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Use of physical and neurologic observations in assessment of gestational age in low birth weight infants

The relative validities of three clinical assessment methods for estimating gestational age in newborn low birth weight infants were evaluated with reference to estimates based on the date of the mother's last menstrual period. For 1246 infants in eight diverse institutions, estimates based on physical criteria correlated more strongly with dates estimates, yielded estimates more similar on average to dates estimates, and yielded higher proportions of correct classifications of prematurity and small for gestational age than did estimates based on neurologic criteria or neurologic and physical criteria combined. These results support the use of physical criteria rather than neurologic or combined criteria for the clinical assessment of gestational age in low birth weight infants. In a subsample of 511 black and white infants, there were no ethnic differences in mean error of estimate for any of the three methods. (J PEDIATR 1987;110:921-8)

Norman A. Constantine, Ph.D., Helena C. Kraemer, Ph.D.,
Kathleen A. Kendall-Tackett, M.A., Forrest C. Bennett, M.D.,
Jon E. Tyson, M.D., and Ruth T. Gross, M.D.

From the Departments of Pediatrics and Psychiatry, Stanford University School of Medicine, Palo Alto, California, and the Departments of Pediatrics, University of Washington Medical School, Seattle, and The University of Texas Health Science Center at Dallas

Low birth weight infants are a heterogeneous group: some are preterm, others small for gestational age, and still others both preterm and SGA. The medical risks for infants may vary according to these categories, so it is important that degree of prematurity be assessed soon after birth. The date of the mother's last menstrual period is often used to estimate gestational age; however, this information frequently is not available.

Most validation studies of clinical gestational age assessment methods have been performed on relatively small samples of predominantly full-term infants. Those studies that have included preterm infants have typically used stringent exclusion criteria, many associated with lack of prenatal care. For example, Parkin et al.[1] included mothers only if they had been under a physician's care during the first trimester of pregnancy. Inasmuch as lack of prenatal care is associated with increased incidence of premature birth, applying such criteria to the LBW population may introduce sampling bias.

A/LGA	Appropriate or large for gestational age
GA	Gestational age
LBW	Low birth weight
SGA	Small for gestational age

The purpose of our study was to assess the validity of the physical and neurologic criteria of the Ballard method for

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Reprint requests: Norman A. Constantine, Ph.D., Infant Health and Development Program, Bldg. 460, Stanford University, Palo Alto, CA 94305-2135.

INFANT HEALTH AND DEVELOPMENT PROGRAM: A Multisite Clinical Trial

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National Study Office (Stanford University Center for the Study of Youth Development)

Ruth T. Gross, M.D. (Director); Donna Spiker, Ph.D.; Norman A. Constantine, Ph.D.; Wendy L. Kreitman

Program Development Office (Frank Porter Graham Child Development Center, University of North Carolina, Chapel Hill)

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estimating gestational age using a large sample of LBW infants representing diverse geographic and socioeconomic origins.

METHODS

Sample. Data used in our analyses were collected in the course of a collaborative clinical trial involving eight sites (*see* box). In total, 4551 inborn LBW (birth weight ≤2500 g) infants were screened. Eligible for our study were all infants born between January 1 and June 30, 1985, to mothers living within specified catchment areas close enough to participate in a 3-year study (n = 1800). Data on the mother's menstrual history were available for 1246 (69.2%) of these infants. This constitutes the general sample of this study. The eligible sample and the general sample did not differ significantly in birth weight, clinically assessed gestational age, or sex. Ethnic information was systematically collected only for those eligible for the clinical trial (limited sample, n = 609). The numbers in the ethnic groups other than black or white were very small at many of the sites. Consequently, only infants classified black or white (n = 511) were used in the analyses of ethnic differences.

Characteristics of the general and limited samples are presented in Table I. Site-to-site variations were exhibited for all characteristics. (Complete versions of Tables I, III, and IV showing site-by-site results are available from the authors by request.)

Gestational age estimates. Gestational age was estimated in four different ways by site pediatric staff participating in the collaborative study. Standardized procedures detailed in the study manual of operations were used.

