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ORIGINAL RESEARCH

Higher concordance in clinical assessment versus ultrasound to estimate fetal weight when compared with birth weight in full-term newborns.

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Abstract

Introduction: The aim of this trial was to estimate fetal weight by clinical and ultrasound methods and to compare it with the weight at birth in full-term newborns.

Methods: This is an epidemiological, observational, cross-sectional study of a cohort of healthy full-term newborns. The sample size was 102 neonates born at the Pablo Arturo Suarez Hospital, in Quito, Ecuador, from November 2019 to January 2020.

Results: In full-term neonates, the estimate on ultrasound was 80.00%, while in the clinical assessment, it was 72.29%. The newborns analyzed were male, mestizo, Ecuadorian, and born in the highlands region with a mean gestational age of 38.67 weeks and a mean birth weight of 3,023 grams. We estimated the fetal weight through ultrasound and clinical assessment. The estimation of the absolute error in both methods analyzed was 2.43% in ultrasound and -4.65% in clinical assessment, and both showed moderate concordance: 78.2% in ultrasound and 85.6% in clinical assessment. Multivariate analysis showed the neonates with modified weight by ultrasound are 13.44 times more likely to show altered weight at birth, while neonates with modified weight by the clinical assessment are 11.95 times more likely to show altered weight at birth.

Conclusions: Accuracy in the clinical assessment was always higher than in the ultrasound method, especially in low-weight newborns.

Key words: Fetal weight; Ultrasonography, Prenatal; Birth Weight; Infant, Newborn; Statistics as Topic.

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Introduction

The weight of a newborn predicts the state of health. The World Health Organization has emphasized the importance of a low-birth-weight neonate (less than 2.5 kg) and the risk of death in the neonatal stage, which means that it increases the risk more than 20 times compared to neonates with adequate weight [1]. These fetuses with abnormal intrauterine growth are associated with increased neonatal mortality and morbidity [2].

Macrosomia describes a newborn whose birth weight is ≥ 4000 g or ≥ 4500 g in term newborns and affects up to 10% of births. Pregnancies reaching 40 weeks gestation can have macrosomia [3-5], which is associated with increased maternal and neonatal risks, including higher rates of emergency cesarean sections, surgical vaginal delivery, and perineal lacerations. It is also associated with an increased risk of shoulder dystocia, and in some cases permanent brachial plexus injury, humerus or clavicle fractures, asphyxia at birth, and fetal death [3]. Over the years, the trend of fetal macrosomia has been shown to be increasing worldwide [6-8] and is a growing problem in most developing countries. It is evident that macrosomic delivery is related to health problems in adulthood since the concept of fetal origin of adult diseases establishes that both infants with limited growth and macrosomic are highly predisposed to coronary heart disease, hypertension, obesity, and insulin resistance in adulthood [9, 10].

Fetal growth restriction and being too small for gestational age are the main causes of adverse perinatal outcomes. Hence, the monitoring of the growth process of newborns arouses interest in obstetricians and gynecologists. In routine clinical practice, prenatal estimation of fetal weight is performed by ultrasound and is reasonably accurate in most cases. At first, the abdominal girth measured by ultrasound was the only method that was used to calculate the fetal weight, but later, more parameters, such as biparietal diameter, head circumference, and length of the femur, were introduced to obtain greater precision. These biometric measurements are reported based on Hadlock's fetal growth curves as the most commonly used standard method. However, it is not clear which method is better for prediction: using a single parameter, such as abdominal circumference, or using estimated fetal weight based on different formulas incorporating multiple parameters [4].

Unlike two-dimensional or three-dimensional ultrasounds, the use of magnetic resonance imaging has shown promising results. The body volume of the fetus is calculated and multiplied by the fetal density, resulting in the fetal weight. The mean percentage error of the estimated fetal weight compared to the actual birth weight is regularly reported to be around 3% [5]. Estimation by the DARE clinical method is a very useful way to estimate weight in pregnant patients and offers advantages due to the low cost that this implies.

