East African Medical Journal Vol. 100 No. 12 December 2023
COMPARISON OF THE HADLOCK AND INTERGROWTH-21ST FORMULAE IN PREDICTING BIRTHWEIGHT CENTILES FOR LOW-RISK PREGNANCY; A SECONDARY ANALYSIS OF DATA
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ABSTRACT

Objective: To compare the accuracy of the Hadlock to Intergrowth-21st formulae in predicting birthweight for low-risk pregnancies.

Methods: A secondary analysis of data from the Routine Third Trimester Ultrasound (ROTTUS) trial was undertaken for 284 low-risk pregnancies between 36 weeks and 37 weeks and 6 days gestation. The estimated fetal weight centiles using Hadlock, and Intergrowth-21st formulae were computed, and the accuracy in predicting birthweight centile compared using ROC curve analysis and absolute percentage error. Logistic regression model was constructed based on ±15% as the dependent variable, to determine factors affecting the accuracy of either method.

Results: The proportion of fetuses within 15% of the birth weight was 78.2% and 62.7% (p<0.0001) for Hadlock and Intergrowth-21st methods, area under the curve =0.8209 (CI 0.74347-0.89838) and 0.872 (CI 0.80865-0.93544) respectively (p<0.039). The mean absolute percentage error was -7.2 and -10.1 (p<0.0001) for Hadlock and Intergrowth-21st respectively. The accuracy of Intergrowth-21st method was influenced by the ultrasound-to-delivery interval.

Conclusion: Overall, the Hadlock formula was more accurate than Intergrowth-21st in predicting birthweight centile for low-risk pregnancies, except in large for gestational age fetuses. Both methods demonstrated a low sensitivity and specificity.

INTRODUCTION

Accurate estimation of birthweight is essential in reducing fetal growth-related morbidity[1-4]. To date ultrasound remains the only objective tool for this purpose[5-10]. Over 36 formulae of fetal weight estimation have been described[11]. Auspiciously, the Hadlock formula remains widely used despite having been derived from a homogenous population[5,6, 11-14]. Recently, the Intergrowth-21st group proposed fetal growth standards based on a more diverse cohort of pregnant women[2]. Interestingly, they reported uniform growth velocity across populations regardless of the physiological and geographical variations[15,16]. It is on this premise that the Intergrowth-21st formula was developed. It contrasts with the customized growth charts that account for ethnic and geographical influence on fetal growth[12,13,17]. Several studies to assess how the Intergrowth-21st formula compares with other modalities have yielded conflicting results[5-8,12,18]. Consequently, the adoption of the Intergrowth-21st formula in clinical practice remains unachievable[16,19,20]. This is not surprising, considering that the comparative studies used mixed populations that were not risk-stratified, yet the Intergrowth-21st standards were based on a low-risk cohort of women[1,3,19]. Furthermore, some studies limited the ultrasound- to -delivery interval to improve the preciseness of the formulae used[1,5,12, 21]. Likewise, most studies used absolute birthweights to determine accuracy. We reason that all women, regardless of the decision-to-delivery interval should be included in any analysis and that centiles and not absolute weight should be used to compare accuracy and appropriately adjusted to allow reproducibility.

We aim to pragmatically compare the accuracy of Intergrowth-21st and Hadlock formulae in estimating birthweight and establish factors that may affect its performance in a low-risk population. This will help determine whether the observed differences could significantly alter our interpretation of fetal growth and if local implementation of the Intergrowth-21st method of fetal weight estimation could lead to alterations in diagnosis of fetal growth disorders.

MATERIAL AND METHODS

A secondary analysis of data from the 'Routine Third Trimester Obstetric Ultrasound (ROTTUS) trial[22] was undertaken. Women aged ≥18 and <45 years with a singleton pregnancy, known last menstrual period and regular cycles or a dating scan between 11-14 weeks, natural conception, and planning to be available for follow-up were included into study. All women with high-risk pregnancies as described in the parent study were excluded[22]. Fetal growth ultrasounds were performed between 36+0 and 37+6-weeks' gestation

The sample size was computed with interest in determining the recommended number of participants required to detect a statistically significant difference between two means with a power of 80% and a significance level of 5%. The assumptions for mean absolute percentage error (MAPE) and standard deviation used in this computation were based on a similar study that compared accuracy of Intergrowth-21st formula with other ultrasound formulae in fetal weight estimation[6]. A minimum of 238 participants were required to achieve our objective.

