IS IT STILL NECESSARY TO PERFORM THE FUNDAL HEIGHT MEASUREMENT IN PREGNANCY ANTENATAL CARE FOLLOW-UP EXAMINATIONS? AN EXPLORATORY PROSPECTIVE COHORT STUDY IN SPAIN

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Abstract: *Objective*: The construction of a predictive model that improves the estimation of the fetal weight (EFW) and determines the symphysis-fundal height role in this equation. *Methods*: a comparative, descriptive study. One hundred and forty pregnant women were recruited using a two-stage sample in a health department in Spain. They were classified in four groups depending on the pre-gestational body mass index (BMI). Fetal weight was estimated by ultrasound at 35-40 weeks (EFW40w) by one gynaecologist. A regression model was created with the variables that reacted to the newborn's weight, symphysis-fundal height (SFH), EFW40w, gestational age (GA), ferritin level, and cigarettes smoked during the third trimester. *Results*: A multivariate model was created for the normal weight (NW) group to estimate the fetal weight (EFWme), resulting in R^2=0.727 (p<0.001). The differences of the averages obtained between EFW40w and EFWme were significant (p<0.001). EFWme underestimates birth weight by 0.07g (mean error 0.53%), and EFW40w overestimates it by 300.89g (mean error 10.12%). In order to evaluate the predictive model and verify the predictions we used the Bland-Altman analysis. The average error when estimating the birth weight with EFWme was an underestimation of 1.94%, whereas the ultrasound error (EFW40w) overestimated the result by 10.93%. *Conclusion*: The multivariate model created for the NW group improves the accuracy of the ultrasound.

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Resumen: *Objetivo*: Construir un modelo predictivo que mejore la estimación del peso fetal y determinar el papel de la altura uterina en esta ecuación. *Métodos*: Estudio observacional descriptivo. Se seleccionaron 140 gestantes mediante muestreo bietápico en un departamento de salud de España. Se clasificaron en cuatro grupos atendiendo al índice de masa corporal (IMC) pregestacional. El peso fetal fue estimado mediante ecografía en la semana 35-40 (PFE40s) de gestación por un ginecólogo. Se elaboró un modelo de regresión con las variables que mostraron significación estadística con el peso al nacer como fueron, la altura uterina, PFE40s, edad gestacional, nivel de ferritina sérica y cigarillos consumidos en el tercer trimestre. *Resultados*: Se construyó un modelo multivariante para la categoría de normo-peso para estimar el peso al nacer (PErm) obteniendo una $R^2 = 0{,}727$ ($p < 0{,}001$). Las diferencias de las medias obtenidas entre PP40s y PErm, con el peso del recién nacido, fueron significativas ($p < 0{,}001$). El PErm infraestima el peso al nacer en 0,07g (error medio 0,53%), y el PP40s lo sobrestima en 300,89g (error medio 10,12%). Para evaluar el modelo predictivo y verificar las predicciones realizadas se utilizó el análisis de Bland-Altman. El error medio de la estimación del peso al nacer mediante el PErm infraestima el resultado en 1,94%, mientras que el error mediante la ecografía (PP40s) sobrestima el resultado en un 10,93%. *Conclusiones*: El modelo multivariante construido para la categoría de normo-peso mejora la precisión de la ecografía.

Palabras clave: peso al nacer, embarazo, ecografía, antropometría, análisis multivariante.

Introduction

The analysis of birth weight must be addressed from a multifactorial perspective[1]. Unfortunately, birth weight is unknown until birth takes place[2]. The use of ultrasound fetal measurements is common, and the measurements have been combined to estimate fetal weight by regression analysis or physical methods[3]. Fetal weight estimation is inaccurate, with poor sensitivity for prediction at term[4]. It is already known that the absolute error average in predicting birth weight varies from 6 to 12% of the actual weight. Several authors[4-6] have shown that the level of intra/inter-observer variability in fetal measurement as well as the impact of errors on growth assessment is unacceptable. Different studies[7-9] have compared, with some discrepancies, the accuracy between clinical and ultrasound methods in order to estimate fetal weight in the third trimester. Birth weight depends on many factors, e.g. maternal, genetic, and environmental ones[10]. This study raises the hypothesis that some factors are not distributed randomly, but according to a profile that determines the weight of a newborn at birth. This could lead us to create a better predictive model of infant weight at birth, rather than the actual birth weight estimation by third trimester routine sonogram. The main aim of the study is the construction of a predictive model that improves the estimation of the fetal weight (EFW) and determines the symphysis-fundal height role in the equation.