Until the early eighties, the estimation of fetal weight was performed exclusively through clinical methods based on abdominal palpation and uterine measurements [7]. This was the case until the advent of ultrasound and the spread of its use for fetal weight. It is now established as the gold standard. However, the clinical method has not lost validity. For example, a study analyzed 35 weight estimation formulas that were clinically established in 2416 fetuses whose weight ranged between 2500 and 4000 g. The study determined and compared the mean percentage error, the mean absolute percentage error, and the proportions of the estimates within the error ranges of 5, 10, 20, and 30%. In addition, the study calculated different regression lines for the connection between the estimated birth weights and the actual weights for the 2500–4000-g weight range. The formulas were examined in this way for possible inhomogeneities [11].

However, it must be taken into account that in the clinical method, the effects of the volume of the amniotic fluid on the precision of the estimated fetal weight depend on the amount of fluid (mainly if it is polyhydramnios or oligohydramnios). Previous studies have shown conflicting results for the effects of amniotic fluid volume on the accuracy of estimated fetal weight [12, 13]. With these antecedents, an observational study was designed to establish the concordance of the estimation of weight with the clinical DARE method, and it was compared with the final weight at birth.

Population and methods

Design of the investigation

The present study is an epidemiological, cross-sectional, and observational study with a cohort of term newborns.

Venue and study period
The study was carried out at the Pablo Arturo Suarez Hospital in Quito, Ecuador, from November 1, 2019, to January 31, 2020.

Sample size
The sample was probabilistic sample with a sample size of 102 newborns. The formula for a finite universe was used: $n = [N * Z^2 * p * (1-p)] / [(N-1) * e^2 + Z^2 * p * (1-p)]$. We worked with the 95% confidence interval, expected proportion of 5%, and margin of error of 5%.

Participants
The newborns included were followed during pregnancy until delivery by mothers with a single pregnancy of any ethnic origin with integrity of the amniotic membranes and an adequate body mass index. Factors that modify the mothers' uterine size such as leiomyoma, obesity, and multiple pregnancies were excluded, and so were mothers with other factors that affect the ability to palpate the uterus (for example, retroversion of the uterus, which reduces the efficiency of diagnosis of the uterus). Additionally, mothers with diabetes and hypertension were excluded according to gestational age. The other elimination criteria were patients who died during the study and patients who rejected the study.

Variables
Sociodemographic variables such as ethnicity, nationality, and region of origin of the mothers were taken. In newborns, sex, gestational age, birth weight, weight estimated by ultrasound, and estimated clinical weight were taken.

Data sources and measurements
Information was collected from medical records and newborns. The clinical file of the study institution was used.

Avoidance of bias
An approved protocol was used for this investigation with all methodological filters. The information was always taken by the same person (the main researcher), and the data were curated and validated by the director of the study. Supervision was carried out by the study director.

Statistical methods
Statistical analysis was performed with SPSS 25 (IBM Corp, Armok-NY; USA). Descriptive statistics were used with tables representing absolute and relative values of qualitative variables, as well as measures of central tendency and variability for quantitative variables. In inferential statistics, we used bivariate analysis to determine the variables to consider in the multivariate analysis.

For the qualitative variables, the Kappa test was applied to determine the consistency of the clinical and ultrasound assessment with the weight of the newborn. For quantitative variables, tests were performed on related samples to compare birth weight with the two estimation methods. A multivariate logistic regression analysis was used to predict any change in newborn weight. Statistical significance to verify proportions, measures, and predictors of variables was established by a value of $P<0.05$.

The Kappa coefficient was used as an estimator of the strength of the consistency between the variables. It was based on the following scale: <0.20: poor; 0.21-0.40: weak; 0.41-0.60: moderate; 0.61-0.80: good; and 0.81-1.00: excellent. Weight was categorized as low at <2,500 g, normal at 2,500 to 3,500 g, and overweight at > 3,500 g.

Ethical criteria
The Institutional Review Committee (CEISH) of San Francisco de Quito University approved this investigation on December 2, 2019, with code P2019-161 TPG.

