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Estimation of fetal weight by measurement of fetal thigh soft-tissue thickness in the late third trimester

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KEYWORDS: estimation of fetal weight; fetal fat; fetal growth; fetal lean mass; fetal thigh; soft tissue thickness

ABSTRACT

Objective *The accuracy of current formulae for the sonographic estimation of fetal weight (EFW) is compromised by significant intra- and interobserver variability of biometrical measurements, particularly circumferences. The aim of this study was to assess the reliability of the linear measurement of mid-thigh soft-tissue thickness (STT) and to derive a novel formula for EFW.*

Methods *This was a prospective study involving 388 singleton uncomplicated pregnancies. There were three consecutive phases: (1) to verify the relationship between STT and birth weight, (2) to derive a novel formula for EFW using femur length and STT only, and (3) to test the accuracy of the new equation. Only the 290 patients who delivered within 48 h of measurement were considered for the analysis. A comparison with other formulae was performed.*

Results *STT was significantly correlated with both abdominal circumference and birth weight ($r^2 = 0.36$ and 0.46, respectively; $P < 0.001$). Both intra- and interobserver variability were satisfactory (0.44 ± 0.27 and 0.57 ± 0.35 mm, respectively). The equation for EFW was developed using multiple stepwise regression analysis ($EFW = -1687.47 + (54.1 \times \text{femur length}) + (76.68 \times STT)$) and tested prospectively on 69 patients. The new formula yielded results ($r = 0.79$) that were slightly better in accuracy than two other published equations, and had an absolute mean error of $< 15\%$ in 97% of cases.*

Conclusions *Our findings confirm the potential of the linear measurement of mid-thigh STT as a valuable parameter for the sonographic assessment of fetal growth and EFW. Our new equation is apparently at least as reliable as the most widely used formulae for EFW.*

INTRODUCTION

Sonographic assessment of fetal growth for the estimation of fetal weight (EFW) is a common practice in obstetrics, providing valuable information for planning the mode of delivery and management of labor. Most formulae were proposed in the early 1980s using different combinations of standardized fetal biometric parameters, such as biparietal diameter (BPD), head circumference (HC), abdominal circumference (AC) and femur length (FL)[1]. Unfortunately, the accuracy of EFW is compromised by significant intra- and interobserver variability, and many of the existing formulae are generally inaccurate at the extremes of fetal weight[2]. AC is widely recognized as the most useful dimension with which to evaluate fetal growth, although it is subject to larger variability compared with linear measurements[3]. None of these parameters, however, accounts for increased soft tissue mass, which leads to an underestimation of fetal weight[1]; this has been demonstrated in infants of diabetic mothers[4], in whom the increased lean body mass was not estimated by standard measurements.

We have proposed the sonographic measurement of fetal mid-thigh soft tissue thickness (STT, involving adipose tissue plus lean mass) as a possible parameter for EFW[5]. This linear measurement ensures a good estimate of lean and fat mass of the fetal thigh. The aim or our present study was to evaluate the association between this new sonographic parameter and birth weight. We investigated technical aspects of this measurement to assess its reliability and reproducibility. Furthermore, we propose a new equation for the prediction of birth weight.

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MATERIALS AND METHODS

Study design and subjects

Over a 26-month period, a total of 388 pregnant women consented to participate in this study, which was approved by the local ethics review board. The study was carried out at the University Hospital of Bari and was based on three consecutive phases. The first phase was a feasibility study for the verification of a relationship between the new sonographic parameter, mid-thigh STT, and birth weight. For this phase, 150 women were enrolled over 10 months. Subsequently, a second cohort of 150 women were recruited prospectively over 10 months in order to obtain a study population sufficiently large to derive a formula for EFW. This formula was then tested prospectively on a third group of 88 women recruited for this purpose in the following 6 months (Phase 3 of the study).

