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Neonatal outcome-based performance of the recent International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) definition of foetal growth restriction: retrospective study

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ABSTRACT

Objective. To evaluate the performance of ISUOG definition for placenta-mediated foetal growth restriction (FGR) in predicting foetuses at risk of adverse neonatal outcomes. The definition is based on a combination of measures of foetal size percentile and Doppler abnormalities.
Materials and Methods. This retrospective study included medical records of 55 singleton pregnancies with FGR who were admitted in Ain Shams University Maternity Hospital. FGR was defined as EFW and/or AC below the10th percentile using Hadlock's foetal growth standard. These criteria were reevaluated in accordance with the ISUOG definition for placenta-mediated foetal growth restriction in predicting adverse outcomes. Our primary outcome was to assess the accuracy of the ISUOG definition in predicting the composite adverse neonatal outcome (ANO) including one or more of the following parameters: neonatal intensive care unit (NICU) admission, 5-min APGAR score < 7, respiratory distress syndrome (RDS), intraventricular haemorrhage (IVH), necrotizing enterocolitis, periventricular leukomalacia, neonatal anaemia, pulmonary hypertension, seizures and/or death.
Results. Of the 245 pregnancies that were evaluated, only 55 records fulfilled the parameters needed to evaluate the performance of the ISUOG definition. The current study revealed that the ISUOG criteria for the diagnosis of FGR identified all pregnancies that were significantly at risk for composite adverse neonatal outcome.
Conclusions. According to the current study, the ISUOG criteria for foetal growth restriction can accurately identify foetuses at risk of adverse perinatal outcomes.

INTRODUCTION

Foetal growth restriction (FGR) is one of the main determinants of perinatal morbidity, neurological and cognitive impairment. It is highly associated with academic and social performance decrements [1]. FGR is a term used to describe the foetus failing to reach its genetically predetermined growth potential, however, this term remains inconsistent and therefore confusing [2, 3].
FGR is thought to affect approximately 10% of pregnancies, with its prenatal recognition being a major factor tackled by different preventive strategies aiming to prevent stillbirth. However, the proposed estimates remain imprecise in the absence of a gold standard diagnostic criteria [3].

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According to Quaresima *et al*., FGR was the most common pregnancy related risk factor associated with stillbirth, occurring in 56.6% of stillbirth cases occurred from 2012 to 2020 in a single tertiary obstetric care unit in Italy [4].

The traditional widely used definition of FGR based on biometric measures of foetal weight and /or AC below the 10th percentile may misdiagnose many of the healthy constitutionally small foetuses as having growth restriction [5].

The diagnosis of FGR is a challenging process due to variability in the used definitions, such as those of The American Congress of Obstetricians and Gynecologists (ACOG) [6] and Royal College of Obstetricians and Gynecologists (RCOG) [7] which use the cutoff value of 10th percentile as a predictor for increased risk of perinatal morbidity and mortality. This definition was adopted by the recent SMFM guidelines in 2020 [8]. On the other hand, The International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) [3] and FIGO [9] adopted the Delphi consensus criteria for the diagnosis of FGR that incorporated sequential ultrasound measurements focusing on declining/crossing growth centiles along with functional parameters such as Doppler waveform analysis and the biometric measurements in order to achieve better identification of the foetuses at risk and to reduce the misdiagnosis of physiological smallness as FGR to avoid unnecessary monitoring and interventions [10].

Despite adopting the recent definition, FIGO reported that the implementation of this definition is limited by the lack of recommendations on which growth chart should be used to define the 10th and 3rd percentiles for EFW and foetal abdominal circumference. Moreover, further research is needed to correlate this definition with adverse perinatal outcomes [8].

Objectives

The purpose of this study was to evaluate the accuracy of ISUOG definition for FGR using biometric measures and Doppler parameters to identify foetuses at risk of adverse perinatal outcomes.