Dates GA estimates were obtained when clinical menstrual history data were available. Examiners were instructed to calculate dates GA as number of complete weeks since the first day of the mother's last menstrual period, based on maternal interview or chart data. No attempts were made to corroborate chart data, and no standardized criteria other than professional judgment of the examiners were used to determine the accuracy of the

last menstrual period date. This method was equivalent to what is commonly applied in clinical practice. A more rigorous verification of the last menstrual period date could have decreased the level of error in the dates GA estimates, thereby increasing the salience of any true differences or effects. Because of the large sample size and the relative (physical versus neurologic) rather than absolute nature of the investigation, however, the consequences of this limitation were minimized.

Ballard GA estimates were determined according to the method described by Ballard et al.,[2] except that the 2-week estimate intervals were interpolated to provide 1-week intervals in the score conversion table (Ballard JL, personal communication, 1984). In addition, scores from the six neurologic Ballard items (posture, square window, arm recoil, popliteal angle, scarf sign, and heel to ear) and the six physical Ballard items (skin, lanugo, plantar creases, breast, ear, and genitalia) were summed into separate half-scores. Physical GA and neurologic GA estimates were determined by doubling the appropriate Ballard half-score and using the interpolated score conversion table.

The examiners were not necessarily blinded to the dates GA estimates at the time they performed the Ballard assessments, suggesting a potential source of bias in the clinical estimates. The amount of possible bias is not likely to be problematic, however, because the examiners rated the individual criteria according to a standardized protocol, and the summing of these criteria and scoring of the resulting sums were computer verified.

Examiners were instructed to perform the assessment between 6 and 48 hours after birth. For 85% of the assessments, hours after birth was recorded; of these, 93% were within the specified range. A preliminary analysis showed no influence of hours within the specified range on outcome of the assessment. The number of infants outside this time range was too few for further analysis.

Infants were classified into three dates GA groups of ≥38 weeks, 36 or 37 weeks, and ≤35 weeks. Infants were classified as SGA if birth weight fell below the 10th percentile for dates GA using the Lubchenco et al.[3] percentiles. All other infants were classified as appropriate or large for gestational age.

Validity. A valid clinical estimate of gestational age correlates strongly with dates GA, has a small mean difference from dates GA and a small standard deviation of this difference, and has a high level of agreement with dates GA when used to diagnose prematurity and SGA. In addition, the validity of a good estimate should be minimally affected by factors such as ethnicity or degree of prematurity.

Spearman correlation coefficients were calculated for dates GA versus physical GA, neurologic GA, and Ballard GA separately for each site and for the total sample. These coefficients show the overall degree of association between each of the three clinical estimation methods and the dates GA criterion.

Mean differences in weeks between the results of each of the three clinical methods and the dates GA criterion are referred to as "biases." This term is used only in a statistical sense to indicate systematic mean differences. The biases are labeled physical bias (physical GA minus dates GA), neurologic bias (neurologic GA minus dates GA), and Ballard bias (Ballard GA minus dates GA).

A three-way analysis of variance model was used to examine the effects of site differences, SGA status, and dates GA group on biases. Three separate analyses of variance were performed using physical bias, neurologic bias, and Ballard bias as the dependent variables. Preliminary analyses showed no relationships between birth weight, sex, or ethnicity and GA estimate correlations or biases. Therefore, these variables were not included in the main analyses. Because of previously reported effects of ethnicity, however, the results of the analyses of ethnic differences are presented.

The performance characteristics (sensitivity, specificity, predictive values, and efficiency) of diagnoses for prematurity (GA <38 weeks, GA <36 weeks) and SGA using each of the clinical assessment estimates versus

Table I. Sample size and description of general and limited samples

Eligible infants	
LBW infants (n)	1800
General sample	
LBW infants with dates GA estimates (n)	
n	1246
Percent eligible infants	69.2
Birth weight group (%)	
≤1000 g	5.8
1001-1500 g	10.8
1501-2000 g	26.2
2001-2500 g	57.2
Dates GA group (%)	
≤35 wk	53.9
36-37 wk	20.8
≥38 wk	25.3
SGA (%)	37.6
Male (%)	46.5
Limited sample (n)	609
Mother's ethnicity (%)	
White	31.5
Black	52.4
Hispanic	12.8
Other	3.2