Methods

We performed an observational and prospective study. Based on the WHO ranges, pregnant women were allocated in four different groups depending on their pre-gestational BMI: underweight (UW <18.5 Kg/m^2), normal weight (NW 18.5-24.9 Kg/m^2), overweight (OW 25.0-29.9 Kg/m^2), and obese (OB >30 Kg/m^2). A sample of 159 pregnant women was collected from February 2011 to March 2012.

A two-stage sampling study was performed. In the first stage, two surgeries (Carlet and Benimodo) were chosen using a simple random probability, sampling from all Primary Care Centres of the La Ribera Health Department (Spain). In the second stage, pregnant women were selected using a probability sampling with random start and systematic monitoring depending on the number of pregnancies per year obtained in both of them.

Inclusions criteria was based on maternal age between 18 and 36 years, first prenatal appointment between 5 and 12 weeks of pregnancy and single-fetus pregnancy with no fetal deformities. Exclusions criteria included refusal to participate in the study, language barrier, an adverse obstetric history during previous pregnancies (2 or more miscarriages, one or more premature pregnancies), medical conditions that modify fetal growth such as pre-gestational diabetes, essential hypertension before pregnancy, maternal infection (TORCH), fetal malformation, amniotic disorders (AFI oligohydramnios <5 or polyhydramnios >20), or any other maternal chronic pathology (endocrine, cardiac, respiratory, addictive factors).

We estimated that for a 95% Confidence Interval (CI), a 5% error and 50% of expected proportion we needed a minimum sample size of 147.

This study was performed according to the basic principles for medical research set out in the Declaration of Helsinki. The study was previously evaluated and approved by the Research Committee of the La Ribera University Hospital.

Six categories of variables were selected: anthropometric, demographic, haematologic, ultrasound, obstetric-neonatal, and toxic.

Anthropometric variables included in the study were pre-pregnancy weight and height, BMI, and symphysis-fundal height (SFH). The mothers' height was measured with a standard scale for height to the nearest centimetre. Pre-pregnancy weight was self-reported and recorded during the initial prenatal examination after enrolment. Pre-pregnancy BMI was calculated as weight in kilograms divided by the squared height in metres (kg/m^2). SFH was measured in centimetres with non-elastic measurement tape from the upper border of the symphysis pubis to the top of the uterine fundus, or reversed direction.

Demographic variables gathered during the study were maternal age, marital status, education level, and occupation.

Haematological variables collected included haemogram and serum ferritin. They were measured in each trimester of pregnancy (<12, 24 and 34 weeks).

Ultrasound variables collected included biparietal diameter (BPD), femur length (FL), and abdominal circumference (AC) of the ultrasound done in the third trimester, between 33 and 35 weeks. They were collected in order to calculate a standardized method[7] used to estimate the birth weight at week 40 (EFW40w). We used the equation devised by Hadlock II, for carrying out their routine obstetric sonograms.

Obstetric and neonatal variables collected were parity and gestational age in weeks (obtained from last menstrual period remembered by women). Regarding the newborn, we recorded gender and weight at birth.

Toxic variables collected were pre-gestational tobacco consumption and number of cigarettes smoked per day in each trimester of pregnancy.

Basic descriptive statistics are presented comparing pre-gestational BMI groups. Afterwards, it was found normal for each of the continuous variables with the Kolmogorov-Smirnov test. The defined level of statistical significance was $p<0.05$.

