full models by choosing the fewest number of items that were the most significant predictors of the BOE. The NBS, DWS, and MS were reduced from 12, 22, 11 to 4, 5, 6 items, respectively, and all 3 reduced total scores were not significantly different from the total score's estimate of GA (p>0.05) (Table 1). Since the 4 items in reduced NBS were also present in reduced DWS and MS, we accepted the reduced NBS as the new SGAS (Table 1). The range of scores for each item was kept the same as in the NBS: Posture (0-4), skin texture (-1-5), and breast and genitals (-1-4) (Table 1). The 3 scores had a higher proportion of babies estimated to be term (>37 weeks) than the SGAS.

Validation Study

We screened 900 neonates and enrolled 179 (95 males and 84 females). SGAS produced GA comparable to BOE in neonates aged <32 weeks (SGAS₁-21.8%, SGAS₂.21.2%, vs. BOA 21.2%), overestimated GA in neonates aged 32 to <35 weeks and 35 to <37 weeks and underestimated neonates in range \geq 37 weeks. NBS scores are also shown for comparison. The agreement between the two raters was fair, with one rater having a higher agreement with BOA than the other.

Test Characteristics

The actual prevalence using BOE was 21.0% for <32 weeks, 25.1% for \geq 32– \leq 35 weeks, 27.9% for \geq 35 weeks– \leq 37 weeks, and 25.7% for >37 weeks. The prevalence for the BOE for <32 weeks category was similar to that of SGAS (Table 2). The simplified gestation age score exhibited high positive predictive values (PPVs) for <32 and \geq 32– \leq 35 weeks GA categories as compared

Table 1: SGAS

to the NBS (Tables 3 and 4). The inter-rater agreement for SGAS was higher (k=0.8250) as compared to NBS (k=0.7092).

DISCUSSION

We believe that is the first study to focus on GA assessment of the high-risk group of LBW neonates in India. The major implications of this are for the need for referral to reduce morbidity and mortality. In our hospital based study, the SGAS showed promising ability to distinguish between term and preterm LBW babies versus USG dating in pregnancy and to distinguish between very preterm (<32 weeks), moderate to late preterm (32– <37 weeks). Of the 4 items included in SGAS, only one - posture - is related to neurologic condition while the other 3 items are unrelated to neurologic examination. Of note, the 4 items are easily adaptable to being supported by pictorial representation in an m-Health application and to avoid the need for computation errors in determining GA category [17].

SGAS performed particularly well in the very preterm group, although it underestimated term babies (>37 weeks). The prevalence of SGAS for <32 weeks was similar to the actual prevalence (BOE). This category has the highest morbidity and mortality; therefore, the cost of false negative will be more than for false positive as early recognition will enable referral for

Maturity sign	SGAS*								
	-1	0	1	2	3	4	5		
Posture			Ŕ	¢C	¢Γ	Ì			
Skin	Sticky, friable, transparent	Gelatinous, red, translucent	Smooth pink, visible veins	Superficial peeling and/ or rash, few veins	Cracking, pale areas, rare veins	Parchment, deep cracking, no vessels	Leathery, cracked, wrinkle		
Breast	Imperceptible	Barely perceptible	Flat areola no bud	Stippled areola 1–2 mm bud	Raised areola 3–4 mm bud	Full areola 5–10 mm bud			
Genitals (male)	scrotum flat, smooth	scrotum empty, faint rugae	testes in upper canal, rare rugae	testes descending, few rugae	testes down, good rugae	testes pendulous, deep rugae			
Genitals (female)	clitoris prominent and labia flat	prominent clitoris and small labia minora	prominent clitoris and enlarging minora	majora and minora equally prominent	majora large, minora small	majora cover clitoris and minora			

Score of <7 - corresponds to GA <32 weeks, 7–10 indicates GA between ≥32 weeks. ≤35 weeks, 10–13 - indicates GA –≥35 weeks and a score >14 indicates GA of ≥37 weeks. SGAS: Simplified gestational age

Table 2: Phase I - frequency distribution of GA of newborns when estimated by BOE and by NBS, DWS, MS, and SGA	1S