Table II. Spearman correlation coefficients between clinical assessment estimates and dates estimates within general sample

	Site								
	1	2	3	4	5	6	7	8	Total
n	109	231	154	177	145	167	181	82	1246
Physical GA/dates GA	0.78	0.88	0.85	0.81	0.84	0.81	0.85	0.81	0.83
Neurologic GA/dates GA	0.70	0.81	0.67	0.71	0.64	0.74	0.77	0.50	0.71
Ballard GA/dates GA	0.78	0.87	0.82	0.79	0.80	0.80	0.85	0.74	0.81

Table III. Gestational age estimate and bias means and standard deviations (in weeks) for general sample

	Mean	SD
Dates GA	34.8	3.68
Physical GA	34.7	3.46
Physical bias	−0.1	2.14
Neurologic GA	36.2	3.60
Neurologic bias	1.4	2.72
Ballard GA	35.4	3.35
Ballard bias	0.6	2.18

Table IV. Black and white bias means (in weeks) for limited sample

Black (n)	319
White (n)	192
Physical bias	
Black	−0.18
White	−0.27
Neurologic bias	
Black	1.64
White	1.23
Ballard bias	
Black	0.73
White	0.48

dates GA estimates were assessed by site and for the total sample.

RESULTS

Physical GA was most strongly correlated with dates GA for the total sample and for six of the eight sites. Neurologic GA at all eight sites was correlated least strongly with dates GA (Table II).

Mean neurologic GA exceeded mean dates GA at every one of the eight sites. Neurologic GA estimates were most different from dates GA, and physical GA estimates were least different from dates GA for the total sample (Table III) and for seven of the eight sites. In addition, at six of the eight sites and overall, physical biases showed the least variability, and at all eight sites, neurologic biases showed the most variability.

The analyses of variance indicated that site, SGA status, and dates GA group are all related to biases individually and in combination. The Figure graphically presents the SGA and dates GA group bias relationships. A more detailed explanation of the analyses of variance is presented in the Appendix.

Table IV presents bias means and standard deviations for infants classified as white or black. None of the biases were significantly related to ethnicity, and white/black differences within sites were uniformly small.

Table V presents statistics describing the performance in the total sample of the clinical assessment estimates for diagnosis of prematurity and SGA. Diagnoses of prematurity (dates GA <37 weeks, dates GA <35 weeks) based on physical GA yield more sensitive and less specific results, with larger predictive values for a negative test but smaller predictive values for a positive test, than those based on neurologic GA or Ballard GA. The percentage of those correctly diagnosed (efficiency) is greatest using physical GA.

In contrast, diagnoses of SGA based on physical GA yield less sensitive but more specific results, with larger predictive values of a positive test and smaller predictive values of a negative test, than those based on neurologic GA or Ballard GA. However, the percentage of those correctly diagnosed is again greatest using physical GA.

Performance characteristics within individual sites followed these patterns closely, with a few exceptions.

DISCUSSION

For more than 30 years, the neurologic examination of the newborn infant has been used to estimate gestational age.[4-6] This approach is based on the relationship between late prenatal cerebral maturation and certain continuous criteria that develop steadily during the late gestation period. These criteria include muscle tone as manifested, for example, by changes in posture, popliteal angle, and scarf sign, and the development of certain reflexes, such as