For all three phases, women considered for the study were at term, with singleton uncomplicated pregnancies, and were likely to give birth within 48 h. Patients were selected consecutively from among those admitted for elective Cesarean section (maternal request or previous Cesarean section), induction of labor (post-term pregnancies or pre-labor rupture of the membranes), or initial spontaneous labor. Entry criteria also included cephalic presentation and sonographic evidence of normal amniotic fluid. As the population referred to our ultrasound department is 99% Caucasian, we excluded from the study all other racial/ethnic groups. Gestational age was confirmed retrospectively by recorded measurement of crown–rump length taken at 11–13 weeks' gestation. Measurements of fetal biometric parameters (BPD, HC, AC and FL) were taken sonographically by a consultant with extensive experience in obstetric ultrasound (M.S., A.V. or F.C.), using an Acuson 128/XP (Mountain View, CA, USA) or Aloka ProSound alpha5 (Aloka Co., Tokyo, Japan) ultrasound machine equipped with a 3.5–5-MHz or a 3.5–6-MHz convex transducer, respectively. Additionally, the mid-thigh STT was measured linearly in the standard longitudinal section used for FL measurement[5,6] (Figure 1): after the appropriate section was obtained, the image was frozen on the screen and then magnified. STT was then measured from the outer margin of the skin to the outer margin of the femur shaft, with the femur lying parallel to the transducer. The measurement was taken in the middle third of the fetal thigh, providing that the greater and the lesser trochanters were turned upwards. This section ensured the correct view of the lateral side of the femur (vastus lateralis, which is the largest part of the quadriceps femoris). In each case, three satisfactory images from different frozen images were measured (in mm to one decimal place) and the mean value was recorded.

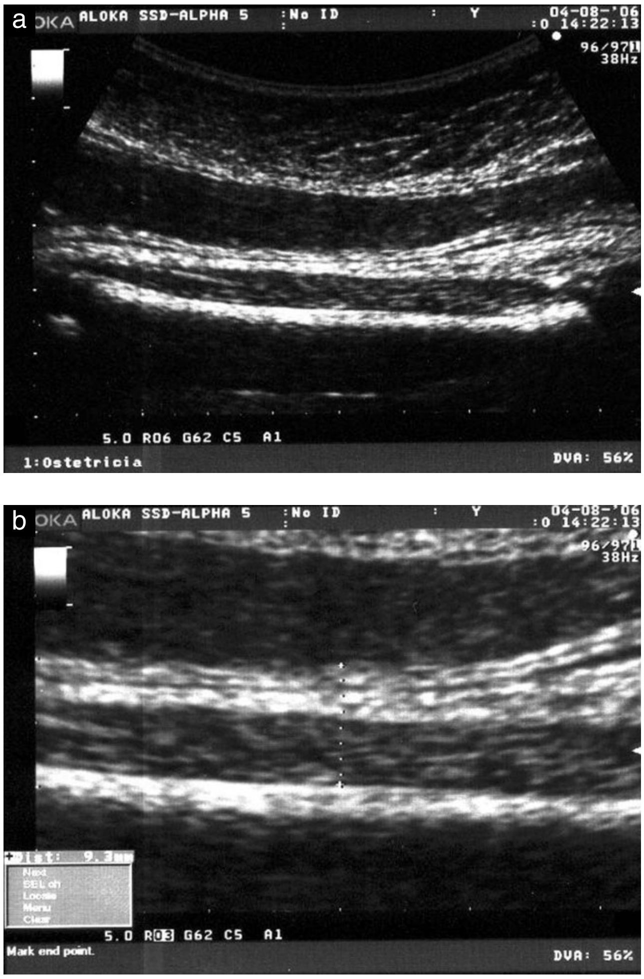

Figure 1 Sonographic measurement technique for fetal mid-thigh soft-tissue thickness. The longitudinal section as used for measuring femur length is obtained (a) and then magnified (b). Calipers are placed on the outer margin of the skin and the outer margin of the femur shaft, with the femur lying parallel to the transducer (b).

Validation of sonographic measurements

Intra- and interobserver variability for fetal biometry (BPD, HC, AC and FL) and STT were assessed in 40 cases enrolled in Phase 1, regardless of whether the woman delivered within 48 h. Patients were selected consecutively according to those who accepted to undergo three scans (by different operators) in the same day. Each operator, who was blinded to data provided by previous scans, took three measurements of all studied parameters from different frozen images.

In another subset of 20 women chosen arbitrarily from those enrolled in Phase 1, measurements of STT were taken from a single frozen image at the mid-thigh (reference point) and at intervals of approximately 3 mm on either side of this reference point throughout the fetal thigh. This was to assess variability caused by measuring away from the midpoint of the femur. Since experienced sonographers can make this measurement correctly within a few attempts, a learning curve was not applicable.

