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Research Article

The Accuracy of Prediction of Birth Weight by Automated Measurement of Fetal Long Bones Using 5D Long Bone versus VOCAL 3D and Conventional 2D Weight Formulae

Abstract

Objectives: To assess the accuracy of 5D automated measurement of long bones, three dimensional VOCAL measurement of fetal thigh volume in prediction of fetal weight in comparison to the conventional two dimensional Hadlock formulas.

Methods: This prospective study was conducted at Ain shams university maternity hospital. Forty four pregnant women with singleton pregnancy at 37 to 41 weeks of gestation admitted for planned delivery within 48 hours were enrolled. All patients were examined by 2D, 3D VOCAL and 5D long bones for the purpose of estimating the fetal weight. Each technique was performed by the same examiner for all the patients who were blinded to the results of the two other techniques. Results were compared to actual birth weights using a unified weight scale. The accuracy, precision and agreement between the three types of ultrasound were calculated as well the time needed to perform each technique.

Results: *The accuracy and precision of 3D measurements were statistically higher than those for 2D measurements (p<0.0001) with poor agreement between these techniques in favor of the 3DVOCAL.On the other hand The accuracy and precision of 5D system was higher than those of 3D with good agreement but the 5D examination is much faster than 3D examination (average 95 seconds versus230 seconds respectively).*

Conclusion: Three dimensional ultrasonographic measurement of fetal thigh volume is more accurate than two dimensional Hadlock formula in fetal weight estimation in our population. The new 5D automated long bone represent a faster, more convenient and accurate method for assessment of birth weight.

Introduction

The assessment of fetal weight is an important indicator for the fetal nutritional state and one of the factors affecting critical obstetrics decisions [1,2]. Over the last decades estimation of the fetal weight was based on 2D ultrasound formulae which had the disadvantage of being inaccurate as shown in pervious systematic reviews [3] and also failed to predict neonatal adipose tissue status which is more affected by nutritional status [4].

Significant improvement of the measurements was achieved after incorporating measurements of the thigh volume using 3D ultrasound [5]. Fractional limb volume is a fetal soft tissue parameter that is based on 50% of the long bone diaphysis length to avoid the falsies obtained from difficult volume acquisition near the end of long bones [6]. Further improvement in accuracy was recorded following the use of VOCAL technique which can be more precise in obtaining volume from regular shaped objects [7]. However, 3D-ultrasound still requires time and effort in reconstructing the image and is affected by the angle used and the experience of the sonographer which affects its reproducibility.

To overcome these defects, long bone automated detection system, five-dimensional 5D Long Bone (5D LB) was introduced with an automated system that allow the volume measurement to be completed in just a few seconds and eliminate operators variability which makes it more useful in clinical practice [8]. Also the fact that ethnic and racial variation exists in fetal biometry [2], mandate testing the hypothesis that 5D or 3D ultrasonography measurement of fetal thigh volume may be more accurate in prediction of fetal weight in comparison to the conventional two dimensional Hadlock formula in this study population

Patients and Methods

This study is a prospective study conducted at Ain Shams University Maternity Hospital, a tertiary care center in Cairo which receives around a hundred and fifty pregnant patients daily in the outpatient and the emergency departments and has a specialized fetal medicine unit. The study protocol was in agreement to the Helsinki Declaration of Ethical Medical Research [updated in South Korea, 2008]. Acceptance of local institutional committee and the ethical committee of the faculty of medicine was obtained before commencing the trial and all participating women signed a written informed consent after proper explanation.

The required sample size has been calculated using G*Power software version 1.1.7 (Germany). The primary outcome measure is the accuracy of 2D, 3D or 5D ultrasonography for estimating the actual weight of the newborn obtained immediately after delivery. So, it was estimated that a total sample size of 44 patients on whom estimation of the birth weight was undertaken would achieve a power of 90% (type II error, 0.1) to detect a statistically significant difference between the overall accuracy of any two techniques for a median effect size (Cohen's dz) of 0.5 using a two- sided paired t test with a confidence level of 95% (type I error, 0.05). This effect size has been chosen as it could be regarded as a clinically relevant difference to seek in this study.

