Original Article

Comparisons of the Accuracy of Fetal Weight Estimation between Various Ultrasound Models and Clinical Assessments in Term Pregnancies Complicated by Diabetes Mellitus

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Objective: To compare the accuracy of fetal weight estimation on admission before delivery between subjective assessment, objective clinical assessment, and 2D-ultrasonography (2D-US) assessment in pregnancy with diabetes mellitus (DM).

Materials and Methods: Pregnancy with DM admitted for delivery at Maharaj Nakorn Chiang Mai Hospital between March 24, 2017 and August 7, 2018, were prospectively recruited. Inclusion criteria were a term, singleton pregnancy with overt or gestational DM without other underlying diseases, no smoking, and no emergency condition for immediate delivery. Fetal weight estimation by subjective assessment (physical examination), objective assessment (a formula using multiple parameters including BMI, fundal height, maternal abdominal circumference, and parity), and 2D-US were performed on admission for delivery. Actual birth weight (BW) was measured within 30 minutes after birth. Accuracy in predicting actual BW by various methods was calculated and expressed as intra-class correlation coefficient (ICC), mean error, mean percentage error, and percentage of estimate within 10% of the actual BW.

Results: Ninety-six women (gestational DM 92 and overt DM 4) were recruited. The 2D-US (Hadlock 4) was most accurate for estimation (ICC 0.896) and conversely objective assessment was least accurate (ICC 0.610). In predicting actual BW (±10%), 2D-US and subjective assessment were significantly superior to objective assessment (p=0.001 and p=0.017; respectively), whereas the accuracy of 2D-US and subjective assessment was comparable (76.4% versus 66.7%; p=0.151).

Conclusion: In singleton pregnancy with DM, the fetal weight estimation with 2D-US (Hadlock 4) had more accuracy than subjective assessment (in terms of ICC), but no significant difference of accuracy between the two methods. The authors suggest using 2D-US as an adjunct in estimation of fetal weight among pregnancies with DM.

Keywords: Pregnancy, Diabetes mellitus, Estimate fetal weight, Ultrasound, Physical examination

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Overt diabetes mellitus (DM) or gestational diabetes mellitus (GDM) is one of the most common medical complications in pregnancies and is classified as high-risk pregnancy due to several adverse maternal and neonatal morbidities and mortalities[1,2]. Concerning neonatal morbidities and mortalities, diabetes in pregnancy causes fetal hyperglycemia and fetal hyperinsulinemia. Consequently, lipid deposit is increased especially at fetal shoulder and trunk[3,4]. Disproportionate size of fetal head and trunk increases risk of shoulder dystocia that can cause birth asphyxia or other adverse neonatal outcomes[5].

Nowadays, fetal weight estimation is usually performed by a physical examination, mainly based on symphysis-fundal height (SFH) and others Leopold maneuver. If SFH (cm) is different from the number of gestational weeks (GA) 3 cm or more, the fetal weight is usually evaluated by ultrasonography.

In pregnancies with overt DM or GDM, evaluation of fetal weight by both physical examination and ultrasonography are more difficult[5-7]. Measurement

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of the abdominal circumference (AC) is less accurate due to increased lipid deposition at the trunk[4,5,7]. However, estimated fetal weight in pregnancies with DM is necessary for planning the route of delivery, which is important to prevent adverse intrapartum events[8]. The present study aimed to determine the accuracy in estimation of fetal weight by various methods including physical examination, subjective assessment, or ultrasonography on admission for delivery. The estimation was performed at the time shortly before delivery so that the estimate fetal weight (EFW) was most likely to represent the actual birth weight (BW). However, in the literature review, the authors found only few previous studies that estimated fetal weight during intrapartum period. Moreover, the study on EFW in pregnancy with DM during intrapartum period is very rare. Most studies on EFW were conducted in low-risk pregnancies or pregnancies with unspecified medical conditions.

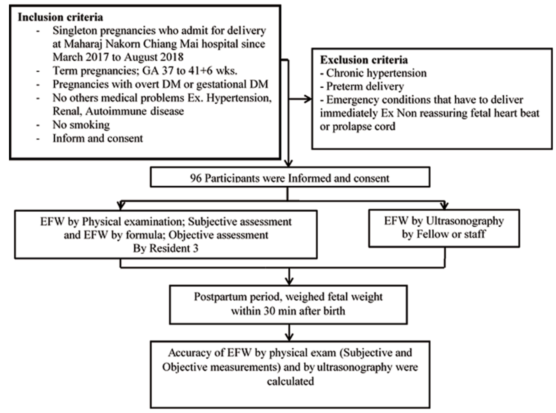

Figure 1. Flow chart shows method of this study.