MATERIALS AND METHODS

Study design and participants

This was a descriptive retrospective study included medical records of 245 pregnancies complicated by FGR (AC/EFW < 10th percentile) who were admitted in Ain Shams University Maternity Hospital during the period from January 2017 till December 2021. The records were reviewed for strict exclusion criteria to include only placental mediated FGR (early or late onset FGR). We excluded cases with foetal structural malformations or chromosomal abnormalities as detected by neonatal examination and anomaly scan during pregnancy. Infectious causes detected during pregnancy or immediately by postnatal examination and multiple pregnancies were also excluded. The records that missed important antenatal or perinatal outcome data, or records in which the gestational age (GA) could not accurately be obtained or with significant discrepancy between GA determined by LMP and that determined by ultrasound (defined as a difference of > 5 days up to 9 weeks' gestation, > 7 days up to 16 weeks, > 10 days up to 22 weeks and > 14 days up to 27 weeks) were excluded.

Ethical considerations

The study was approved by the Ethical and Research Committee of the Council of Obstetrics and Gynecology Department, Faculty of Medicine Ain Shams University Ethical Research Committee (FMASU ERC) (FMASU MS 254/2021) on 17/4/2021 and Ethical Committee of the Council of Obstetrics and Gynecology Department. The study was conducted and reported in accordance with STROBE guidelines for reporting observational studies.

Baseline data of the enrolled subjects were collected, including maternal age, parity, mode of conception, inter-pregnancy interval, past maternal medical disorders, any pregnancy induced disorder such as gestational HTN or preeclampsia, previous pregnancies outcomes especially placental mediated disorders such as previous FGR, preeclampsia or stillbirth, index pregnancy information including gestational age calculation, medications received during pregnancy, sonographic findings including biometric measurements, amniotic fluid volume and Doppler velocimetry, data regarding the mode and indication of pregnancy termination, urgency of delivery, birth weight, and sex as well.

The required data to evaluate the performance of ISUOG definition was available in only 55 medical records. For the analysis, the studied population which consist of 55 cases diagnosed to be FGR

using the current biometric definition (EFW or AC < 10th percentile) were subdivided into 2 groups according to the ISUOG definition (group A that fulfilled the ISUOG new criteria, and group B that did not fulfil ISUOG criteria).

The ISUOG definition of FGR has been proposed by a Delphi procedure and includes either EFW or AC < 3rd percentile or EFW or AC < 10th percentile combined with abnormal Doppler findings or a decrease in growth centiles, depending on gestational age at FGR diagnosis. Abnormal Doppler criteria was either abnormal uterine artery pulsatility index (PI) a value > 95th percentile, and/or abnormal umbilical artery PI as a value > 95th percentile in early onset FGR and abnormal umbilical artery PI as a value > 95th percentile and/or abnormal cerebroplacental ratio as a value < 5th percentile in late onset FGR.

The primary outcome was to assess the accuracy of the ISUOG definition for predicting composite adverse neonatal outcome (ANO) including one or more of neonatal intensive care unit (NICU) admission, 5-min APGAR score < 7, respiratory distress syndrome (RDS), intraventricular haemorrhage (IVH), necrotizing enterocolitis, periventricular leukomalacia, neonatal anaemia, pulmonary hypertension, seizures and death.

Statistical methods

Sample size was calculated using PASS 11 program, setting power at 80% and x-error at 0.05. Result from previous study by Rizzo *et al*. [11] showed that the expected incidence of adverse perinatal outcomes was 32.5%, area under ROC curve for consensus for prediction of adverse outcomes 0.74, so sample size needed is at least 55 women that had pregnancies with FGR (EFW < 10th percentile).

Data were collected, tabulated and subjected to the proper statistical analysis using SPSS© Statistics version 22 (IBM© Corp., Armonk, NY, USA).

Categorical variables were presented as number and percentage and inter-group differences were compared using the Pearson chi-squared test or Fisher's exact test as appropriate. Ordinal data were compared using the chi-squared test for trend. Continuous numerical variables were presented as mean and SD. P-values < 0.05 were considered statistically significant.

Multivariable binary logistic regression analysis was used to examine the relation between EFW, and composite ANO as adjusted for possible confounding factors.