Gestational age (in weeks)			n (%)		
	NBS	DWS	MS	SGAS	BOE
<32	13 (7.6)	11 (6.4)	13 (7.6)	12 (7)	13 (7.6)
≥32-<35	8 (4.7)	11 (6.4)	15 (8.8)	13 (7.6)	28 (16.4)
≥35-<37	12 (7)	16 (9.4)	12 (7)	43 (25.1)	33 (19.3)
≥37	138 (80.7)	133 (77.8)	131 (76.6)	103 (60.2)	97 (56.7)
Total	171 (100)	171 (100)	171 (100)	171 (100)	171 (100)

NBS: New Ballard Score, DWS: Dubowitz score, MS: Meharban Singh score, BOE: Best obstetric estimate. SGAS: Simplified gestational age score, GA: Gestational age

Simplified gestational age score in LBW newborns

Test	Gestational age (weeks)	Prevalence (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	LR (+) (95% CI)	LR (-) (95% CI)
SGAS 1	≤32	21.8 (16.0–28.6)	87.2 (72.6–95.7)	97.1(92.8–99.2)	89.5(75.2–97.1)	96.5 (91.9–98.8)	30.51(11.53-80.76)	0.13(0.06-0.30)
	≥32–≤35	30.2 (26.1-40.4)	63.0 (48.7–75.7)	91.2(84.8-95.5)	75.6(60.5-87.1)	85.1 (77.9–90.6)	7.15 (3.93–13.04)	0.41(0.29-0.58)
	≥35–≤37	33.0 (23.5–37.5)	52.5 (39.1-65.7)	84.2(76.4-90.2)	62.0(47.2–75.3)	78.3 (70.2–85.1)	3.32 (2.06-5.35)	0.56(0.43-0.75)
	≥37	15.1 (10.2–21.2)	85.2 (66.3–95.8)	84.9(78.2-90.2)	50.0(34.9-65.1)	97.0 (92.5–99.2)	5.63 (3.74-8.47)	0.17(0.07-0.43)
SGAS 2	≤32	21.2 (15.5–28.0)	86.8(71.9–95.6)	96.5(91.9–98.8)	86.8(71.9–95.6)	96.5 (91.9–98.8)	24.49(10.26-58.44)	0.14(0.06-0.31)
	≥32–≤35	33.0 (26.1–40.4)	55.9 (42.4-68.8)	90.0(83.2-94.7)	73.3(58.1-85.4)	80.6 (79.2-86.9)	5.59 (3.12–10.02)	0.49(0.37-0.66)
	≥35–≤37	28.5 (22.0-35.7)	58.8 (44.2-72.4)	84.4(76.9–90.2)	60.0(45.2–73.6)	83.7 (76.2-89.6)	3.76 (2.37-5.98)	0.49(0.35-0.68)
	≥37	17.3 (12.1–23.7)	87.1 (70.2–96.4)	87.2(80.7-92.1)	58.7(43.2-73.0)	97.0 (92.5-99.2)	6.78 (4.36–10.55)	0.15(0.06-0.37)
NBS 1	≤32	20.7 (15.0-27.3)	89.2 (74.6-97.0)	96.5(92.0-98.8)	86.8(71.9–95.6)	97.2 (92.9–99.2)	25.33 (10.63-60.35)	0.11(0.04-0.28)
	≥32–≤35	16.8 (11.6–23.1)	70.0 (50.6-85.3)	83.9(77.0-89.4)	46.7(31.7-62.1)	93.3 (87.6–96.9)	4.35 (2.81-6.71)	0.36(0.21-0.62)
	≥35–≤37	32.4 (25.6–39.8)	46.6(33.3-60.1)	81.0(72.9-87.6)	54.0(39.3-68.2)	76.0(67.7-83.1)	2.45 (1.55-3.88)	0.66(0.51-0.85)
	≥37	30.2 (23.5-37.5)	64.8 (50.6–77.3)	91.2(84.8-95.5)	76.1(61.2-87.4)	85.7 (78.6–91.2)	7.37 (4.05–13.39)	0.39(0.27-0.56)
NBS 2	≤32	17.9 (12.6–24.3)	93.8 (79.2–99.2)	94.6(89.6–97.6)	78.9(62.7–90.4)	98.6 (95.0-99.8)	17.23 (8.7–33.9)	0.07(0.02-0.25)
	≥32–≤35	16.8 (11.6–23.1)	66.7 (47.282.7)	83.2(76.2-88.8)	44.4(29.6-60.0)	92.5 (87.6–96.4)	3.97 (2.56-6.16)	0.40(0.24-0.67)
	≥35–≤37	35.8 (28.7-43.2)	50.0 (37.2-62.8)	84.3(76.4–90.5)	64.0(49.2–77.1)	75.2 (66.8-82.4)	3.19 (1.96–5.21)	0.59(0.46-0.77)
	≥37	29.6 (23.0-36.9)	69.8 (55.7-81.7)	92.9(86.9-96.7)	80.4(66.1–90.6)	88.0 (81.2–93.0)	9.77 (5.08–18.8)	0.33(0.22-0.49)