Statistical and mathematical analyses

The sample size calculation for each phase of this project was based on previous studies[7–11]. One hundred cases delivering within 48 h was considered sufficient to provide significant information for Phase 1, and a similar study population was recruited for derivation of the new formula (Phase 2). For the prospective recruitment of patients to test the new formula (Phase 3), 64 cases were required to obtain a statistical power of 0.9 with alpha set at 0.01 and an expected coefficient of determination of 0.46 (as calculated at completion of Phase 2).

Continuous variables were assessed using Student's *t*-test if a normal distribution was confirmed by the method of Kolmogorov and Smirnov.

Phase 1

All sonographic parameters (BPD, HC, AC, FL and STT) were assessed for a significant linear relationship with actual birth weight. Furthermore, the correlation between STT and AC was studied, since AC is considered as the key dimension in the assessment of fetal growth and prediction of birth weight[1]. Intra- and interobserver variation for sonographic parameters (BPD, HC, AC, FL and STT) was calculated as the deviation from the mean value for each parameter and is reported as both a length value (mm) and a percentage.

Phase 2

Although deletion of outlier data is a controversial practice in statistics, outlier values play an important role in mathematics[12]. The derivation of a formula is based on a mathematical approach for finding the best-fitting curve for a given set of points, and so quality control of data was performed using Grubb's test. Extreme outliers (observations beyond 1.96 SD from the mean, $n = 4/108$) were rejected. The birth-weight estimation equation was obtained using multiple linear regression analysis, with actual birth weight as the dependent variable. FL and STT were considered as explanatory (independent) variables, as well as their square root, natural logarithm, square and cube transformations. Cross products of the form FL × STT, $FL^2 \times STT$ and $FL \times STT^2$ were also included in the modeling process, giving a total of 13 explanatory variables. All $2^{13} - 1$ possible linear regression analysis models were computed in order to find an equation that was both accurate and simple to use. Models exhibiting multicollinearity were discarded, as hidden mutual dependence between explanatory variables could cause results to be unreliable. The possibility of multicollinearity was evaluated by calculating Dillon and Goldstein's condition number, C, from eigenvalues of the correlation matrix[13] and testing the threshold condition $C > 30$. The adjusted coefficient of determination, ${R_a}^2$, was used to assess the compromise between accuracy and simplicity of the different models. A higher R^2 corresponds to a lower standard error of a regression formula, but R^2 always increases when a further explanatory variable is added, regardless of how much (or how little) explanatory power it has. ${R_a}^2$ corrects this behavior by adjusting the coefficient for the number of variables in the model, therefore taking into account the loss of degrees of freedom that results from using more variables[14].

Statistical significance of candidate models was verified by ANOVA and the *F*-test for overall fit, as well as *t*-tests for individual parameters. Furthermore, for the best candidate models, the histogram of residual values over the Phase 2 data was examined visually in order to confirm the hypothesis of normality[12].

Phase 3

The relationship between actual birth weight and EFW using the developed formula (based on FL and STT) and the formulae of Hadlock *et al.* (based on BPD, HC, AC and FL)[7] and Shepard *et al.* (based on BPD and AC)[8] was analyzed using Pearson's correlation. The performance of different models for EFW was assessed by calculating the signed mean percent difference (EFW − actual birth weight) ×100/actual birth weight), with the SD and SE of the percent differences representing the variability and the precision of the mean, respectively. Furthermore, we assessed the concordance between birth weights and all three formulae by means of Bland–Altman limits of agreement analysis[15].

Data were analyzed using the GraphPad Prism software system (version 4.00 for Windows, GraphPad Software, San Diego, CA, USA) with significance set at $P < 0.05$. For the derivation of the new EFW formula, we used the KyPlot data analysis package (version 2.0, KyensLab Inc., Tokyo, Japan, 2002).

RESULTS

Delivery within 48 h occurred in 290 (74.7%) cases and these were included in the analysis. The study populations had similar characteristics, as reported in Table 1. The birth weights ranged from 2210 to 4200 g, with a similar mean value in the three groups. The mean STT was 14.2 ± 3.0 mm and its distribution was normal (Kolmogorov–Smirnov > 0.1).