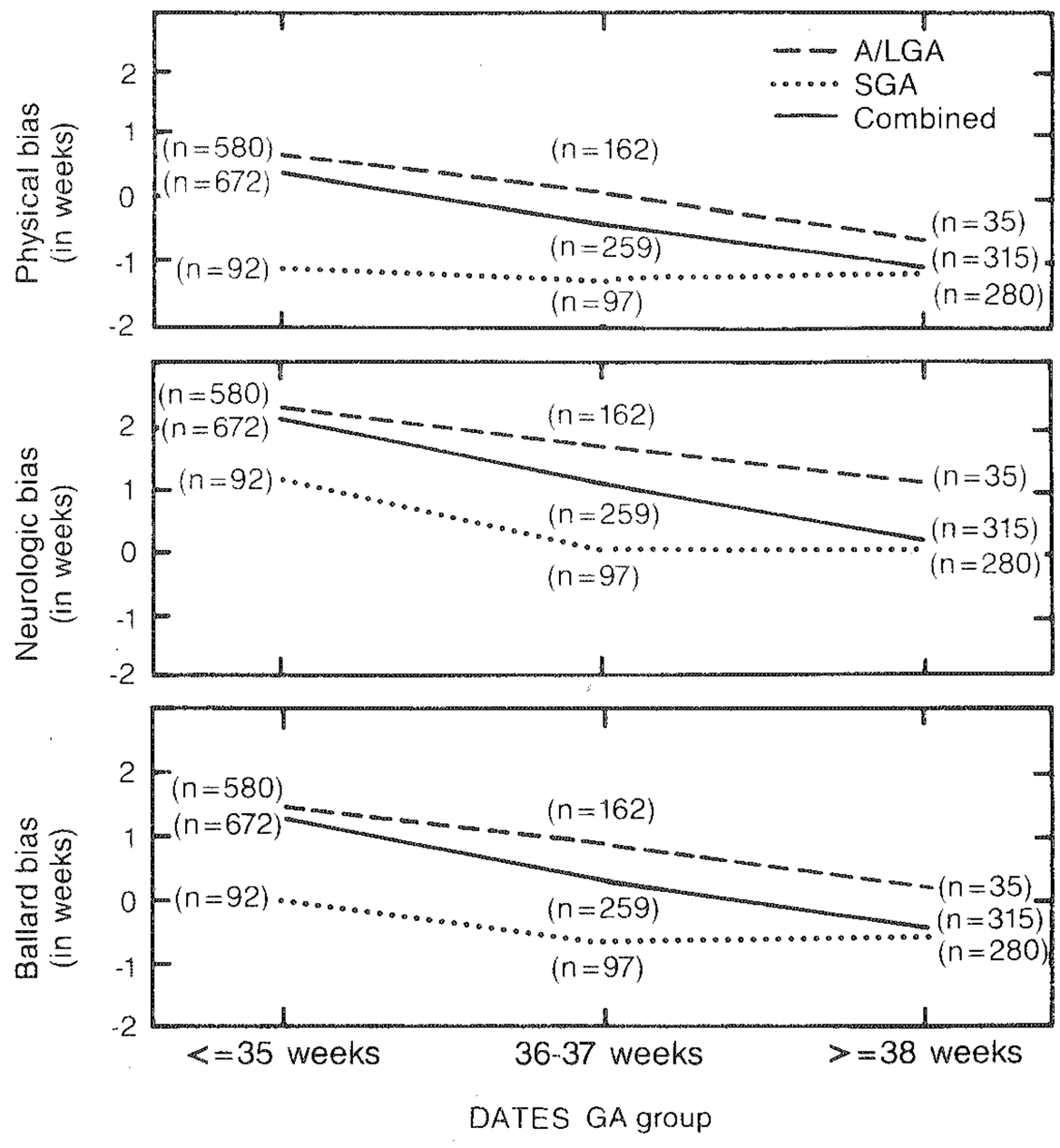

Figure. Bias means by dates GA group and SGA for general sample.

the Moro reflex and the crossed extension reflex. Robinson[7] has expanded on this approach to include discontinuous criteria that abruptly change from negative to positive during a specified developmental period. These criteria include the appearance of pupillary reactions to light, the neck righting reflex, and head turning to diffuse light.

Despite the popularity of clinical methods using neurologic criteria, problems with the implementation and accuracy of these methods have been reported. Poor interjudge reliability suggests the necessity of extensive clinical experience to detect small changes in posture and muscle tone. Some of the primitive reflexes listed by Robinson[7] have been difficult for other researchers to elicit. Many of the neurologic criteria are difficult to assess in sick infants or those in incubators.[2] Neurologic criteria can be affected by birth trauma and breech birth.[8] Even more important, intrauterine factors such as chronic stress or maternal hypertension can accelerate neurologic development.[9,10] This can lead to a positive bias for neurologic GA assessment in stressed populations.