Accordingly throughout the period between June and December 2015, 44 pregnant women with singleton pregnancy at 37 to 41 weeks of gestation, who were admitted for planned delivery within 48 hours either by induction of labor or elective caesarean section, were enrolled. Gestation age was calculated from the first day of the last normal menstrual period (LMP) provided it is sure and reliable (regular cycles for the preceding three months with no history of hormonal contraception or recent termination of pregnancy). Otherwise gestation age was calculated from early first -trimester ultrasound with crown rump measurement. Patients with fetal anomalies, abnormal amount of liquor and factors influencing proper measurements as pelvic lesions were excluded from the study.

Demographic data were recorded and all patients underwent a formal 2D ultrasound scan by the same examiner to calculate the expected fetal weight by using the Hadlock IV model, which incorporates biparietal diameter (BPD), head circumference, abdominal circumference (AC) and femoral diaphysis length (FL) [9]. 3D ultrasonography were used by another examiner blinded to the previous measurements for thigh volume measurement according to the principle described by Benini et al. (7). "The conventional plane for measurement of femur length was first identified for orientation of the thigh then the plane was rotated to put the femur accurately in a horizontal position. A stepwise measurement using the Virtual Organ Computer-aided Analysis (VOCAL) technique were performed as follows: The data set containing the fetal thigh was initially displayed on the screen in three orthogonal planes, the sagittal view of the femur were displayed in Plane A and this image were rotated so that the orientation of the thigh and whole diaphysis coincides with the y-axis. Two demarcating arrows were positioned at each end of the diaphysis to define the limits of the thigh to be included in the volume calculation. Volume estimates were computed utilizing the VOCAL program with a manual trace at 30 of rotation. At the end of the 180 rotation, the built in software was used to calculate the volume automatically" Birth weight (BW) were calculated through the following formula BW = 1025.383 + 12.775 × Thigh volume. Biometric measurements were taken as the average of 2 readings. The machine used for examination was Voluson E6 BT12 with a volumetric abdominal probe RAB 6D-4D curved Array (General Electric Medical Systems, AUSTRIA).

Subsequently, the long bone length was measured by another analyzer using the 5D LB with the following procedures described by Hurr et al. [8]. "The volume data used in the manual 3D-ultrasound measurement were displayed in an offline multiplanar mode, and the 5D LB set key was pressed on the system, wherein the system automatically analyzed the 3D volume data, reconstructed the 3D image of the long bones, and displayed the measured lengths of the long bones on the screen". All the deliveries were conducted in Ain shams maternity hospital attended by one of the study team and all neonates' weights were obtained using the same digital weight scale immediately after birth and recorded in the hospital files.

Data were analyzed using MedCalc© Statistical Software version 15.8 (MedCalc© Software bvba, Ostend, Belgium, 2015). Continuous numerical variables were presented as mean ± SD and categorical variables as number (%) or ratio. Accuracy of 2D, 3D or 5D US for estimation of birth weight was assessed by calculation of the standard error of the estimate. The accuracy and precision of different techniques were alternatively assessed by calculation of the *systematic error* and *random error* respectively for the signed and absolute error as well as for the signed and absolute percentage error. The accuracy of the different techniques was compared by running the *paired Student t test* on the estimated mean error (systematic error) for each assessment tool. The precision was compared by running the *Pitman t test* [10], on the variance of the error of each technique. The Bland-

Table 1: Characteristics of the study population.

Variable	**Value**
Age (years)	28.3 ± 5.7
BMI (kg/m^2)	33.5 ± 2.4
Parity	
P0	14 (31.8%)
P1	6 (13.6%)
P2	12 (27.3%)
P3	6 (13.6%)
P4	6 (13.6%)
Number of previous abortions	
Nil	38 (86.4%)
One	2 (4.5%)
Two	3 (6.8%)
Three	1 (2.3%)
Gestational age (weeks)	38.6 ± 0.9

Data are mean ± SD or number (%).