SGAS: Simplified gestational age score, NBS: New Ballard Score, BOE: Best obstetric estimate. SGAS: Simplified gestational age score, GA: Gestational age, CI: Confidence interval, LR: Likelihood ratio, PPV: Positive predictive values

Test	Gestational age (weeks)	Prevalence	Sensitivity	Specificity	PPV	NPV	LR (+)	LR (-)
SGAS	≤32	21.5	87.0	96.8	88.1	96.5	27.5	0.13
	≥32–≤35	31.6	59.4	90.6	74.4	82.8	6.3	0.45
	≥35–≤37	30.7	55.6	84.3	61.0	81.0	3.5	0.58
	≥37	16.2	86.1	86.0	54.3	97.0	6.2	0.16
NBS	≤32	19.3	91.5	95.5	82.8	97.9	21.2	0.09
	≥32–≤35	16.8	68.3	83.5	45.5	92.9	4.1	0.38
	≥35–≤37	34.1	48.3	82.6	59.0	75.6	2.8	0.62
	≥37	29.9	67.3	92.0	78.2	86.8	8.5	0.36

PPV: Positive predictive values, NPV: Negative predictive values, SGAS: Simplified gestational age score, NBS: New Ballard Score, SGAS: Simplified gestational age, LR: Likelihood ratio

appropriate management. Test with better PPV for the preterm categories of <32 weeks and ≤35 weeks will enable prompt referrals and management. Interestingly, we also found that NBS overestimates GA [18], possibly because NBS was not developed for our population and may have influenced assessment of skin color, opacity, and texture [19]. The inter- observer reliability was encouraging. High correlation of most physical signs with LMP-based GA dating has also been observed by several studies conducted in health facilities and neonatal care units from developing countries (correlation coefficients ranging 0.5–0.8) [19,20]. Further assessment of its diagnostic accuracy is needed in first level healthcare facilities and normal birth weight newborns.

Strengths of our study include using GA dating by USG [14,15,21,22] and by selecting mothers of infants whose recall of the LMP was within 2 weeks of the USG dating. Since systematic differences in the NBS may vary by ethnicity [20,23,24], it is important to develop a simplified GA scoring system in the population to which it will be applied. Limitations of our study include the sample size of this development and initial validation

study conducted at tertiary care hospital, in otherwise healthy LBW neonates. Another limitation is the use of any trimester US which might have marginally affected the diagnostic accuracy for the GA as compared to an early first trimester scan. SGAS is currently being validated at first level healthcare facilities with assessments being conducted on approximately 14,000 neonates by auxiliary nurse midwives and including normal birth weight neonates and those with comorbidities, particularly birth asphyxia and infection. The goal of this follow-on study is to determine whether first level healthcare workers can improve on the accuracy of the need for referral for preterm neonates to reduce neonatal morbidity and mortality.

CONCLUSIONS

The new method, SGAS was able to correctly identify the gestation in 21.0% newborns <32 weeks, 25.1% in \geq 32– \leq 35 weeks, 27.9% in \geq 35– \leq 37 weeks, and 25.7% in >37 weeks neonates. SGAS comprises just four criteria from the NBS and is promising for accurate estimation of GA in LBW newborns.

Statement

None of the authors has a conflict of interest to declare. The study protocol has been approved by the institute's committee on human research.

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