In the bivariate analysis, the Student t-test was used to compare the means of two quantitative, normalised variables. Each variable was calculated and compared between the group of pre-gestational BMI test using c^2, and the analysis of variance (Scheffe's test). In order to estimate the birth weight, a multivariate regression equation (EFWme) using only variables with statistical significance, was used. Correlation between both estimation methods (EFW40w and EFWme) and birth weight was adjusted by gestational age (38-42 weeks). Accuracy of birth weight estimation was determined by calculating the absolute error of each estimation method ([estimated fetal weight - actual birth weight] / actual birth weight). The Student t-test was used to determine if this mean was significantly different from zero. Differences between both methods in the mean absolute error were assessed by the paired *t* test. The mean error represents the sum of the positive (overestimation) and negative (underestimation) deviations from the actual birth weight, approximating zero in a method with very low or no systematic error. In order to evaluate the difference between EFW40w and EFWme, an analysis of the individual differences proposed by Bland-Altman[11] was used. Then, bias (mean absolute error) and precision (SD percentage error) were obtained. Data was analysed using the Statistical Package for Social Sciences (SPSS Inc., Chicago, IL), Version 15.0, and Analyse-it 3.7.

Results

A total of 140 pregnant women were approached for inclusion in the study. A comparison of demographic and clinical variables among the four groups showed significant differences in occupation, type of work, social status, and parity (Table 1).

Multivariate models of maternal categories UW, OW, and OB showed no statistically significant differences with respect to EFW40w in predicting birth weight, and therefore were eliminated. The variables that showed statistical significance with birth weight in the NW were:

SFH 35-40 weeks ($R=0.74$, $p<0.001$), EFW40w ($R=0.63$, $p<0.001$), GA ($R=0.47$, $p<0.001$), Ferritin ($R=-2.84$, $p=0.007$), and number of cigarettes smoked in the third trimester (3T) ($R= -2.82$, $p=0.006$). The difference between the groups (ANOVA) was not significant. Linear regression analysis between birth weight and NW group with these five predictors explains its 72% variance. This and multivariate regression equation are shown in Table 2.

Then, the differences for the actual weight of the newborn between EFW40w and EFWme were studied. T-test was applied for the samples related and the differences were statistically significant ($p<0.001$) between both.

EFW40w, adjusted by gestational age, had a correlation of 0.59 ($p=0.01$) at 40 weeks, and 0.69 ($p=0.002$) for EFWme.

Comparing the mean differences between EFW40w, EFWme, and birth weight, we observe that the measurement by ultrasound overestimates all birth weights. In contrast, the estimation of the multivariate equation underestimates the birth weights at weeks 38 and 41, and overestimates it at weeks 39, 40 and 42 (Figure 1).

The differences in the averages obtained from both EFW40w and EFWme with birth weight were statistically significant ($p<0.001$). The EFWme underestimated birth weight by 0.07g, and the EFW40w overestimated it by 300.89g. Therefore, prediction absolute error was 0.53% (95% CI: -2.19 -1.12) compared to 10.12% (95% CI: 12.81 -7.43).

TABLE 1
Demographic and clinical characteristics of the study sample by pre-pregnancy body mass index

Variable	*UW (n=10)*		*NW (n=95)*		*OW (n=30)*		*OB (n=5)*		*Total (n=140)*		*p-value*
	n	%	n	%	n	%	n	%	n	%	
Maternal Age (years)											
<25	4	40.0	13	13.7	4	13.3	0	0.0	21	15.0	0.365*
26-29	3	30.0	28	29.5	5	16.7	1	20.0	37	26.4	
30-34	3	30.0	39	41.1	16	53.3	3	60.0	61	43.6	
>35	0	0.0	15	15.8	5	16.7	1	20.0	21	15.0	
Mean (S. D.)	29.91 (4.62)										
Marital Status											
Married	7	70.0	78	82.1	25	83.3	5	100	115	82.1	0.548*
Single	3	30.0	17	17.9	5	16.7	0	0.0	25	17.9	
Education											
8th grade	5	50.0	33	34.7	14	46.7	3	60.0	55	39.3	0.544*
High school	4	40.0	36	37.9	11	36.7	2	40.0	53	37.9	
University	1	10.0	26	27.4	5	16.7	0	0.0	32	22.9	
Occupation											
Employed	3	30.0	74	77.9	15	50.0	2	40.0	94	67.1	0.001*
Unemployed	7	70.0	21	22.1	15	50.0	3	60.0	46	32.9	
Pre-gestational weight (Kg)											
Mean (S. D.)	10	48.4 (4.49)	95	57.3 (6.60)	30	68.6 (7.41)	5	93.2 (8.40)	140	60.4 (10.7)	0.30*
Parity											
0	7	70.0	59	62.1	6	20.0	1	20.0	73	52.1	0.000**
³1	3	30.0	36	37.9	24	80.0	4	80.0	67	47.9	
Birth weight (g)											
Mean (S. D.)	10	3176.50 (456.63)	95	3216.37 (451.39)	30	3343.67 (507.62)	5	4153.00 (648.48)	140	3274.25 (498.95)	0.000**