Table 2: Standard error of the estimate, *SE(est)*, for 2D, 3D, or 5D US in prediction of birth weight.

	Mean ± SD	SE(est)
EFW by 2D US (kg)	3.09 ± 0.38	±0.258
EFW by 3D US (kg)	3.16 ± 0.38	±0.072
EFW by 5D US (kg)	3.18 ± 0.38	±0.034
Actual birth weight (kg)	3.18 ± 0.38	-

SE(est): $SE(est)=\sqrt{\frac{Ó(Y-Y')^2}{N}}$, where SE(est) is the standard error of the estimate, Y is the actual birth weight, Y' is the estimated birth weight, Σ (Y-Y') is the sum of squared differences, and N is the total sample size.

Table 3: Comparison of the accuracy of 5D US versus 3D US and 2D US versus 3D US for estimation of birth weight.

Measure of accuracy	5D US	3D US	*T*	*df*	*p-value*¶
Signed birth weight estimation error (kg)	-0.005 ± 0.044	-0.027 ± 0.075	-2.016	43	0.050
Signed percentage birth weight estimation error (%)	-0.143 ± 1.374	-0.850 ± 2.249	-2.046	43	**0.047**
Unsigned (absolute) birth weight estimation error (kg)	0.030 ± 0.033	0.058 ± 0.054	4.718	43	**<0.0001**
Unsigned (absolute) percentage birth weight estimation error (%)	0.953 ± 0.993	1.823 ± 1.549	4.683	43	**<0.0001**
Measure of accuracy	**2D US**	**3D US**	**T**	**df**	**p-value¶**
Signed birth weight estimation error (kg)	-0.089 ± 0.245	-0.027 ± 0.075	1.596	43	0.118
Signed percentage birth weight estimation error (%)	-2.589 ± 7.950	-0.850 ± 2.249	1.366	43	0.179
Unsigned (absolute) birth weight estimation error (kg)	0.226 ± 0.127	0.058 ± 0.054	-8.803	43	**<0.0001**
Unsigned (absolute) percentage birth weight estimation error (%)	7.172 ± 4.174	1.823 ± 1.549	-8.524	43	**<0.0001**

Data are mean ± SD.
Signed error is the estimated weight by US minus the actual birth weight.
Signed percentage error is the estimated weight by US minus the actual birth weight/actual birth weight * 100.
Absolute error is the unsigned difference between the estimated weight by US and the actual birth weight.
Absolute percentage error is the unsigned difference between the estimated weight by US and the actual birth weight/actual birth weight * 100.
t, t statistic; *df*, degree of freedom.
¶Paired Student *t* test.

Table 4: Comparison of the precision of 5D US versus 3D US and 2D US versus 3D US for estimation of birth weight.

	SD		Variance					
Measure	**5D US**	**3D US**	**5D US**	**3D US**	***F***	***r***	***r²***	***p-value*¶**
Signed birth weight estimation error (kg²)	0.044	0.075	0.002	0.006	2.825	0.392	0.153	**0.001**
Signed percentage birth weight estimation error (%)	1.374	2.249	1.887	5.060	2.681	0.273	0.074	**0.002**
Unsigned (absolute) birth weight estimation error (kg²)	0.033	0.054	0.001	0.003	2.649	0.676	0.456	**0.002**
Unsigned (absolute) percentage birth weight estimation error (%)	0.993	1.549	0.986	2.400	2.681	0.607	0.369	**0.004**
Measure	**2D US**	**3D US**	**2D US**	**3D US**	***F***	***r***	***r²***	***p-value*¶**
Signed birth weight estimation error (kg²)	0.245	0.075	0.060	0.006	10.734	-0.045	0.002	**<0.001**
Signed percentage birth weight estimation error (%)	7.950	2.249	63.209	5.060	12.492	-0.083	0.007	**<0.001**
Unsigned (absolute) birth weight estimation error (kg²)	0.127	0.054	0.016	0.003	5.554	0.225	0.050	**<0.001**
Unsigned (absolute) percentage birth weight estimation error (%)	4.174	1.549	17.422	2.400	7.259	0.193	0.037	**<0.001**

SD, standard deviation; *F*, variance ratio; *r*, correlation coefficient; r^2, coefficient of determination.
¶Pitman *t* test for comparison of paired variances.