Materials and Methods

A cross-sectional study was conducted at Maharaj Nakorn Chiang Mai Hospital between March 2017 and July 2018 with ethical approval by the Institute Review Board (OBG-2560-04513). All participants were enrolled to the study with written informed consent. The study population was pregnancies complicated with overt DM or GDM. Most cases were detected by screening pregnancies at average or high risk for DM by glucose challenge test (GCT)[1], and then, in cases of positive GCT, the diagnosis was confirmed by a 100-gm oral glucose tolerance test (100 gm OGTT). Criteria for diagnosis pregnancies with overt DM or GDM followed the recommendation by the National Diabetes Data Group[1].

Inclusion criteria were 1) singleton term pregnancies (gestational age between 37 complete weeks and 41^{+6} weeks), admitted for delivery, 2) being complicated with overt DM or GDM as mentioned above, without other medical problems such as renal disease hypertension, autoimmune disease etc., and not smoking. Pregnancies with chronic or gestational hypertension or pre-eclampsia, preterm labor, or had emergency conditions needed termination of pregnancy immediately such as non-reassuring fetal heart rate (FHR) pattern or prolapse cord were excluded from the study. At the admission room, all participants were assessed and collected the baseline data and then were estimated for fetal weight.

For the first method, the fetal weight was subjectively estimated by the attending obstetrician (subjective assessment). The obstetricians were the third-year residents who had been standardized for estimation of fetal weight before the study.

For the second method, the fetal weight estimation (objective assessment) was performed by measuring, SFH, maternal AC (mAC) and pre-gestational body mass index (BMI), and then calculating the fetal weight using a formula proposed by Curti et al[9] as follows: EFW (g) = 1,485.61 + [SFH (cm)×23.37] + [11.62 (cm)×mAC] + [BMI×(–6.81)] + [parity (0=nulliparous, 1=multiparous)×72.25]

For the third method, the fetal weight was estimated using 2D trans-abdominal ultrasonography (2D-US). On ultrasound examination, biparietal diameter (BPD), head circumference (HC), AC, and femur length (FL) were measured as standard technique. Estimation of fetal weight by the measured parameters was performed using various sonographic models as presented in Table 1. The BPD and HC were measured at the transthalamic view on which both thalami and cavum septum pellucidum were visualized. The BPD was measured from the outer edge of the skull table close to the transducer to the inner edge of the skull table far from the transducer. The HC was measured along perimeter of the outer edge of the skull[10]. The AC was measured on the cross-section plane of the upper abdomen in which the stomach, portal sinus, and spine were visualized. The AC was measured along the outer border of the skin[10]. Finally, FL was measured in the long axis of the shaft of the femur, not including epiphysis[10]. In each participant, 2D-US was performed by the single operator to avoid inter-observer variability which was statistically different as reported in a previous study[11]. All ultrasound examinations were performed by maternal-fetal-medicine doctors, using ultrasound machines ‘Voluson E8’ or ‘Voluson E10’ (GE Medical

Table 1. Models for estimated fetal weight by 2D ultrasonography, publication years and regression formulas

Formula	Author	Year	Regression equation
F1	Hadlock1	1985	Log10 (EFW) = 1.304 + (0.05281×AC) + (0.1938×FL) – (0.004×AC×FL)
F2	Hadlock2	1985	Log10 (EFW) = 1.335 – (0.0034 × AC × FL) + (0.0316×BPD) + (0.0457×AC) + (0.1623×FL)
F3	Hadlock3	1985	Log10 (EFW) = 1.326 – (0.00326×AC×FL) + (0.0107×HC) + (0.0438×AC) + (0.158×FL)
F4	Hadlock4	1985	Log10 (EFW) = 1.3596 – (0.00386×AC×FL) + (0.0064×HC) + (0.00061×BPD×AC) + (0.0424×AC) + (0.174×FL)
F5	Campbell	1974	Log10 (EFW) = [–4.564 + (0.282×AC) – (0.00331×AC^2)] × 1,000.0
F6	Shepard	1982	Log10 (EFW) = [–1.7492 + (0.166×BPD) + (0.046×AC) – (0.002646×AC×BPD)] × 1,000.0
F7	Merz1	1991	EFW = –3,200.40479 + 157.07186 × AC + 15.90391 × BPD^2
F8	Merz2	1991	EFW = 0.1 × AC^3
F9	JSUM (Shinozuka)	2003	EFW = 1.07 × BPD^3 + 3.00 × 10^{-1} × AC^2 × FL

EFW=estimate fetal weight; AC=abdominal circumference; FL=femur length; BPD=biparietal diameter; HC=head circumference

Systems, Zipf, Austria). After delivery, the babies were weighed as true objective measurements of fetal weight within 30 minutes. Additionally, the infant's sex, mode of delivery and postpartum complications were also recorded.