Some researchers have found that black or nonwhite infants received higher neurologic GA estimates than did white infants of the same gestational age.[11-13] Brett[11] suggested two possible explanations: unconscious examiner bias or inherently greater neurologic maturity in black infants. Dubowitz and Dubowitz[12] proposed that the differences were the result of poorer socioeconomic status of the nonwhite group and that "chronic malnutrition of the fetus in utero may well induce accelerated maturation of some of the neurologic parameters."

Assessments of physical criteria have also been applied to the estimation of gestational age. The set of physical criteria most often described was initially defined by Farr et al.,[14] and later elaborated by Finnstrom.[15] These include skin color, nipple formation, ear firmness, and plantar skin creases. These criteria are considered easier to determine and more reliable than neurologic criteria.[15-17] Finnstrom has suggested, however, that assessments based on physical criteria routinely underestimate gestational age in SGA infants. If true, this would lead to the underidentification of SGA infants.

The method of Dubowitz et al.[18] was the first to combine the assessment of physical and neurologic criteria. This method combines a subset of 11 neurologic criteria from Amiel-Tison[4] with a subset of 10 physical criteria from Farr et al.[14] The method was standardized on a sample of

Table V. Performance characteristics of tests for prematurity and SGA for general sample

		P*	Q†	Sensitivity	Specificity	Predictive value of positive test	Predictive value of negative test	Efficiency
GA <37 wk	Physical GA	65	69	92	74	87	87	85
	Neurologic GA	65	51	70	84	89	60	75
	Ballard GA	65	62	85	81	89	75	84
GA <35 wk	Physical GA	44	50	87	80	77	89	84
	Neurologic GA	44	33	61	89	81	75	77
	Ballard GA	44	38	74	91	87	81	83
SGA	Physical GA	38	34	65	86	73	80	78
	Neurologic GA	38	59	79	54	51	81	63
	Ballard GA	38	48	78	71	62	84	74

*All values represent percent. Diagnosis based on dates GA.
†Diagnosis based on physical GA, neurologic GA, or Ballard GA.

Table VI. Analyses of variance with physical bias, neurologic bias, and Ballard bias as dependent variables

	Physical bias	Neurologic bias	Ballard bias
Site	<0.01	<0.01	<0.01
SGA	<0.01	<0.01	<0.01
Dates GA group	<0.01	<0.01	<0.01
Site by SGA	NS	<0.05	NS
Site by dates GA group	<0.01	<0.01	<0.01
SGA by dates GA group	<0.05	NS	NS
Site by SGA by dates GA group	<0.05	<0.01	<0.01

NS, not significant.

167 infants, 53 of whom were premature. Estimates based on the physical criteria alone were found to be more valid than those based on the neurologic criteria alone, and the combination of both types of criteria was found to yield more valid estimates than the use of either alone.[18]

Based on a sample of very low birth weight infants, Malan and Higgs[19] found that estimates using the Dubowitz method correlated strongly with estimates derived from dates. Parkin et al.[1] found that a subset of four physical items was as valid as the 21-item Dubowitz method within a sample of mostly full-term infants. Others have found that the Dubowitz method overestimates gestational age for full-term infants[20] and for LBW infants.[21]

The Dubowitz assessment can be impractical to administer. For example, ventral suspension is too stressful for very sick infants or infants in incubators. For this reason, Ballard et al.[2] developed a simplified method using subsets of six neurologic and six physical items from the Dubowitz method. Ballard estimates of gestational age correlated strongly with Dubowitz estimates and with estimates derived from dates.[2]

The results of our study show that for LBW infants gestational age estimates derived from the physical subset of the items on the Ballard examination are closer to estimates derived from last menstrual period date than are estimates derived from either the neurologic subset of items or the full set of Ballard items. This has been demonstrated through patterns of stronger correlations, smaller mean differences, and greater proportions of correct diagnoses of prematurity and SGA relative to dates GA estimates based on the mother's recollection of the first day of the last menstrual period. These patterns prevailed across eight sites, with considerable variation on a variety of infant factors, including birth weight, sex, ethnicity, degree of prematurity, and SGA status. We suggest that for LBW infants, estimates based on the subset of physical items are the most valid of the three clinical assessment methods considered.