Phase 1

Of the 150 women recruited for the first phase of this study, 113 (75%) delivered within 48 h. Actual birth weight and AC were significantly correlated with STT ($r^2 = 0.46$ and 0.36, respectively; $P < 0.001$) (Figure 2). In the subgroup of 40 women, all fetal biometric parameters correlated with actual birth weight to different degrees (Table 2). AC and FL correlated better with birth weight, confirming for the fetus what is already known postnatally that weight is a combination of fatness and height. The intra- and interobserver variability of linear measurements of BPD and FL were all < 1% and the variability of STT was about 0.5 mm (Table 2). The measurements of STT taken at various points in the middle third of the fetal thigh were not significantly different (Figure 3).

Table 1 Demographic and clinical data of the study population

*Characteristic**	*Phase 1: feasibility study* (n = 150)	*Phase 2: derivation of new formula* (n = 150)	*Phase 3: application of the formula* (n = 88)	*Total population* (n = 388)
Delivered within 48 h (*n* (%))	113 (75.3)	108 (72.0)	69 (78.4)	290 (74.7)
Age (years, mean (SD))	31.1 (4.6)	31.7 (4.0)	32.9 (4.8)	31.8 (4.4)
BMI (kg/m^2, mean (SD))	23.6 (3.9)	22.9 (3.8)	24.2 (4.3)	23.5 (4.0)
Gestational age (weeks, mean [median] (SD))	39.0 [39] (1.5)	39.3 [39] (1.4)	38.9 [39] (1.7)	39.1 [39] (1.5)
Femoral soft tissue thickness (mm, mean [median] (SD))	13.9 [13.4] (3.0)	14.5 [13.8] (3.2)	14.1 [13.5] (2.7)	14.2 [13.6] (3.0)
Birth weight (g, mean (SD))	3331.0 (440.5)	3411.1 (429.6)	3372.7 (453.1)	3370.7 (439.4)

*All characteristics refer to patients who delivered within 48 h, i.e. those considered for analysis. BMI, body mass index.

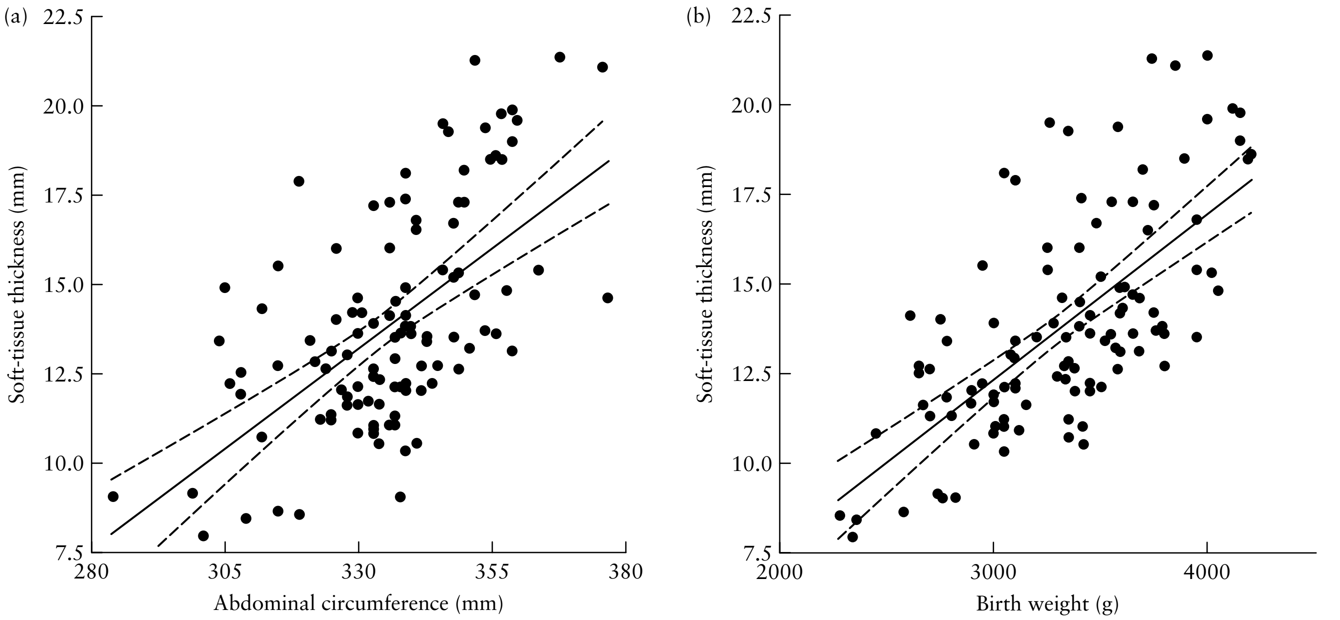

Figure 2 Fetal mid-thigh soft tissue thickness correlated well with both abdominal circumference ($P < 0.001$; $r^2 = 0.36$) (a) and actual birth weight ($P < 0.001$; $r^2 = 0.46$) (b) (data from Phase 1, $n = 113$). Dashed lines represent 95% confidence intervals.