All sonographic measurements were digitally stored and later used to calculate the EFW by nine estimation models described by Ozdamer et al[8], as presented in Table 1. The accuracies of subjective, clinical objective and 2D-US (including nine models) assessment were calculated to compare the levels of agreement with the actual BW, using intra-class correlation coefficients (ICC). Additionally, the accuracy of all estimations was also evaluated by mean error (ME), mean percentage error (MPE), a percentage of estimate within 10% of the actual BW (±10%). Baseline characteristics of the participants were described by mean ± standard deviation (SD). McNemar test was used to compare the number of correct predictions (categorical data) among the various methods. The definition of statistical significance was p-value of less than 0.05. To gain the power of test of 80% at 95% confidence interval (CI), the present study needed a sample size of at least 96 participants. The statistical analysis was performed using SPSS version 21.0 (IBM Corp., Released 2012; IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY).

Results

Ninety-six term singleton pregnancies with overt DM (four cases; 3.2%) and GDM (92 cases; 95.8%) met the inclusion criteria and were available for analyses. The baseline characteristics are presented in Table 2. Mean of pre-pregnancy BMI was 24.66 kg/m². Mean gestational age was 39 weeks. Actual BW ranged from 2,240 to 4,540 gm.

Table 2. Baseline characteristic of pregnancy with diabetic patients

Characteristic	Total n=96 Mean±SD
Maternal age (year)	31±4.89
Parity, n (%)	
Nulliparity	49 (51.0)
Multiparity	47 (49.0)
Gestational age at the time of EFW (week)	39±0.93
Diabetes mellitus, n (%)	
Overt DM	4 (4.2)
Gestational DM	92 (95.8)
BMI before pregnancy (kg/m²)	24.66±4.73
Height of fundus (cm)	36.29±2.76
Abdominal circumference (cm)	102.65±10.48
Birth weight (g)	3,269±439
True birth weight showed LGA, n (%)	26 (27.1)

EFW=estimate fetal weight; DM=diabetes mellitus; BMI=body mass index; LGA=large for gestational age; SD=standard deviation

To compare the levels of agreement with the actual BW, ICC of all methods were calculated and are shown in Table 3. The highest ICC, representing the most accurate method of fetal weight estimation was 2D-US: Formula 4 (F4; Hadlock 4) and Formula 9 (F4; JSUM) (ICC 0.896). The clinical objective assessment

Table 3. Intra-class coefficient to assess validity between estimated and actual birth weight

Formula/method	Intra-class correlation coefficient	95% CI lower	95% CI upper
Subjective assessment	0.809	0.714	0.873
Objective assessment	0.610	0.416	0.740
2D ultrasonography assessment			
F1	0.885	0.826	0.924
F2	0.895	0.840	0.932
F3	0.895	0.839	0.931
F4	0.896	0.841	0.932
F5	0.861	0.787	0.909
F6	0.857	0.781	0.906
F7	0.885	0.825	0.925
F8	0.804	0.703	0.871
F9	0.896	0.840	0.932

CI=confidence interval

Subjective assessment: estimated birth weight by physical exam by physician

Objective assessment: calculated estimated birth weight by formula; EFW (g) = 1,485.61 + [SFH (cm)×23.37] + [11.62 (cm)×mAC] + [BMI×(–6.81)] + [parity (0=nulliparous, 1=multiparous)×72.25]

was the least accurate with the lowest ICC of 0.610. Based on the ICCs, 2D-US was more accurate than the subjective assessment. In comparisons of ME technique, the accuracy of 2D-US tended to be better than subjective assessment, but not to a statistical significance (p=0.151, 95% CI –2.87 to 0.69). In contrast, objective assessment method had the lowest ICC (ICC 0.610) and had a significantly higher ME than the subjective assessment and the 2D-US methods (p=0.017 and 0.001, 95% CI –7.00 to –2.84 and –8.35 to –3.20, respectively).

The accuracy of all methods for EFW were compared with gold standard, which was the actual BW. The ME, MPE, and percentage of estimate within 10% of the actual BW were calculated. Note that the 2D-US assessment tended to be superior to subjective assessment (76.4% versus 66.7%) but was not statistically significant. Accuracy of each method was compared (p-value and 95% CI) and are presented in Table 4.