All women who had an ultrasound in the parent study[22], were included in the analysis regardless of the allocation arm. The following data were extracted: The maternal socio-demographic data: age, body mass index (BMI), parity; biometric parameters: Estimated Fetal Weight (EFW), Abdominal Circumference (AC), Head Circumference (HC), Femur Length (FL), EFW centile, AC percentile, gestational age at ultrasound. Maternal intrapartum characteristics and neonatal characteristics: birthweight, gestational age at delivery and fetal sex.

All ultrasounds were performed in accordance with the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) guidelines[23] . The patients were then followed up as per unit protocol until delivery when their intrapartum and neonatal outcomes were recorded.

Data on the gestational age at the time of the scan and head circumference HC were extracted from ultrasound reports. The EFW using Hadlock formula was available from the parent study and the biometric parameters (AC, HC) were extracted from the dataset and used to calculate the EFW using Intergrowth-21st method. This was generated using a customized excel-based formula which incorporated AC and HC as shown below :

Log (EFW) = 5.084820 - 54.06633 × (AC/100)3 - 95.80076 × (AC/100)3 × log (AC/100) + 3.136370 × (HC/100) [g, cm]

The estimated fetal weights were converted to their corresponding centiles using Hadlock and Intergrowth-21st calculators available for general use[24,25]. Neonatal birthweights were converted to centiles using the validated Fetal Medicine Foundation charts as a reference standard[26]. We chose this as a standard since it is validated in a low-risk population. The ultrasound-to-delivery interval was computed from existing data.

The demographic, maternal, ultrasound and neonatal characteristics of the study population were summarized using means (standard deviation) for continuous variables and proportions for categorical variables. The estimated fetal weights were converted to corresponding centiles and adjusted for the varying ultrasound-to-delivery intervals.

The accuracy of the different formulae was compared using 3 methods: 1) Receiver Operating Characteristics (ROC) curve analysis: The EFW percentiles for Hadlock and Intergrowth-21st methods were grouped into 3 categories (large for gestational age (>90th percentile), small for gestation age (<10th percentile) and appropriate for gestational age (10th-90th percentile)). The ROC Curve and area under the curve (AUC) were used to determine the accuracy of each method in predicting these categories. Sensitivity and specificity tests were also applied. 2) The MAPE: The mean of the percentage error was used as a marker for the systematic error over time expressed as a percentage of birthweight.

MAPE = |EFW- birthweight | / birthweight x 100

The corresponding standard deviation (SD) of the percentage errors were used as a marker for the random measurement error. 3) The proportion of fetuses with an EFW within ±15% of the birth weight centiles: This was used as a marker of acceptable margin of error. The differences between the accuracy measures (continuous variables) of Hadlock and Intergrowth-21 formulas were compared using paired t-tests, Wilcoxon signed rank test or McNemar tests, as appropriate. The differences of the other accuracy measures (discrete variables) were analysed using Chi-square test or Fisher's exact test.

Demographic, maternal, ultrasound, and neonatal characteristics of the study population that may affect the accuracy of EFW estimation by Hadlock and Intergrowth-21 formula were analysed based on MAPE using paired t-tests or Wilcoxon signed rank test, as appropriate (or based on EFW within ±15% of birth weight using Chi-square test or Fisher's exact test, as appropriate). A logistic regression model was constructed for the two ultrasound formulae based on EFW within ±15% of birth weight as the dependent variable against parameters (i.e., fetal sex, maternal BMI, fetal size, and ultrasound to delivery interval) on bivariate analysis. A Multivariate analysis was further conducted on these parameters to adjust for confounding factors. Statistical significance was interpreted at 5% level ($p < 0.05$). Analysis was done using Stata® version 16. Ethical approval was obtained from the Aga Khan University, Institutional Scientific Ethics Review Committee. All women provided informed consent for the data collected in the ROTTUS trial to be used for any secondary analysis.

RESULTS

A total of 335 ultrasounds were performed, of which 284 were eligible for the final analysis (Figure 1).