Results
Table 1 shows the sociodemographic characteristics of the mothers. There were significant differences related to ethnicity, where 83.33% of the mothers were mestizo, 10.78% were Afro-American, and 5.88% were native Amerindians. The presence of mothers of mestizo origin is considerably high compared to the rest of the mothers. The most prominent nationality was Ecuadorian with 65.69%, Venezuelan mothers at 35.29%, and one Argentine mother (0.98%). The region of origin showed that most came from the Ecuadorian highlands.

Regarding sex, most of the newborns were male (67.33%). Birth weight is presented at the end of table 1. The association between birth weight (control) with

the weight estimated by ultrasound had a statistical correlation with *P* value = 0.003. The correlation was positive and linear with a Pearson coefficient of r = 0.782. The association was greater with the control and clinically estimated weight with a *P* value <0.0001 and a Pearson correlation coefficient of 0.856.

Table 2 shows the estimation errors related to the weight of the newborns with the clinical and ultrasound assessment. The mean of the absolute value presented significant differences with a *P* value <0.001. The mean error was 79.46 g for ultrasound versus -128.17 g for clinical assessment. The mean absolute percentage error also showed differences of 2.43% for ultrasound versus 4.65% for clinical evaluation.

Table 3 shows the Kappa test analyses. The results show that between the ultrasound estimation method and birth weight, there is concordance with a value of P <0.001. There is a moderate agreement (Kappa = 0.56) with 88.23% agreement. The clinical evaluation of the weight estimate shows concordance with the birth weight with a *P* value of 0.0001. It also shows moderate concordance with Kappa = 0.60 and 87.25% agreement.

Table 4 shows the parameters of the diagnostic tests by the methods of estimating birth weight. It was observed that the low weight has greater reliability, which reaches 97.7%. The sensitivity for low weight was 66.67% for the clinical assessment compared to 100% for the ultrasound. The specificity was 98.84% for the clinical method versus 90% for ultrasound. The positive predictive value was 66.67% for the clinical method versus 25% for ultrasound. The negative predictive value was 98.83% for the clinical method versus 100% for ultrasound. There was 97.75% reliability for clinical evaluation versus 90.32% for ultrasound. For those with high weight, the sensitivity was 75% for both methods.

Table 5 shows the results where the altered weight by ultrasound and clinical assessment yielded *P* values <0.05. The predictors of altered weight are where the regression model reached 95.10% precision in the classification of neonates who presented altered birth weight. Observation of the multivariate relationship of the model shows that infants with ultrasound-modified weight are 13.44 times more likely to present altered weight at birth, while infants with weight modified by clinical evaluation are 11.95 times more likely to present altered weight at birth.

Table 1 Sociodemographic characteristics of the study mothers and characteristics of the newborns.

Characteristics of the mother	Frequency
Ethnicity	
Hispanic	85 (83.33%)
Afro-american	11 (10.78%)
Indo-american	6 (5.88%)
Nationality	
Ecuatorian	67 (65.69%)
Venezuelan	36 (35.29%)
Argentina	1 (0.98%)
Región de origen	
Mountain	60 (58.82%)
Coast	40 (39.22%)
East	2 (1.96%)
Newborn characteristic	Frequency
Sex	
Male	68 (67.33%)
Female	33 (32.67%)
Scale variables	Average, SD
Gestacional Age (weeks)	38.67 ±1.57
Weight at birth (grams)	3,023.75 ± 380
Estimated US weight (grams)	2,944.28 ± 412
Clinically estimated weight (grams)	3,151.91 ± 349

SD: Standard deviation. US: Ultrasound

Table 2 Estimation error in both methods studied

Estimation of the error	US	CM	*P*
Absolute error (mean, SD)	79.46 ± 263.48	-128.17 ± 197.98	<0.001*
% absolute error	2.43	-4.65	0.001**
% estimated within 10% of BW 1/	80.00	72.29	0.256

SD: Standard deviation. US: Ultrasound CM: clinical method *significant differences in the mean based on samples related to the t-test; ** significant difference in proportion based on rank test; 1 / estimated that it was in absolute value within 10% of the birth weight (BW) based on the range test.