Altman [11], method was used to examine inter-method agreement. A two-sided p-value <0.05 was considered statistically significant.

Results

The study was conducted over a period of six months. All 44 patients finished the three modalities of ultrasound within 48 hours of delivery. The characteristics' of the included patients are summarized in Table 1.

The mean birth weight for all included patients were 3.18 ± 0.38 Kg. The standard error of the estimate for 2D ultrasound assessment of the birth weight was higher than that for the 3D and 5D assessment as evident in Table 2.

Comparing the accuracy of 2D ultrasound to 3D ultrasound in the assessment of birth weight (Table 3), showed that 2D estimated fetal weight was significantly less accurate than 3D estimated fetal weight as measured by absolute birth weight estimation error and percent birth estimation error. On the other hand comparing the accuracy of 5D to 3D ultrasound showed a statistical significance in favor of the 5D but the difference was so small (absolute error in Kg 0.030 ± 0.033 VS 0.058 ± 0.054) to impose a clinical significance in obstetric practice.

Also, 3D ultrasound estimation fetal weight was significantly more precise than 2D ultrasound estimation fetal weight as determined by absolute birth weight estimation error and absolute percent birth weight estimation error (Table 4), on the other hand 5D ultrasound estimation was more precise than 3D ultrasound estimation with a minor difference in the absolute error (0.033 VS 0.054 Kg).

Figures 1 and 2 show the results of Bland-Altman analysis for agreement between5D and 3D and between 2D and 3D US as regards the estimation of birth weight respectively. The narrow limit of agreement between estimates of the 5D and 3D ultrasounds (-0.12 and 0.16 Kg) imply that the two methods may be used interchangeably. On the other hand, the rather wide limits of agreement between estimates of the 2D and 3D ultrasounds (-0.571 kg and 0.446 kg) imply that the

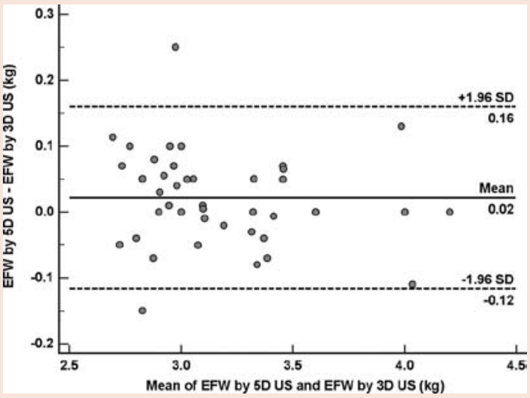

Figure 1: Bland-Altman plot for agreement between 2D and 3D US as regards the estimation of birth weight.

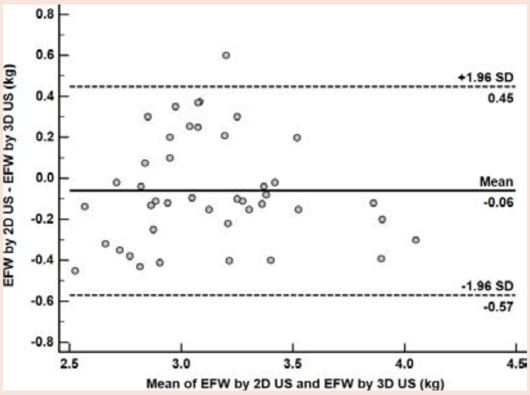

Figure 2: Bland-Altman analysis for agreement between 2D and 3D US as regards the estimation of birth weight.

two methods may not be used interchangeably.