S. D., standard deviation; UW, underweight, BMI<18.5; NW, normal weight, BMI: 18.5-24.9; OW, overweight, BMI:25-29.9; OB, obese, BMI³30.0.
* c2 test.
** t-test.

TABLE 2

Linear regression analysis showing predictors of birth weight by pre-pregnancy body mass index (NW)

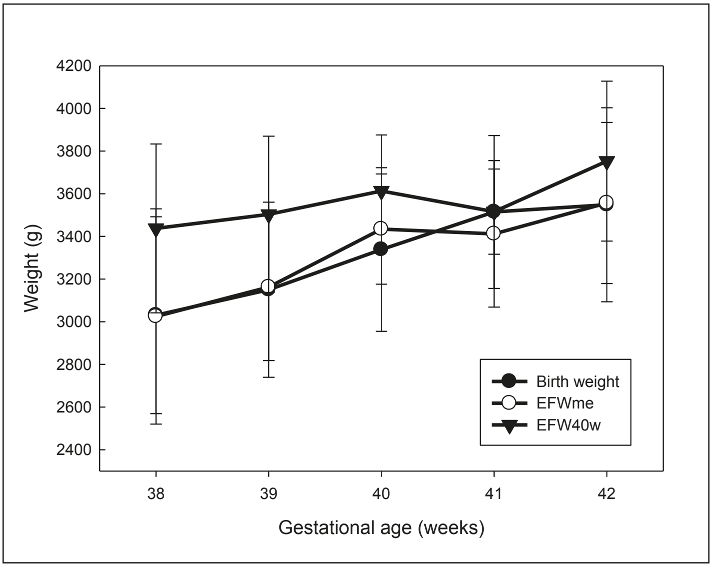
Adjusted R^2 0.727 Variables	*B*	*S. E.*	*Sig.*
(Constant)	-5667.22	850.46	0.000
SFH 35-40w	109.21	15.78	0.000
FERRITIN 3T	-3.35	1.56	0.035
EFW40w	0.35	0.09	0.001
GA	13.81	3.08	0.000
Cigarrettes smoked 3T	-20.78	7.29	0.006

Normal weight (NW), BMI≥ 18.5 but <24.9; SFH, symphysis-fundal height; EFW40w, estimated fetal weight at term (40 weeks); GA, gestational age. B, unstandardised regression coefficient; S.E., Standard Error of the estimate.

Multivariate regression equation = -5667.22+.35*EFW40w+109.21*SFH+13.81*GA-3.35*Ferritin 3T 20.78*Cigarettes smoked 3T.

FIGURE 1

Difference in birth weight between EFW40w and EFWme by Normal-Weight of Pre-Pregnancy Body Mass Index (n=95)



In order to evaluate the predictive model, an observational and retrospective study was designed. From the initial one, 138 NW pregnant women who met criteria were selected. Next, differences between EFW40w and EFWme as well as the absolute error regarding birth weight were calculated. To verify the consistency of the predictions we used the Bland-Altman analysis (Figure 2). The birth weight values provided by the EFW40w are higher than the EFWme, with a difference of 398.6g (95% CI: 450.5-346.7) (Table 3). The average error when estimating birth weight with EFWme was an underestimation of 1.94% (95% CI: 0.8-30.0), whereas the ultrasound error overestimated the result by 10.93% (95% CI: -8.9 -12.5).