Table 3 Estimate association

	LW	NW	HW	Kappa	*P*
Ultradound					
LW	3 (2.94)	9 (8.82)	0 (0.00)		
NW	0 (0.00)	81 (79.41)	2 (1.96)	0.56	0.001*
HW	0 (0.00)	1 (0.98)	6 (5.88)		
Clinical method					
LW	2 (1.96)	1 (0.98)	0 (0.00)		
NW	1 (0.98)	85 (83.33)	2 (1.96)	0.60	0.001*
HW	0 (0.00)	5 (4.90)	6 (5.88)		

NW: Normal weight; LW: low weight, HW: high weight

Figure 1 shows a scatter diagram, where in cases of r = 0.782 and P <0.001, there is a direct linear relationship between the estimation of fetal weight with the ultrasound method and the real weight at birth. The weight estimated by ultrasound explains 61-110% of the variations in the real weight. Figure 2 shows a scatter diagram where in cases of t = 01856 and *P* <0.001,

there is a direct linear relationship between the fetal weight estimated with the clinical method and the real weight at birth, where the weight estimated by clinical method explains 73.20% of the real weight variations.

Table 4 Diagnostic tests according to the weight estimation method

Parameters (%)	Low weight		Normal weight		High weight	
	CM	US	CM	US	CM	US
Sensitivity	66.67	100.00	75.00	75.00	72.73	81.8
Specificity	98.84	90.00	94.44	98.78	93.41	89.0
Predictive value +	66.67	25.00	54.55	85.71	57.14	47.4
Predictive value -	98.83	100.00	97.70	97.59	96.59	97.6
Accuracy	**97.75**	90.32	**92.86**	96.67	**91.18**	88.2

CM: clinical method. US: Ultrasound. Low weight <2500 gr, normal weight 2500-3500gr, high weight> 3500 gr.

Table 5. Logistic regression model for prediction of weight change in newborns

Variables	B	Wald	*P*	OR	OR 95%CI		Cc %
					LL	UL	
Altered weight (US)	2.60	7.4	0.006*	13.44	2.08	86.9	95.1
Altered weight (CM)	2.48	7.4	0.007*	11.95	1.99	71.7	
Constant	-4.07	27.1	0.001*	0.02			

Note: Based on Chi2 test; * significant value P <0.05, OR: odds ratio, LL: lower limit, UL: upper limit. US: ultrasound. CI: Clinical method. CC: Correct classification.

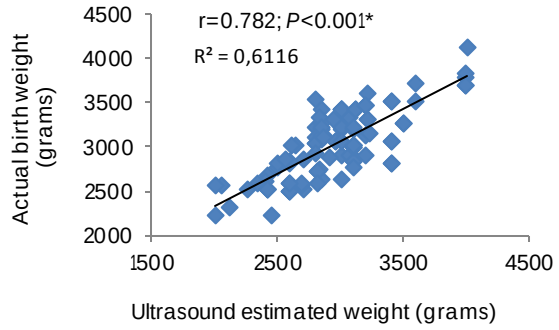

Fig. 1 Correlation between the estimation of birth weight measurement of the newborn at birth versus prenatal US.

Discussion

The estimation of fetal weight is very useful to prevent prematurity and choose a way to interrupt the pregnancy because it helps in the evaluation of cephalopelvic disproportion, detecting macrosomia-related products, and deciding the type of preterm delivery. Currently, the weight estimated by ultrasound is considered the best predictor of fetal growth since it allows a timely diagnosis of normal and abnormal fetal growth patterns. In the current research, the estimated clinical fetal weight was obtained with the DARE formula. With the use of ultrasound, when comparing both estimates, it was verified that the clinical method was as accurate as ultrasound for the estimation of fetal weight with a direct correlation that is proportional and significant between both estimates and birth weight ($P<0.001$). This significant correlation is similar to that reported in other studies [14-16] between the clinical method and ultrasound ($r = 0.729$; $P<0.001$). The number of estimates within 10% of the actual weight for the clinical method (72.2%) was less than for ultrasound (80%).

The difference between ultrasound and the clinical method was not statistically significant. In this study, the mean absolute error of each of the method used was around 79 g in favor of ultrasound and -128 g for the clinical assessment, which was not significant. Analysis of the diagnostic value or accuracy of both methods in cases with healthy fetal growth was found to be more sensitive with either of the two techniques. However, ultrasound ended up being more specific than the clinical method, although the total precision of each method did not show significant differences.