Large for gestational age (LGA) fetuses, which is of most concern for major fetal morbidities among pregnancies with DM[2,3], accounted for 27.1% of the infants in the present study. Routes of delivery among LGA infant group were normal delivery in 30.76%, cesarean delivery due to cephalopelvic disproportion (CPD) in 26.9%, and cesarean delivery due to fetal weight estimation of LGA in 23.07%. When comparing the accuracy of the three methods to detect LGA fetuses, estimation by the subjective assessment had the least sensitivity (40%) but most specificity (94%), whereas, the objective assessment had the most sensitivity (92%) but the least specificity (37%). Positive predictive value (PPV) of subjective assessment and 2D-US were similar (71% and 70%, respectively) and higher than objective assessment. Negative predictive value of objective assessment was highest in objective assessment and lowest in subjective assessment (92% and 81%, respectively). All of the results of detection of LGA are shown in Table 5.

Discussion

One of the most common problems associated with diabetic mothers is large-for-date fetuses or macrosomia. This is because DM in pregnancy causes hyperglycemia in mother and fetus and fetal macrosomia. Truncal obesity may be found in some cases, especially in poor glycemic control pregnant[1]. Consequently, macrosomia significantly increases risk of perinatal morbidity and mortality. Accordingly, correct estimated fetal weight is important for large fetuses in diabetic mother and critical for selecting route of delivery to prevent adverse outcomes in intrapartum and postpartum period such as shoulder dystocia or postpartum hemorrhage due to uterine atony[12]. However, estimation of fetal weight, either by ultrasound or clinical assessment, tends to be less

Table 4. Accuracy of estimating birth weight

	ME±SD (g)	MPE±SD (%)	±10% (%)	p-value (95% CI)
Subjective assessment vs. 2D-US assessment				0.151 (–2.87 to 0.69)
Subjective assessment	253.85±86.10	7.98±6.33	66.7	
2D-US assessment	223.26±87.94	6.92±6.07	76.4	
Objective assessment vs. 2D-US assessment				0.001 (–8.35 to –0.20)
Objective assessment	383.53±86.27	12.91±11.35	49.0	
2D-US assessment	223.26±87.94	6.92±6.07	76.4	
Subjective assessment vs. objective assessment				0.017 (–7.00 to –0.84)
Subjective assessment	253.85±186.10	7.98±6.33	66.7	
Objective assessment	383.53±86.27	12.91±11.35	49.0	

ME=mean error; MPE=mean percentage error; SD=standard deviation; ±10%=percentage of estimate within 10% of the actual birth weight

Subjective assessment: estimated birth weight by physical exam by physician

Objective assessment: calculated estimated birth weight by formula; EFW (g) = 1,485.61 + [SFH (cm)×23.37] + [11.62 (cm)×mAC] + [BMI×(–6.81)] + [parity (0=nulliparous, 1=multiparous)×72.25]

2D-US: estimated birth weight by 2D-ultrasonography

Table 5. Detection of large for gestational age

Methods		LGA	Non-LGA	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Subjective assessment	+ve	10	4	38.5% (18.8 to 57.2)	94.3% (88.8 to 99.7)	71.4% (47.8 to 95.1)	80.5% (59.7 to 100.0)
	–ve	16	66				
Objective assessment	+ve	24	44	92.3% (82.1 to 100.0)	37.1% (25.8 to 48.5)	35.3% (23.9 to 46.7)	92.3% (86.7 to 99.0)
	–ve	2	26				
Ultrasound assessment	+ve	17	8	65.4% (47.1 to 83.7)	88.5% (81.1 to 96.0)	68.0% (49.7 to 86.3)	86.3% (74.3 to 100.0)
	–ve	9	62				

LGA=large for gestational age; CI=confidence interval; PPV=positive predictive value; NPV=negative predictive value

Subjective assessment: estimated birth weight by physical exam by physician

Objective assessment: calculated estimated birth weight by formula: EFW (g) = 1,485.61 + [SFH (cm)×23.37] + [11.62 (cm)×mAC] + [BMI×(–6.81)] + [parity (0=nulliparous, 1=multiparous)×72.25]

accurate when applied to the large fetuses. Moreover, diabetic mothers also tend to be overweight or obese, leading to difficulty in lineate fetal body outline by clinical assessment and poor quality of ultrasound images. In the present study, the average BMI was 24.66 kg/m², which is higher than the normal population and classified as overweight for Thai women. As shown in previous studies, high maternal BMI could affect the accuracy of fetal weight estimation[12-14]. Accordingly, pregnancies with higher BMI in the present study should be considered as a special group, which was more difficult for estimation of the fetal weight either by the clinical assessment or 2D-US, and the most accurate methods for estimation still needed to be sought for. Therefore, the authors conducted the present study to determine the most accurate method to EFW in term, singleton pregnancy with DM.