FIGURE 2

Difference in birth weight between EFW40w and EFWme by Normal-Weight of Pre-Pregnancy Body Mass Index (n=138)

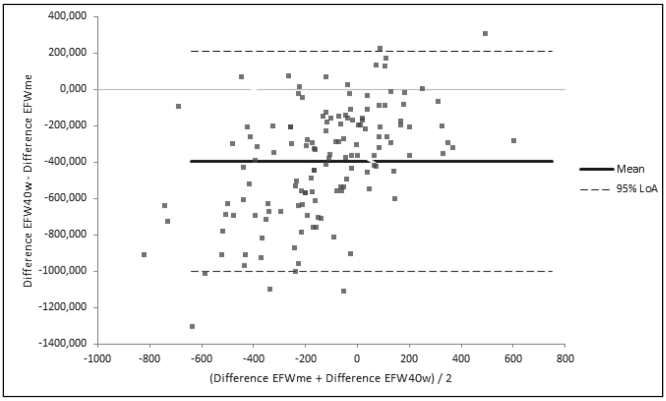


TABLE 3

Analysis of birth weight differences between the multivariate model and the ultrasound scan EFW in pregnant women (n=138) with normal BMI

	Value	*CI (95.0 %)***	
Mean of differences	-398.61	-450.50	-346.72
SD of differences	308.28		
*Mean -2SD**	-1002.84	-1091.74	-913.94
*Mean +2SD**	205.61	116.71	294.51

*SD= Standard Deviation.

**CI (95 %)= Confidence Interval stated at the 95% confidence level.

Discussion

In our study, there were a number of variables related to birth weight in the bivariate analysis. Those were subsequently used to construct the multivariate models. Eventually, we have shown that there is a statistically significant difference in predicting birth weight for the NW category when it is compared to EFW40w.

In a bivariate form, SFH measured between 35-40 weeks was associated with birth weight for the maternal category NW. It got the highest coefficient of determination of all the variables studied, even higher than EFW40w at the third trimester. Rogers et al.[12] correlated SFH with small-for-gestational-age (SGA) infants, and 73% were detected by measuring 3cm or even below the average in pregnancy. In normal-weight mothers, Meler et al.[13] obtained a normal curve adjusting the SFH for gestational week, and an SFH below the 10^{th} percentile was related to a low birth weight (LBW). In contrast, Buchmann et al.[14] described a SFH higher than 40cm as associated with an increased number of feetal macrosomia, cephalo-pelvic disproportion and/or shoulder dystocia. In our case, fundal height measured between 35 and 40 weeks, and in the presence of the other variables in the multivariate model, indicates that birth weight increases 109.21g for every centimetre of uterine height (95% CI: 77.6-140.6).

EFW40w was associated with birth weight for the maternal category of NW. In the presence of the other variables, the coefficient of determination was higher than that obtained by Ben-Haroush[5]. The use of ultrasound as a diagnostic method is well documented[5,14-17]. Depending on the formula used, predicted weight differs in its accuracy[5-16]. In our multivariate model, and in the presence of the other adjusted variables, for each gram of target weight at 40 weeks in the third trimester's ultrasound, birth weight increases 0.35g (95% CI: 0.15-0.54).

GA showed statistically significant correlation with birth weight. The average delivery GA was 278 days in primiparous mothers and 279 days for multiparous mothers. Our multivariate analysis showed that for every extra day, there is a fetal weight gain of 13.81g. This is slightly higher than the data obtained by Nahum et al.[16], with 9.66g and 9.15g for boys and girls respectively, but it is lower than Carvalho et al.[18] with 28.21g.

The smokers' ratio before pregnancy was 35.0%, and 20.7% in the last trimester, similar to other studies reviewed[19-21]. Our results indicate clearly that smoking during the third trimester of pregnancy is associated with birth weight. It is a negative correlation where increasing numbers of cigarettes consumed decreases weight at birth. Consequently, smoking during the third trimester seems to have the greatest impact on birth weight. In fact, it is known that women who gave up smoking in the third trimester have babies with birth weights similar to those of non-smokers[21]. This is in agreement with our results, as smoking in the first two trimesters showed no statistical significance in the adjusted model. The newborn with low birth weight becomes important with this toxic habit, and there is a possible relationship with the children's health deterioration because of the cytotoxic effect[22]. Petridou et al.[23] described a reduced newborn weight of smoking mothers of 190.8g as compared to the newborns of non-smoking mothers. Our results are somewhat lower: birth weight is reduced about 21g for every cigarette smoked; the average number of cigarettes smoked per day was 5, so the total decrease was about 105g, the same results obtained by Gupta et al.[24].