Table 2 Correlation matrix of sonographic variables with actual birth weight

Sonographic variable	*Correlation with actual birth weight* (r) *(n = 113)*	*Intraobserver variability (n = 40)* %	*Intraobserver variability (n = 40)* *mm*	*Interobserver variability (n = 40)* %	*Interobserver variability (n = 40)* *mm*
Biparietal diameter	0.52	0.76	0.71	0.85	0.79
Head circumference	0.49	1.19	3.84	1.52	4.90
Abdominal circumference	0.69	1.74	6.21	2.17	7.73
Femur length	0.66	0.82	0.62	0.83	0.62
Mid-thigh soft tissue thickness	0.67	3.17	0.44	4.10	0.57

All variables were significantly correlated with birth weights ($P < 0.001$). Inter- and intraobserver variability was assessed in a subgroup of 40 patients from Phase 1.

Phase 2

Of the 150 women recruited for the second phase of the study, 108 (72%) delivered within 48 h. Four patients (the extreme outliers) were excluded from mathematical processing, so the final study population consisted of 104 observations. In this subgroup of patients, the correlation matrix of FL and STT with actual birth weight was 0.78 and 0.79, respectively, while their mutual correlation was noticeably lower ($r^2 = 0.26$). Mathematical analysis yielded the following equation for EFW:

$$EFW = -1687.47 + (54.1 \times FL) + (76.68 \times STT),$$

with EFW in g and FL and STT in mm.

The proposed formula had a Dillon–Goldstein condition number C of 3.3; thus, multicollinearity was not suggested. The adjusted coefficient of determination was $R_a^2 = 0.795$. ANOVA for statistical significance of the overall regression equation resulted in $F_{(2, 97)} = 193.32$ ($P < 0.001$). Table 3 reports the Student's *t*-tests for statistical significance of individual coefficients, showing high significance for each of the three ($P < 0.001$). The histogram of residual values of the proposed regression equation over the sample data showed a Gaussian distribution that departed slightly from a zero-mean normal distribution (data not shown). Other computed models either were affected by multicollinearity or did not justify higher complexity with significant improvement in performance.

Phase 3

Of the 88 women recruited for the third phase of the study, 69 (78%) delivered within 48 h. There was a significant linear relationship between birth weight and EFW (Figure 4) using the three formulae. Among the studied estimates, the model using STT proposed herein was apparently more accurate compared with the other two multiparameter equations (Table 4). All three formulae tended to over- and underestimate fetal weight in small and large fetuses, respectively (Figure 5). Nevertheless, our formula and that of Hadlock *et al.* can be considered satisfactory in their ability to estimate the actual birth weight, with an absolute mean error of < 15% in > 90% of cases (Table 4). Moreover, the differences between EFW and actual birth weight were more spread out using the estimates of Hadlock *et al.* and Shepard *et al.* than they were using ours (Figure 5), although the analysis of SDs (variability) was not significantly different (Bartlett's test 4.53, $P > 0.05$).

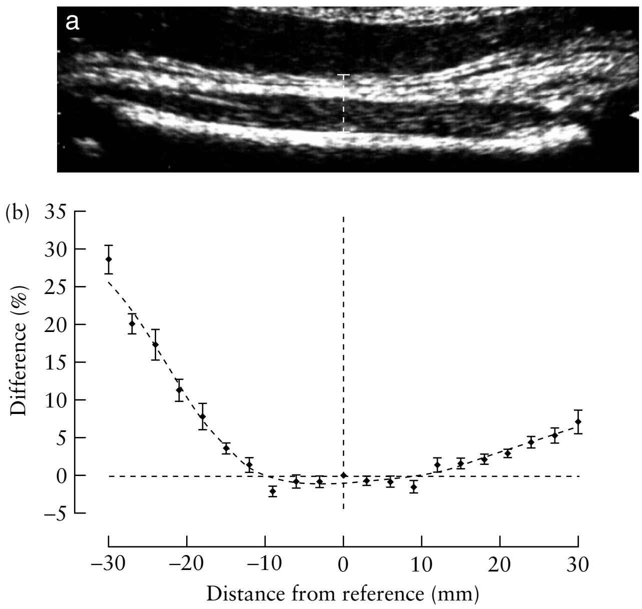

Figure 3 Variation of measurements of fetal mid-thigh soft tissue thickness moving away from the central mid-thigh reference point. Difference (mean and SE) was calculated as the measured value minus the reference value divided by the reference value (data from Phase 1, $n = 20$).