Table 1. *Baseline demographic and clinical criteria.*

Variable	FIGO definition		P-value
	FGR (n = 40)	No FGR (n = 15)	
Maternal age	28.42 ± 5.77	29.6 ± 7.57	0.54
Parity			0.452
Primiparous	15 (27.3%)	4 (7.3%)	
Multiparous	25 (45.5%)	11 (20.0%)	
Birth weight	1927.62 ± 603.15	2552.0 ± 287.77	< 0.001*
Birth weight z score	-3.71 ± 2.25	-1.44 ± 0.636	< 0.001*
Pregnancy induced disorders			
No	21 (38.2%)	8 (14.5)	0.645
Preeclampsia with severe features	15 (27.3%)	6 (10.9%)	
Preeclampsia with no severe features	1 (1.8%)	1 (1.8%)	
Gestational HTN	3 (5.5%)	0 (0)	
Past medical disorders			
No	33 (60.0%)	11 (20.0%)	0.275
Apas	2 (3.6%)	0 (0)	
Chronic HTN	1 (1.8%)	2 (3.6%)	
Pregestational DM	1 (1.8%)	1 (1.8%)	
Epilepsy	2 (3.6%)	0 (0)	
Asthma	0	1 (1.8%)	
Hbv	1 (1.8%)	0 (0)	

*Statistically significant; APAS: antiphospholipid syndrome; HTN: hypertension; DM: diabetes mellitus; HBV: hepatitis B viral infection.

Table 2. *Different sonographic parameters in the studied cases.*

Variables	FGR		no FGR		P-value	95%CI	
	Mean	SD	Mean	SD		Lower	Upper
HC	295.05	29.52	322.40	10.26	0.001*	-43.07	-11.62
HC percentile	14.33	17.72	35.66	19.21	0.000*	-32.38	-10.27
AC	268.179	32.57	304.6	12.87	0.000*	-53.88	-18.95
AC percentile	4.231	5.5034	12.867	7.9988	0.000*	-12.46	-4.811
FL	63.949	7.2799	69.467	3.3138	0.007*	-9.4542	-1.5817
FL percentile	23.263	24.885	39.067	27.295	0.048*	-31.45	-0.1504
EFW	1,955.25	549.89	2,594.13	254.043	0.000*	-936.10	-341.65
EFW percentile	1.575	1.6154	5.267	2.0862	0.000*	-4.7557	-2.6276
UAPI	1.1385	0.3924	0.8967	0.08950	0.022*	.03550	.44816
UPI percentile	75.18	28.63	58.73	17.742	0.043*	0.53	32.35
UA RI	0.67	0.146	0.60	0.068	0.174	-0.032	0.173
MCA PI	1.4493	0.2642	1.5533	0.12952	0.266	-.29087	0.08278
MCAPI percentile	23.536	22.473	35.000	8.8176	0.147	-27.165	4.2368

*Statistically significant; HC: head circumference; AC: abdominal circumference; FL: femur length; EFW: estimated foetal weight; UAPI: umbilical artery pulsatility index; UA RI: umbilical artery resistance index; MCA PI: middle cerebral artery pulsatility index.

Receiver-operating characteristic (ROC) curve analysis was used to examine the predictive value of different ultrasound parameters in predicting composite ANO.

RESULTS

A total of 55 singleton pregnancies complicated by foetal growth restriction identified according to our current definition (AC or EFW < 10th centile) were enrolled. Of the cohort, only 40 cases (72.7%) fulfilled the recent ISUOG criteria; therefore, the cohort was divided into two groups: FGR and non FGR group.

There was no significant difference between both groups in the baseline demographic and clinical criteria (**Table 1**) while, birth weight differed significantly between both groups.

There was a significant difference between both groups regarding all biometric measurements and the umbilical artery pulsatility index as shown in **Table 2**.

As noted in **Table 3**, composite ANO occurred in 21 (38.2%) of the 55 included pregnancies (all were in FGR group according ISUOG definition). The new ISUOG definition of FGR significantly succeeded in predicting composite ANO ($p < 0.0001$) including principally RDS ($p = 0.001$) and NICU admission ($p < 0.001$).