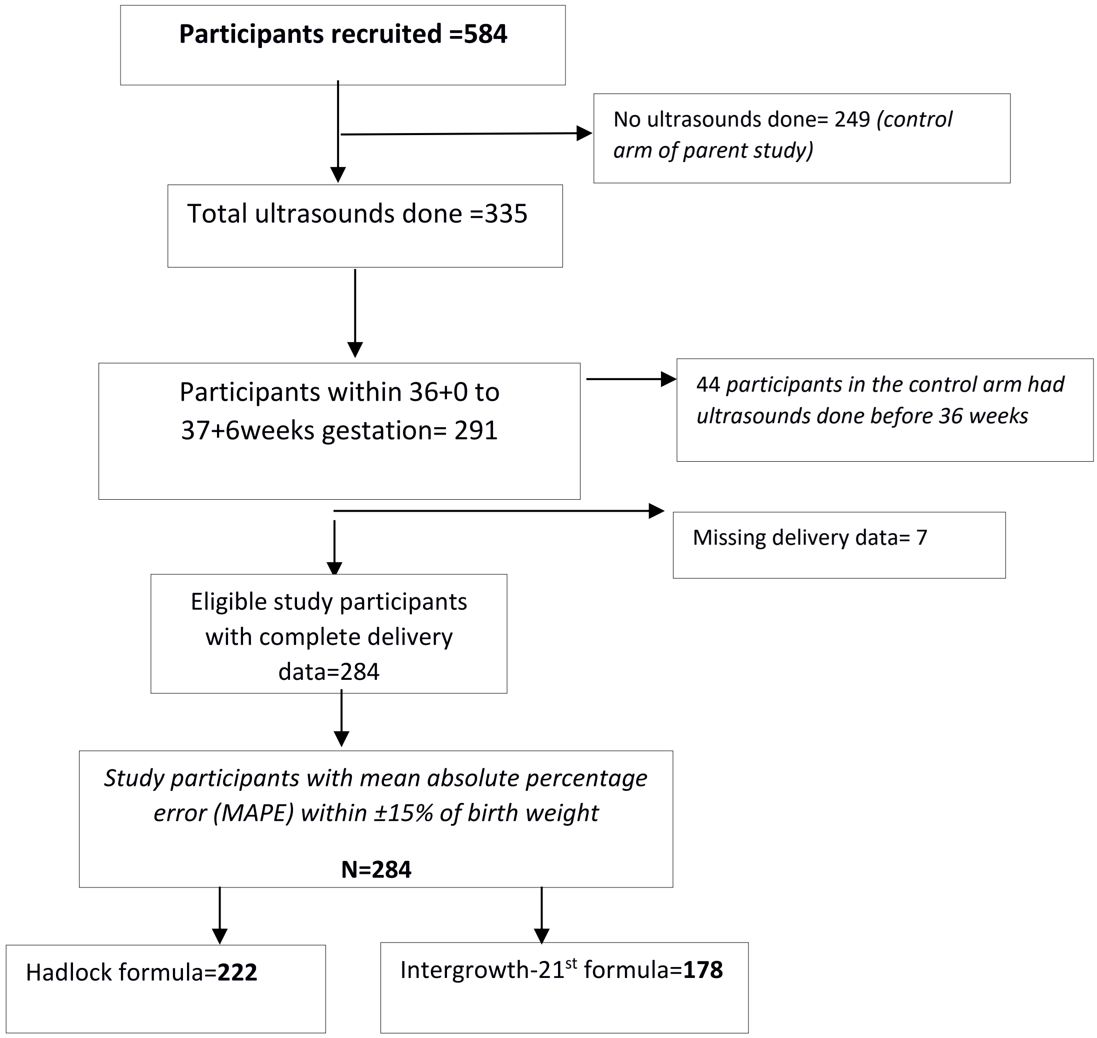

Figure 1: Flow of participants in the study

The socio-demographic, obstetric and neonatal characteristics of the participants are summarized in Table 1.