The amount of ferritin in the third trimester had an inverse relation with birth weight in the NW category mothers, so that the less ferritin, the higher the birth weight. In the studies reviewed, we found the opposite effect in both cases: high ferritin levels were associated with preterm birth, LBW and premature rupture of membranes[25,26]. Other authors tried to explain a possible association between high levels of ferritin and fetal growth restriction[27], arguing that ferritin may be a vascular response to both infectious and non-infectious inflammatory diseases. Further studies are needed to confirm this. Hämäläinen et al.[28] observed that anaemia and low ferritin levels during the first trimester were associated with LBW, while anaemia in the second and third trimester was not associated with preterm birth, fetal loss, or risk of perinatal complications. The effect found in our study could be explained as a relation between depletion of maternal iron stores and an increase of iron transfer to the fetus, although this increase may be limited[29]. The depletion of iron in the second and third trimesters of pregnancy in the NW category women declines physiologically from the first trimester. At the same time, iron-carrying capacity increases (transferrin), even when the deficit is eliminated by oral supplementation[30]. In our multivariate model, as a negative relation, for each ferritin unit that dropped (ng/dl), there was a gain of 3.35g in birth weight.

The limitations of the multivariate model (NW) have to do with the accuracy of the ultrasound and the GA at birth due to the estimated weight, which should be accurate at 40 weeks. All the newborns aged less than 280 days will be overestimated.

Nowadays the prediction of the birth weight through ultrasounds (EFW40w) has an absolute error that varies from 6% to 12%[3-5]. Accuracy can be improved in two different ways: first, by controlling the limitations of the technique, and second, by adding maternal variables from the multivariate model to the ultrasound measurement.

We decided to implement what can be considered a test of predictive validity, through the use of a multivariate equation, to improve the estimation of birth weight in women with a normal pre-gestational BMI. Then, in order to evaluate the equation, the model was used to analyse the correlation with a different group of pregnant women in a retrospective study. In this case, 138 pregnant women, belonging to the BMI group of

NW, and meeting all inclusion/exclusion criteria of the initial study, were selected. The average error with our multivariate model underestimated the birth weight, whereas the ultrasound at the third trimester overestimated the result.

The average error in the estimation of birth weight with EFWme was 1.94% (95% CI: 0.8-30.0), and reduced by 8.99% (10.93%-1.94%) the ultrasound scan error. There are discrepancies between methods when estimating fetal weight[17,31,32]. Clinical and ultrasound accuracy during the third trimester may differ. Unfortunately, none of these studies conclusively stated that a particular method of fetal weight estimation is absolutely better than the other one. Only few studies have combined different methods for an improvement of the estimation of birth weight at term[17,33,34]. The objective of the present study was to derive a reliable equation that, based on maternal characteristics (SFH) and third trimester ultrasound biometry, could improve scan birth weight prediction in women with low risk pregnancy. This equation is valid only for the NW group and, therefore, we should proceed by extending this study to the rest of the maternal pre-gestational BMI groups, which showed no statistical significance, to develop a new model for each one. We cannot improve the detection rate of fetal growth restriction and macrosomia because more explanatory covariables that affect fetal growth are required. According to our study, the role of obstetric and maternal factors in birth weight prediction at term of pregnancy in the NW group is confirmed, but a prospective study with a bigger sample size is necessary to confirm the efficacy of the equation fitted by using the data enrolled in this study. If confirmed, the value of the variables used to build up the statistical algorithm is higher than the clinical estimation performed with scan at third trimester by an expert obstetrician. Finally, we can conclude that:

- The SFH is the variable which affects the most the prediction of weight at birth.
- The multivariate model created improves the ultrasound measurement by 8.99%.
- The accuracy of the clinical method must be determined in situations which can alter the evaluation of weight birth in atypical women, and it should be studied in future ways of investigation.

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