Table 3 Statistical significance test for individual coefficients of the proposed formula for estimated fetal weight ($EFW = b_0 + b_1 \times$ femur length $+ b_2 \times$ mid-thigh soft tissue thickness) on patients in Phase 2 ($n = 104$)

Coefficient	*Estimate*	*SE*	$t_{(0.05,97)}$*	*95% CI*
b_0	−1687.47	387.6	−4.35 ($P < 0.001$)	−2456.75; −918.19
b_1	54.10	5.92	9.14 ($P < 0.001$)	42.36; 65.85
b_2	76.68	7.81	9.81 ($P < 0.001$)	61.18; 92.19

*Student's *t*-test.

DISCUSSION

This multi-phase study confirms the potential of the linear measurement of mid-thigh STT as a valuable parameter in the sonographic assessment of fetal growth and EFW. This measurement is easy to make and has great reproducibility. Furthermore, the novel equation for EFW that we have proposed is apparently at least as reliable as the most widely used formulae for EFW.

It is intuitive that body weight derives from a combination of height as well as lean and fat mass. Several studies have been carried out to verify the ability of fetal fat tissue measurement to correctly predict fetal macrosomia[11,16–18], and sonographic evaluation of fetal fat mass has been proposed as a method for assessing fetal overgrowth[19]. In contrast, very few studies have been published on fetal lean mass[20,21]. Reduced lean mass was demonstrated in fetuses with growth restriction[22], which may explain the increasing error of EFW in these cases[2].

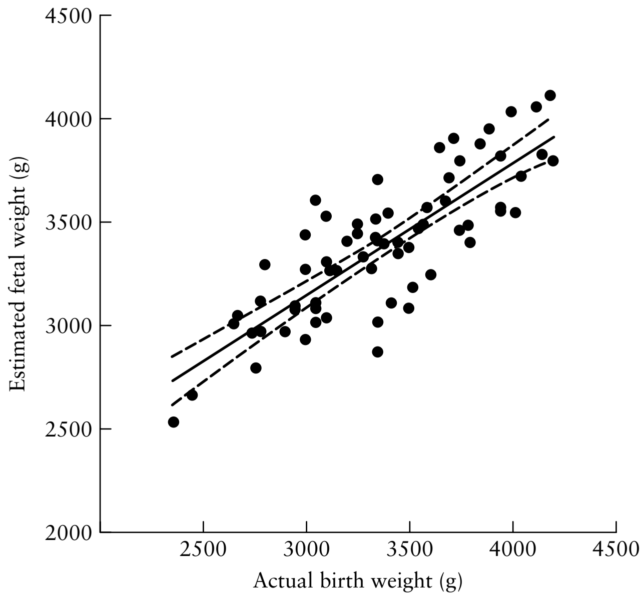

Figure 4 Correlation between fetal weight estimated using the new formula and actual birth weight ($P < 0.001$; $r^2 = 0.68$) (data from Phase 3, $n = 69$). Dashed lines represent 95% confidence intervals.

Table 4 Correlation between estimated and actual birth weights using three different formulae on patients in Phase 3 ($n = 69$)

	Formula		
	Hadlock et al.[7]	*Shepard* et al.[8]	*This study*
Correlation with birth weight (r, 95% CI)	0.73 (0.66–0.79)	0.73 (0.64–0.80)	0.79 (0.68–0.87)
Signed mean percent difference (%, mean (SD) [SE])*	−3.59 (8.56) [1.03]	−1.94 (9.85) [1.19]	0.91 (7.61) [0.92]
Absolute mean error (% of cases)			
<5%	31.88	36.23	49.28
<10%	73.91	63.77	78.26
<15%	89.86	84.06	97.10

*Calculated as estimated birth weight minus actual birth weight divided by actual birth weight × 100.