Table 1

Socio- demographic, obstetric and neonatal characteristics

Variable	Category	n(%)
Age	20-24	8(2.8)
	25-29	81(28.5)
	30-34	117(41.2)
	35-39	67 (23.6)
	>40	11(3.9)
BMI	<19	4(1.4)
	19-25	86(30.3)
	26-29	126 (44.4)
	>30	68(23.9)
Parity	Nulliparous	89(31.3)
	Multiparous	195(68.7)
Sex of baby	Female	126(44.4)
	Male	158(55.6)
Birth weight (grams) mean (SD)	3333	49.4
Gestational age in weeks at time of ultrasound; mean (SD)	36.4	0.490
Gestational age in weeks at delivery; mean (SD)	39.2	1.197
Ultrasound to delivery interval days; mean (SD)	19.4	8.57

Accuracy of Hadlock and Intergrowth-21st formulae

Predicting the composite birthweight centiles

The MAPE for Hadlock and Intergrowth-21st method was -7.2 and -10.1 respectively (p<0.0001). There was a statistically significant difference in the proportion of fetuses with EFW centile classified within ± 15% of birthweight centile in the two categories. Of the 284 study participants, 222 (78.2%) had their EFW centile within ±15% of the birthweight centile when Hadlock formula was used, compared to 178 (62.7%) when Intergrowth-21st formula was used; chi-square 33.38(P<0.0001).

Predicting small for gestational age fetuses

The Intergrowth-21st formula had an area under the curve (AUC) of 0.9029 (p=0.7907; 95% CI: 0.8575-0.9484) while Hadlock formula had an AUC of 0.8973 (95% CI 0.8511-0.9435 p=0.7907) (Figure 2) with a specificity of 97.9% and 99.6% and detection rate for SGA of 46.3% and 26.8% and respectively

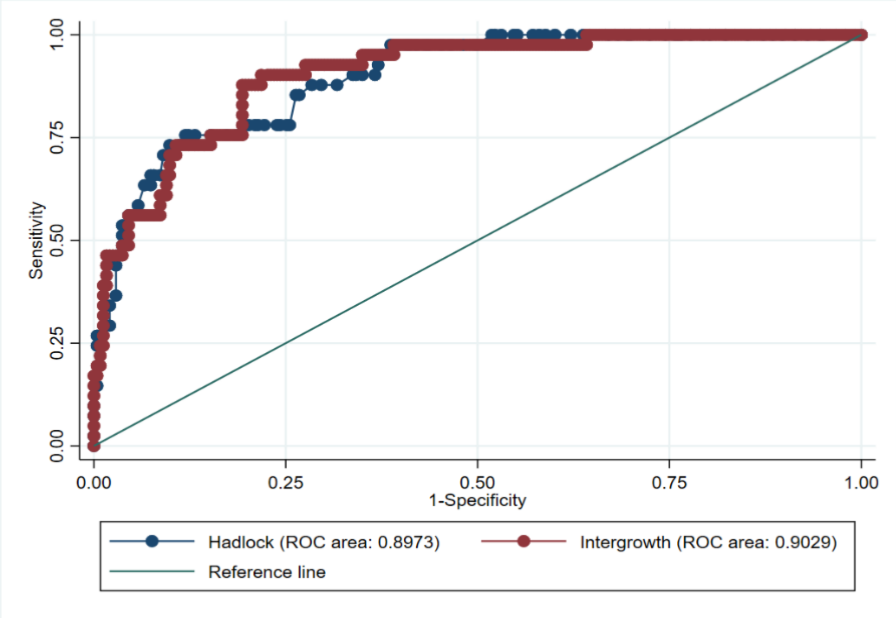

Figure 2: Accuracy in predicting birthweight of small for gestational age (SGA) fetuses

Predicting large for gestational age fetuses

The AUC for Hadlock and Intergrowth-21st methods was 0.872 (P=0.0393; 95% CI 0.8087-0.9354) and 0.8209 (P=0.0393; 95% CI 0.7435-0.89848 respectively (Figure 3); with a specificity of 90% for predicting LGA fetuses compared to Intergrowth (78.4%).