The role of ultrasound in predicting fetal weight has long been accepted and many ultrasound models have been proven to be accurate. Nevertheless, good ultrasound training is essential, and most recent proposed formulas have their own limitation of accuracy[15]. Moreover, most previous studies did not focus on special group with difficulty like diabetic mothers. Of all most commonly used models, the authors have found the formula 4 proposed by Hadlock and formula 9 proposed by JSUM (Shinozuka) gave the best prediction. Thus, the authors used the formula 4, representing models of 2D-US in the present study to compare the effectiveness with the other methods.

Of the three methods, the authors found the 2D-US was the most accurate method for fetal weight estimation in term, singleton pregnancies with DM, in terms of ICC. Additionally, 2D-US yielded the better or lower ME than the others, though not statistically significant from subjective assessment. It is possible that the sample size was not large enough to express the significance, if it existed. Nevertheless, the accuracy of 2D-US based on ICCs and ME were concordant. Since subjective assessment by experienced obstetricians had nearly the same accuracy as 2D-US, the technique might be acceptable for fetal weight estimation in pregnancy with DM, in cases that 2D-US is unavailable. Similar to the present finding, some previous studies demonstrate that in term normal pregnancy, clinical fetal weight estimation is as accurate as ultrasonography(16-18), but those studies did not focus on diabetic mothers. The authors' finding may encourage general obstetricians to gain higher skill on subjective careful assessment in daily practice. In contrast, objective assessment based on the formula of clinical parameters was much less accurate and should not be used. The authors found that objective assessment tended to overestimate the fetal weight. Though, it had a rather high sensitivity, specificity and PPV in detection of LGA fetuses were very low.

In cases of predicting LGA fetuses, intrapartum or postpartum adverse outcomes might be monitored more intensively and the plan of intrapartum management especially route of delivery must be more carefully considered. Thus, an accurate method in prediction of LGA is important. In comparison of accuracy among the three methods, the authors found that subjective assessment had the lowest sensitivity because it had a trend to under EFW, but its specificity and PPV were similar to the 2D-US assessment. The 2D-US also had a relatively low sensitivity or was likely to underestimate the fetal weight as well. Accordingly, the present study findings supported that prediction of LGA, either by subjective assessment or 2D-US, is more difficult, similar to the findings reported in previous studies(19,20). The difficulty might partly be explained by the fact that the fetal head might be completely or partially engaged, leading to smaller fundal height or inappropriate plane BPD and HC measurement.

The strengths of this study included 1) high reliability and homogeneity of assessment: clinical assessment performed by the clinicians with the same levels of experience (the third-year residents) and ultrasound examination performed by maternal-fetal medicine (MFM) doctors, 2) actual BW could represent the fetal weight at the time of estimation, since the time of fetal weight estimation, in early labor in most cases, was in the same day of delivery, and 3) the model of estimating fetal weight by ultrasound, used to compare with clinical assessment, was the best model selected from the nine models tested for accuracy in the same study population. The weaknesses of the present study were 1) the sample size was relatively small for subgroup analysis, probably not enough power to show significance, if it existed, such as accuracy in a group of large-for-date fetuses, and 2) a very small number of the women with overt DM, not permitting the researcher to evaluate the impact of DM subtype on accuracy of estimation or on other pregnancy outcomes.

Conclusion

In singleton pregnancy with DM, the fetal weight estimation with 2D-US had more accuracy than physical examination (in term of ICC), but no significant difference of accuracy between the two methods. The authors suggest using 2D-US as an adjunct in estimation of fetal weight among pregnancies with DM. Though 2D-US seems to be the best method available nowadays, the accuracy is still limited, with only 76% that could be accurately predicted. As mentioned earlier, the best model of 2D-US is not much better than subjective assessment. Further improvement may possibly be achieved through new approaches in ultrasonography, such as 3D-ultrasound technic.

What is already known on this topic?

Previous study showed that ultrasound 2D had more accuracy than physical examination for fetal weight estimation in normal pregnancy. Ultrasound 2D is more accurate than other methods for macrosomic fetal prediction. There is no study about fetal weight estimation in the group of pregnant women effected with DM.

What this study adds?

The 2D-US is not much better (no statistical significance) than subjective assessment for fetal weight estimation in pregnant women effected by DM. Therefore, the subjective assessment could be used in a primary method for fetal weight estimation and 2D-US might be performed in uncertain cases.

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Conflicts of interest

The authors declare no conflict of interest.

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