The average time for obtaining the volume measurements and assessment of fetal weight by 3D VOCAL system was 230 seconds while the average time for analysis of the data using the 5D automated long bone system was 92 seconds which is an additional advantage for the 5D measurements.

Discussion

The accurate prediction of birth weight is essential not only in macrosomic fetus to avoid unplanned birth injuries or operative deliveries but also in low birth weight growth restricted fetus to avoid perinatal asphyxia [12-14]**.** Previous studies demonstrated up to 10%standard error for most of the commonly used 2D formulae for estimation of fetal weight specially at the birth weight extremities [5]. It is debaTable if this observation is attributed to inter-observer variability or to the lack of incorporation of soft tissue measurements in most of these formulae [5]. Subsequently improvements in the accuracy of BW estimation were achieved after incorporating measurement of fetal ThV using 3D with earlier study showing absolute percentage errors of less than 6% [7].

In the current study 2D EFW was significantly less accurate that 3D EFW as measured by absolute BW estimation error &absolute percentage BW estimation error. Also in this study, 3D U/S EFW was significantly more precise than 2DU/S EFW as determined by absolute BW estimation error &absolute percentage BW estimation error. These results agreed with the previous work of Schild et al. 2000, Isobe 2004 and Sriantiroj et al. [15-17], who agreed that fractional ThV was the best predictor for actual birth weight and is superior to 2D U/S formulae which need head measurement which is usually inaccurate at term pregnancy especially if the fetal head is deeply impacted in the pelvis and also lacks the ability to assess the effect of fat distribution in the limbs, facts which further compromised fetal-weight estimation by 2D formulae .

On the other hand, Lindell et al. [18], reported no difference between 2D and 3D ultrasound in the estimation of fetal weight in a group of women with post term pregnancy, a different cohort from our study population. Also Bellini et al. 2011, postulated that the previous superiority of 3D formulae over 2D might be attributed to phenotypic differences between different patients used to create each of these formulae [7]. Yang et al. 2011, emphasized on the fact that ethnic and racial variations can significantly affects fetal biometry [2], which prompt careful interpretation of data obtained from different studies.

Despite the obvious superiority of 3D ultrasound in estimation of fetal birth weight, the technique is still operator dependent and requires a learning curve for proper acquisition and manipulation of volume data [8]. In an effort to overcome this drawback, long bone automated detection system by 5D was introduced to create an operator independent, quick and efficient method for accurate estimation of fetal birth weight. In the current trial, this fully automated system revealed absolute birth weight estimation error of 0.95% which is comparable to the previous work of Hurr et al., who reported an overall error rate of 5.4% in a larger sample [8].

In the current trial, 3D assessment of fetal volume was done using the VOCAL technique with a 30 rotation angle which was previously shown by Benini et al. 2011 [7], to be significantly faster than multiplanner method ($P < 0.001$).A former trial reported that 3D volume data was acquired within 2 minutes and interpreted in 6 to 7 minutes [19]. In The current trial the average time to complete the entire 3D session was around 4 minutes possibly due to improved efficacy of updated equipment's. On the other hand the 5D automated long bone systems took only few seconds (average 95 seconds) and had the additional advantage that it can be performed in an offline manner after the patient has left the room which makes it more convenient to both patients and operators. The low inter and intra observer variability for the 5D long bone automated measurements previously proven by Hurr et al. [18], with the current data showing significant agreements with data obtained from 3D VOCAL technique may allow this technique to be used for a faster and accurate prediction of birth weight in future practice.

The points of strength in this study lies in its ability to complete the three modalities in all patients who were examined with the same examiner for each technique, all patients were delivered within 48 hours from the ultrasound scan detected to avoid falsies from longer intervals and birth weights were recorded by the same digital weight scale attended by an examiner to ensure accuracy.

On other hand the authors recognize the fact that fetuses with abnormal growth were not assessed as the random selection resulted in a study population which was within normal range of birth weight. The implication of these findings on babies in the extremes of body weight might be a point of interest for future research

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