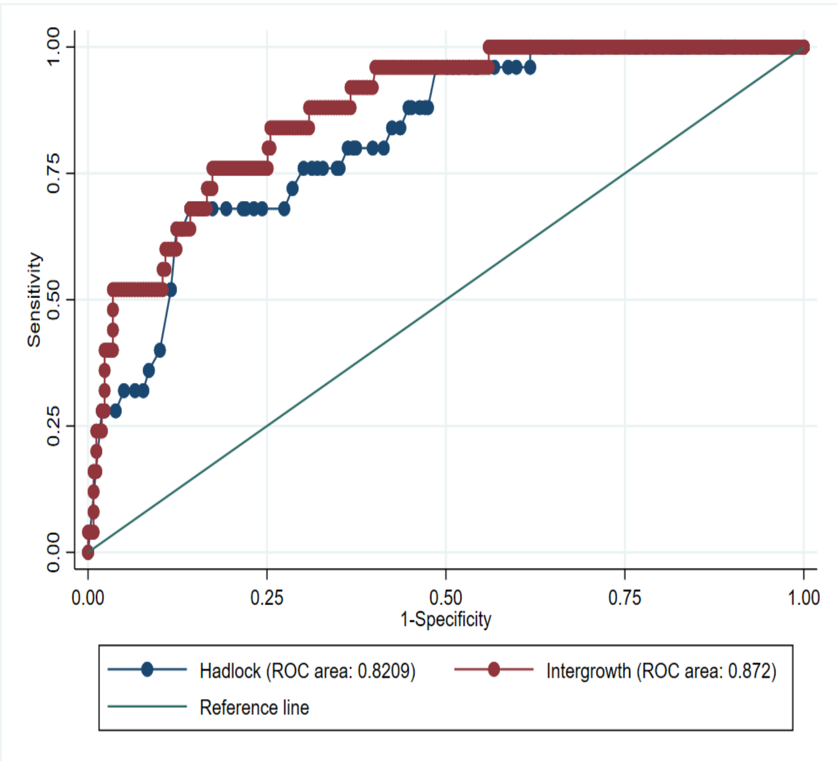

Figure 3: Accuracy in predicting birthweight in large for gestational age (LGA) fetuses

Predicting appropriate for gestational age fetuses

The AUC for Hadlock and Intergrowth-21st formulae was 0.6116 (p=0.308; CI 0.0497-0.5141) and 0.6307(p=0.308; CI 0.5376-0.7236) respectively (Figure 4). Compared to Hadlock, Intergrowth has a sensitivity of 87.6% versus 31% respectively and specificity of 72% versus 57.6%.

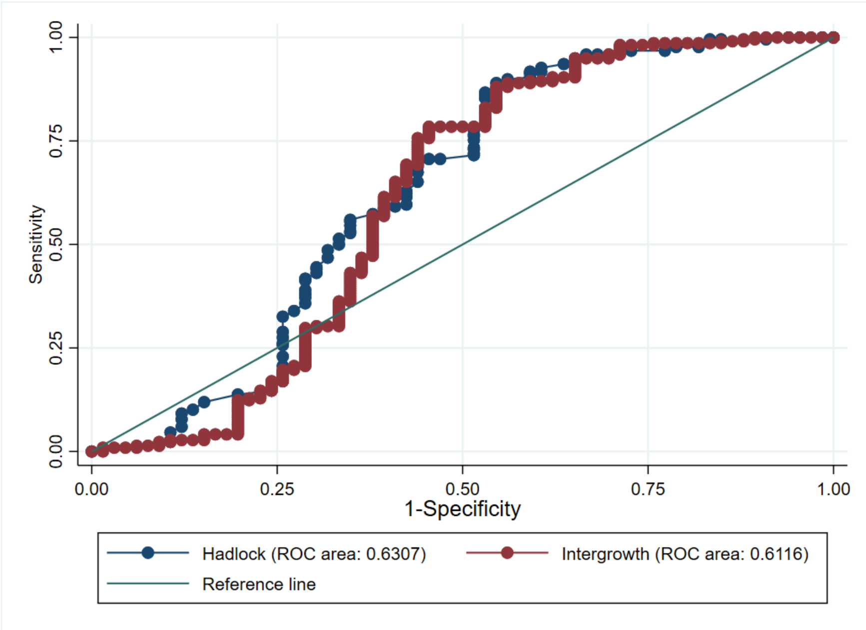

Figure 4: Accuracy in predicting birthweight in appropriate for gestational age (AGA) fetuses

Factors affecting the accuracy of Hadlock and Intergrowth-21st formulae

On performing a logistic regression, the accuracy of Intergrowth formulae in predicting the birthweight centile was significantly affected by the ultrasound-to-delivery interval. However, it was less affected by a large for gestation age fetus 57.1% (aOR 0.6; 95% p=0.2) CI 0.25-1.45 p=67.9% (aOR 0.4; 95% CI 0.17-1.08 p=0.0073) (Table 2 and 3). The sex of the fetus and maternal BMI did not have any impact on the accuracy of estimating birthweight when either formula was used.