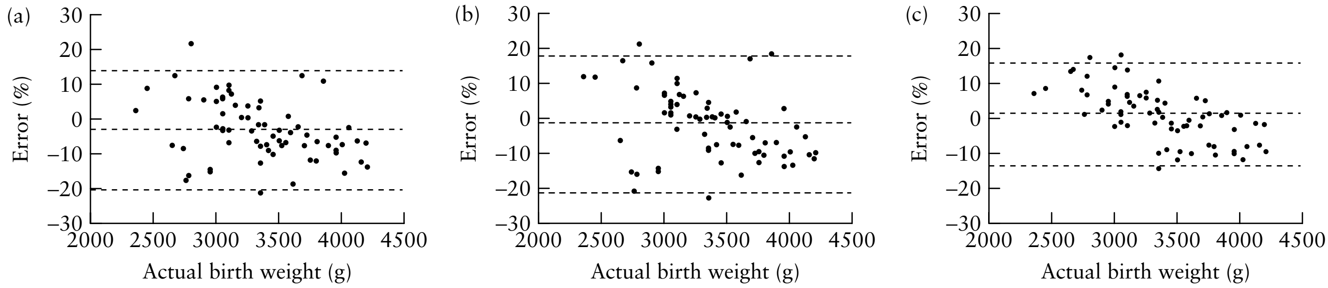

Figure 5 Limits of agreement between birth weight and sonographically estimated fetal weight according to the formulae of Hadlock *et al.*[7] (a), Shepard *et al.*[8] (b) and this study (c) (data from Phase 3, $n = 69$).

The assessment of adipose tissue in fetal limbs to evaluate fetal growth and EFW has been investigated previously. Santolaya-Forgas *et al.*[11] proposed the fetal subcutaneous tissue/FL ratio as a novel parameter for identification of large-for-gestational-age fetuses (involving the measurement of subcuticular adipose tissue only). Subsequently, the introduction of three-dimensional ultrasound has led some authors to propose new formulae that incorporate volumetric data from fetal limbs. Lee *et al.*[23,24] utilized 3D ultrasound to derive fractional arm and thigh volumes as fetal soft tissue parameters for assessment of growth and weight estimation. Although the results showed potential, the application of this technique is limited by the excessive time required (for scanning and data processing) and by the need for a 3D ultrasound machine and specific software. Nevertheless, these findings further support the potential of measuring soft mass (fat and lean mass) in the assessment of fetal growth and EFW.

Here, we have proposed a novel approach for the measurement of fetal soft mass. The linear measurement of the tissue above the external side of the fetal femur provides an easy and straightforward method with which to assess the amount of fat and muscular mass of the fetal thigh.

The deviation of EFW from actual birth weight is due to a combination, in approximately equal proportions, of measurement error and the intrinsic properties of the formula[25]. Most sonographic formulae for EFW are based on multiple fetal measurements[1]. Formulae combining more than two parameters are deemed more reliable than are those with one or two measurements[26], although a clear explanation for this has not yet been proposed. From a purely statistical point of view, the presence of different variables in a formula increases the risk of multicollinearity and enhances the internal error of each measurement.

Clinically, the proposed formula can be of practical use in situations in which head measurements cannot be taken properly due to fetal head engagement. In contrast, we excluded from this study all breech presentations, in which the fetal hip can be down into the pelvis, causing distortion of the thigh profile. However, such cases represent only a small percentage of all deliveries. Furthermore, compared with circumferences, linear measurements are more easily taken by obstetricians/midwives who have little experience in sonography[27], and linear measurements of fetal biometry are more reproducible than are circumferences[3]. Of the standard sections for fetal biometry, the view for FL measurement is probably the easiest image for non-expert sonographers to obtain adequately[28], while quality images for AC measurement are less easily obtained, even for operators with some experience[27]. Measurements made from suboptimal images contribute to interobserver variability and are a major bias in EFW[27].

The limitations of this study must be considered. The population consisted of Caucasian women with singleton cephalic pregnancies and evidence of normal amniotic fluid volume. Strict statistical and mathematical approaches were used to test STT as a possible new parameter for the assessment of fetal growth and estimation of birth weight. Our findings are promising, but larger studies are required to confirm the reliability of this novel parameter and the accuracy of the proposed formula for

EFW under different circumstances, such as breech presentation, oligohydramnios and fetal growth alterations.

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