Figure 1 shows that EFW had poor predictive value with an area under the ROC curve (AUC) of 0.689 (95%CI 0.550-0.807, P-value = 0.0017). The best cut-off criterion is < 3rd centile which had a sensitivity of 85.7% and specificity of 52.9%.

AC had good predictive value with an area under the ROC curve (AUC) of 0.807 (95%CI 0.676-0.901, P-value < 0.0001). The best cut-off criterion is < 3rd centile which had a sensitivity of 66.6% and specificity of 90.9% as shown in **Figure 2**.

UAPI had fair predictive value with an area under the ROC curve (AUC) of 0.747 (95%CI 0.612-

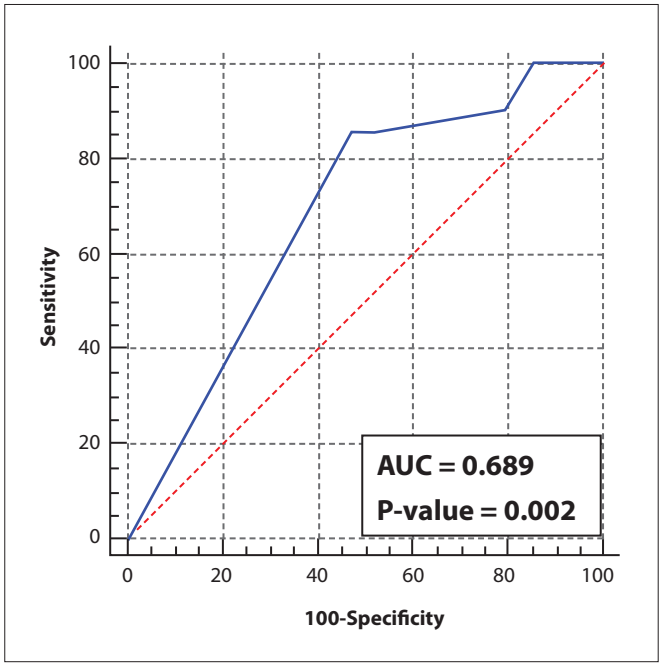

Figure 1. *ROC curve for prediction of ANO using EFW centile'.*

Table 3. *The relationship between FGR using new definition and neonatal outcomes.*

Neonatal outcome	According to new definition		P-value
	FGR	No FGR	
Composite adverse outcome			< 0.0001*
Yes	21 (38.2%)	0 (0)	
No	19 (34.5%)	15 (27.3%)	
Respiratory distress syndrome			0.001
Yes	20 (36.4%)	0 (0)	
No	20 (36.4%)	15 (27.3%)	
Neonatal death			0.112
Yes	6 (10.9%)	0 (0)	
No	34 (61.8%)	15 (27.3%)	
Neonatal ICU admission			< 0.001*
Yes	21 (38.2%)	0 (0)	
No	19 (34.5%)	15 (27.3%)	
SGA neonate			0.01*
Yes	38 (69.1%)	8 (14.5%)	
No	2 (3.6%)	7 (12.7%)	

% within total sample used for validation; *statistically significant.