Table 2

Bivariate analysis of factors associated with accuracy of Hadlock and Intergrowth-21st formulas in estimating fetal weight (N=284)

	Hadlock accuracy		**Intergrowth accuracy**	
Variables	Accurate (±15%)	P value	Accurate (±15%)	P value
Fetal sex				
Female	95 (75.4%)	0.313[a]	76 (60.3%)	0.463[a]
Male	127 (80.4%)		102 (64.6%)	
Ultrasound to delivery interval				
<8days	22 (81.5%)	0.168[a]	24 (88.9%)	<0.0001[a]
8-14days	39 (86.7%)		35 (77.8%)	
15-21days	66 (81.5%)		55 (67.9%)	

>21days	95 (72.5%)		64 (48.9%)	
Maternal BMI				
<19	2 (50%)	0.46 [b]	2 (50%)	0.938[b]
19-25	66 (76.7%)		55 (64.0%)	
26-29	101 (80.2%)		79 (62.7%)	
>=30	53 (77.9%)		42 (61.8%)	
Fetal weight				
SGA	33 (80.5%)	0.372[a]	26 (63.4%)	0.816[a]
AGA	170 (79.1%)		136 (63.3%)	
LGA	19 (67.9%)		16 (57.1%)	

a =Chi square test; b =Fisher's Exact test; SGA = small for gestational age; BMI=body mass index; 284 observations were used in the bivariate analysis.

Table 3

Multivariate logistic regression analysis of factors associated with accuracy of Hadlock and Intergrowth-21st formulas in estimating fetal weight (N=284)

	Hadlock accuracy				**Intergrowth accuracy**			
Variables	Accurate (±15%)	aOR	95% CI	P value	Accurate (±15%)	aOR	95% CI	P value
Fetal sex								
Female	95 (75.4%)	Reference	0.76-2.45	0.291	76 (60.3%)	Reference	0.67-1.90	0.645
Male	127 (80.4%)	1.4			102 (64.6%)	1.1		
Ultrasound to delivery interval								
<8days	22 (81.5%)	Reference			24 (88.9%)	9.6	2.65-34.92	0.001
8-14days	39 (86.7%)	1.7	0.45-6.78	0.422	35 (77.8%)	4.4	1.92-10.15	<0.001
15-21days	66 (81.5%)	1.1	0.33-3.39	0.932	55 (67.9%)	2.4	1.30-4.27	0.005
>21days	95 (72.5%)	0.6	0.20-1.73	0.333	64 (48.9%)	Reference		
Maternal BMI								
<19	2 (50%)	0.3	0.03-2.24	0.222	2 (50%)	0.3	0.03-2.63	0.271
19-25	66 (76.7%)	Reference			55 (64.0%)	Reference		
26-29	101 (80.2%)	1.3	0.64-2.53	0.489	79 (62.7%)	0.9	0.48-1.61	0.674
>=30	53 (77.9%)	1	0.44-2.19	0.964	42 (61.8%)	0.7	0.36-1.50	0.392
Fetal weight								
SGA	33 (80.5%)	1.1	0.46-2.63	0.839	26 (63.4%)	0.8	0.36-1.64	0.493
AGA	170 (79.1%)	Reference			136 (63.3%)	Reference		
LGA	19 (67.9%)	0.4	0.17-1.08	0.0073	16 (57.1%)	0.6	0.25-1.45	0.2

aOR = adjusted odds ratio; SGA = small for gestational age; BMI=body mass index; 284 observations were used in the multivariate analysis

DISCUSSION

The Hadlock formula significantly performed better than Intergrowth-21st in estimating birthweight centiles in low-risk pregnant women and had a higher proportion of fetuses within ±15% of the birthweight centile with a lower MAPE. On average, the estimated fetal weight centile fell within 7.2% of the birthweight when Hadlock method was used, compared to 10.1% for Intergrowth-21st. The Intergrowth-21st formula was more accurate than Hadlock in predicting birthweight centiles of LGA fetuses. The two formulae were comparable in their ability to predict birthweight for SGA and AGA fetuses, albeit with low sensitivity and specificity.

The ultrasound-to-delivery interval affected the accuracy of the Intergrowth-21st formula more than Hadlock. The EFW was nine-times more likely to fall within ±15% of the birthweight when an ultrasound was performed within 8 days than after 21 days of delivery. For a scan performed within 15 to 21 days of delivery, the EFW was 2 times more likely to fall within 15% of the birthweight. Maternal BMI and fetal sex did not influence the accuracy of the either method.