The inclusion of the neurologic items in the assessment procedure decreased the correlations between clinical assessment estimates and dates estimates at six of the eight sites (and had no effect at the other two sites). This attenuation of validity associated with the neurologic items for our LBW sample is consistent with the findings of Amiel-Tison[4] and of Gould et al.[10] regarding accelerated neurologic maturity after high risk and chronically stressed pregnancies, and with the speculation of Dubowitz and Dubowitz[12] regarding a similar acceleration as a result of chronic fetal malnutrition. Within a sample of appropriate birth weight newborn infants, the prevalence of accelerated neurologic maturity may not be sufficient to bias the contribution of neurologic criteria to a gestational age estimation procedure. Within an LBW sample, however, the increased prevalence of such acceleration is likely to be more influential.

The less than perfect but unknown reliabilities of the predictors and the criterion limit the precision of validity comparisons and necessitate caution in the clinical application of gestational age estimates. The significant site effects on the estimate biases reinforce the need to include multiple sites in validation studies of subjective clinical assessment techniques. These site differences also emphasize the importance of thoroughly training examiners to perform assessments in a manner as standardized as possible.

The absence of effects of ethnicity on any of the clinical estimates and the uniformly small white/black bias differences at each of the eight sites indicate that both the physical and neurologic methods perform similarly for LBW infants in either of these two ethnic groups. Previously reported ethnic differences in perinatal neurologic status are difficult to interpret. Prior studies compared African infants with European infants[12] or with European norms[13] or compared nonwhite European infants of various ethnic backgrounds with white European infants.[11] In none of these studies can neurologic discrepancies be attributed clearly to ethnicity.

Our study was originally conceived in response to site medical personnel who believed that the estimates obtained from the full Ballard method of assessment were overestimating gestational age within the LBW population, and proposed that the common clinical practice of doubling the physical half-score should be formally evaluated. Our results give convincing support in favor of this practice for the clinical assessment of gestational age in LBW infants.

APPENDIX

Interpretation of the results of the analyses of variance presented in Table VI and the Figure must be approached with caution. Individual factor effects are difficult to interpret separately because of unequal and disproportionate cell sizes and significant interaction effects. In addition, the effects of SGA can be attributed at least partially to statistical regression effects.

Of the three factors in the model, the effects of site are the least ambiguous. Statistically significant site differences indicate that either the dates estimates or the clinical methods, or all, were not uniformly applied across sites, despite an effort to standardize methods. The implication is that in less structured situations even greater variability would be expected, yielding estimates of gestational age and diagnoses of prematurity or SGA that may be less reliable than assumed.

For all three dependent variables, the dates GA group effect was statistically significant (after adjustment for disproportionate cell sizes). In addition, the dates GA group by SGA interaction was significant for physical bias. This is illustrated in the Figure by the strong negative trends with increasing dates GA group for all three dependent variables in the total sample and in the A/LGA group, together with weaker negative trends for neurologic bias and Ballard bias and no trend for physical bias in the SGA group. The SGA effect was also significant for all three dependent variables. The bias differences of approximately $-1\frac{1}{2}$ weeks for SGA infants compared with A/LGA infants were reasonably consistent for all dependent variables within both the preterm and borderline groups. For full-term infants the bias differences were smaller, and were smallest for physical bias.

Before interpreting this apparently robust effect of SGA, it is important to recognize the potential effect of statistical regression. Infants classified as SGA are those with relatively extreme dates GA estimates (high relative to infants of similar birth weight). Because of nonrandom measurement error, it is to be expected that with subsequent estimates these infants will tend toward less extreme (lower) gestational age estimates. Milner and Richards[22] have documented a similar phenomenon in investigating birth weight distributions of preterm infants of different gestational ages. This possibility is further supported by the smaller SGA differences in biases for the full-term group, in which, given our LBW population, SGA is the norm. We conclude that some, but not all, of the SGA effect is attributable to statistical regression. This conclusion might also be applied to a similar SGA effect reported by Finnstrom.[15] Still, the SGA effect should not be dismissed completely. Instead, extreme caution is called for when clinical or research decisions are made regarding categorizations of weight relative to gestational age.

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