It was observed that the estimation of low weight has greater sensitivity that reaches 97.7%. Low weight had a sensitivity of 66.67% for the clinical method compared to 100% for ultrasound. We also observed 98.84% specificity for the clinical method versus 90% ultrasound. 66.67% positive predictive value for the clinical method versus 25% ultrasound, 98.83% negative predictive value for the clinical value versus 100% ultrasound, and 97.75% reliability for the clinical method compared to 90.32% for ultrasound. Regarding the identification of fetuses with macrosomia, both methods were found to be quite specific.

However, the clinical method showed greater sensitivity than ultrasound. Similar results were found in similar studies [17-19], in which the clinical method detected fetal macrosomia with a margin of error of ± 126 g.

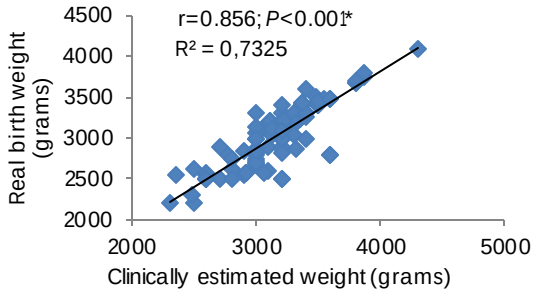

Fig. 2 Correlation between estimation of birth weight: newborn measurement at birth versus prenatal clinical estimation.

This was found within the limits of variation established for the technique (± 2240 g) considering the effective formula to detect fetuses of more than 4000 g. Likewise, it corresponds to 68.1% of precise estimates for weight greater than 4000 g found in another investigation [3]. However, other studies [4, 16, 20-22] have found that ultrasound is more specific, with a specificity rate between 54 and 77.2%.

This study verified the usefulness of both the clinical method and ultrasound. The results show the usefulness of the clinical method, which does not require many resources for its application. However, the sample analyzed in this research represents a local sample, and although the results seem consistent, other studies on more significant samples should be carried out before generalizing the results obtained. The methods studied have benefits for both the mother and child. They allow us to know the ideal moment for delivery with greater decision and the appropriate way to proceed in the event of low weight, healthy weight, high weight, or any other type of inconvenience.

A limitation of the study is the size of the sample. Although it was considered sufficient, it cannot be said that it does not represent either the total population of the province or the population of the country. In future research, the sample has to be more extensive, and a multicenter study is required. It would then be possible to generalize to other populations.

Conclusions

This study analyzed male, mestizo, Ecuadorian newborns born in the mountainous region with a mean gestational age of 38.67 weeks and a mean birth weight of 3.023 g, for whom the fetal weight was estimated by ultrasound and clinical assessment. The estimate of the absolute error in both methods analyzed was 2.43% for ultrasound and -4.65% for clinical evaluation, and both showed moderate agreement: 78.2% for ultrasound and 85.6% for clinical evaluation. The precision in the clinical assessment was always greater than in the ultrasound method, especially in low-birth-weight newborns. Multivariate analysis showed that newborns with ultrasound-modified weight were 13.44 times more likely to show altered weight at birth, while newborns with modified weight by clinical evaluation were 11.95 times more likely to show altered birth weight.

Abbreviations

CM: clinical method. US: Ultrasound. SD: Standard deviation

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Authors' contributions

All authors contributed equally to this scientific article.
All authors read and approved the final version of the manuscript.

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Availability of data and materials

The data sets generated and / or analyzed during the current study are not publicly available due to the confidentiality of the participants, but are available through the corresponding author upon reasonable academic request.

Ethical statements

Protection of people

The authors declare that the procedures followed were in accordance with the ethical standards of the responsible human experimentation committee and in accordance with the World Medical Association and the Singapore Declaration.

Data confidentiality

The authors declare that they have followed the protocols of their work center on the publication of patient data without identification.

Publication consent

Informed written consent was obtained from the legal guardian of the patients for the publication of this research. A copy of the written consent is available for review by the Editor-in-Chief of this journal.

Conflicts of interest

The authors declare not to have any interest conflicts.

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