A similar trend in performance was observed in a different population[6]. Likewise, in a secondary analysis of data obtained from women between 22 and 34weeks gestation, the proportion of fetuses with an EFW within ±15% of the birth weight was 86.8% and 78.2% ($p<0.001$) for Hadlock and Intergrowth 21st methods respectively[19]. In contrast, Milner and colleagues found that the EFW was overestimated in 68% of the methods analyzed (including Hadlock), however, Intergrowth-21st was not included in this review[1]. Our study differed from the above since ultrasounds were performed from 36 weeks' gestation. This elucidates the greater tendency for underestimation.

In predicting EFW for LGA fetuses, our study differed from a recent cohort study in which Hadlock was slightly more accurate in predicting LGA fetuses than Intergrowth-21st method ($p<0.0001$; AUC 0.85, 0.83) [27]. The study was conducted in a population between 28 and 36weeks gestation with a 4.6% proportion of LGA fetuses. Our study, however, had almost five times the rate of LGA fetuses (26%). It was postulated that the difference in accuracy may have been attributable to the large population of LGA fetuses, which likely influenced the results. Our study also differed in that women with factors that could affect the trajectory of fetal growth were excluded. Despite the difference between the two methods, Hadlock had an acceptable accuracy with more than 80% chance of correctly predicting birthweight of LGA fetuses.

Sovio and colleagues found Hadlock EFW percentile to have a significantly better accuracy ($p<0.0001$; AUC 0.87; 95% CI 0.85-0.89) than Intergrowth-21st EFW percentile (AUC 0.85; 95% CI 0.83-0.87 respectively) for SGA fetuses [27] . A similar comparison comparing the discriminatory ability of Hadlock and Intergrowth-21st methods in SGA fetuses also found Hadlock to have a significantly better performance (AUC 0.69, 0.62) [28]. However, these studies had different populations from that on which the Intergrowth -21st formula was derived and therefore any comparison may not be plausible.

Increasing gestational age is inversely related to the accuracy of ultrasound formulae[1]. This has been thought to be due to the technical difficulties encountered in obtaining the fetal head biometric measurements as fetuses start to engage into the maternal pelvis. Despite this, the utility of performing ultrasounds closer to delivery time was demonstrated in a study by Roma *et al*. They were able to demonstrate that ultrasounds done at 36weeks had a higher detection rate for fetal growth restriction than those done at 32weeks[29] . We found the mean ultrasound-to-delivery interval to have a significant influence on accuracy of EFW for the Intergrowth-21st formula. Other studies have reported that increasing ultrasound-to-delivery interval reduces the accuracy of fetal weight estimation for both formulae[6,19]. These findings support a common theory which suggests that increasing the interval reduces the accuracy due to physiological and pathological growth differences that may occur during this period[1]. Interestingly, there was no association between either fetal sex or maternal BMI and the accuracy either Hadlock or Intergrowth-21st formulae. To the contrary Milner and colleagues reported that most of the studies reviewed found a significant association between BMI and accuracy[1]. It was postulated that maternal BMI affected the image quality, consequently reducing the accuracy. The Intergrowth-21st formula was not included in this analysis. In addition, the specific populations incorporated were heterogenous with no limitation on maternal characteristics.

Overall, the sensitivity of both formulae in predicting birthweight for SGA, LGA and AGA was worryingly low, considering ultrasound remains the most relied upon tool for determining fetal growth disorders.

We remain cognizant of the fact that this was a single-center study, and the results may not be generalizable and should therefore be cautiously interpreted. There was also a wide variation in the ultrasound-to-delivery interval which may have influenced the interpretation of the results. However, we aimed to be pragmatic and to the best our knowledge, this is the first study comparing the accuracy of the two formulae in estimating birthweight using both centiles and absolute fetal weights in a population with similar characteristics to the Intergrowth-21st study.

CONCLUSION

There are no conspicuous differences in the accuracy of both the Intergrowth-21st and the Hadlock formula in predicting birthweight to justify a shift in practice. However, the sensitivity and specificity of ultrasound in predicting birthweight remains worryingly low which would not be expected of a diagnostic modality heavily relied upon in decision making. We therefore recommend clinicians' judgment in unique circumstances such as large for gestation fetuses or when the ultrasound-to-delivery interval is protracted.

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