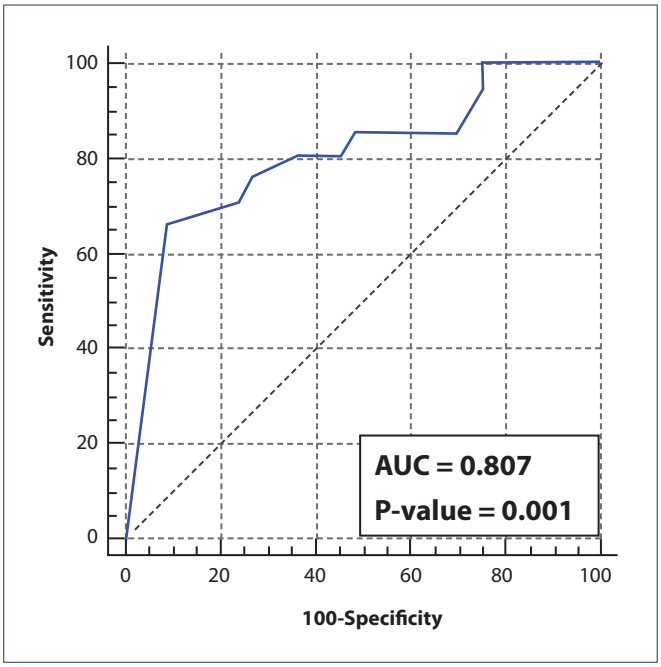

Figure 2. *ROC curve for prediction of ANO using AC centile'.*

0.855, P-value 0.0014). The best cut-off criterion is > 95th centile which had a sensitivity of 71.4% and specificity of 79.4% (**Figure 3**).

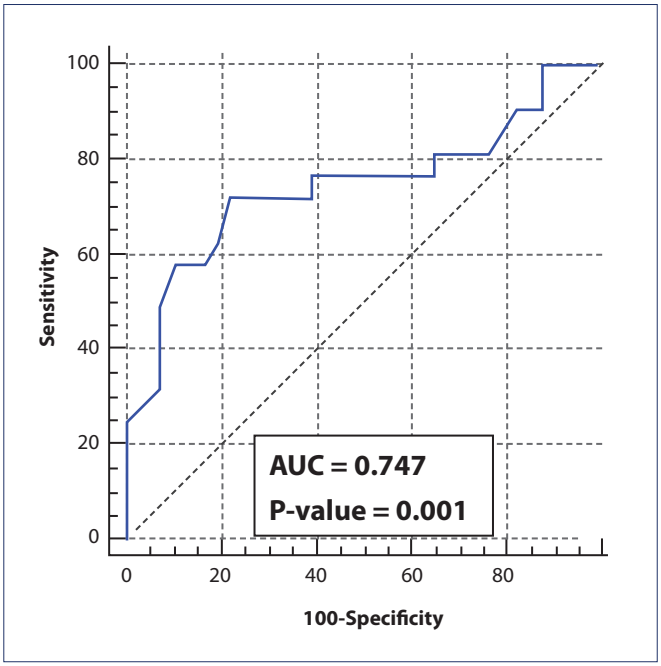

Figure 3. *ROC curve for prediction of ANO using umbilical artery PI percentiles.*

DISCUSSION

Defining FGR by the presence of aberrations in biometric measures of foetal weight and/or abdominal circumference < 10th centile usually misdiagnoses healthy but constitutionally small foetuses as FGR. Thus, provoking unnecessary parental anxiety and precludes the allocation of resources to caring for the foetuses that are actually at risk for adverse outcomes [12].

The current study showed that the recent ISUOG criteria identified all pregnancies that were complicated by composite adverse neonatal outcome and SGA neonates when compared to the traditional definition ($p < 0.0001$ and $p = 0.01$, respectively).

According to Roeckner *et al*. [13] and Schreiber *et al*. [14] the traditional definition (using biometric measurements only) had higher detection rates of SGA neonates. In their studies, both the definition based on biometric and Doppler parameters and that used only the biometric measurements performed poorly in predicting adverse neonatal outcomes.

Molina *et al*. [12] reported that the definition encompassing biometric and Doppler parameters identified more pregnancies that were significantly at risk for composite ANO when compared to the traditional definition. However, the definition encompassing biometric and Doppler parameters

identified fewer SGA neonates than did the traditional definition.

The admission to the NICU mainly due to RDS is one of the most significant contributors to estimating FGR related adverse neonatal outcomes. The current study showed that ISUOG definition could accurately detect all foetal growth restricted cases that developed RDS or needed NICU admission. On the contrary, Roeckner *et al*. [13] found that neither the traditional definition nor the new definition was able to predict RDS, while the new definition was associated with increased odds of NICU admission (OR 2.3, 95%CI 1.19-4.55).

Of the individual components of the ISUOG criteria, EFW < 3rd percentile was the most prevalent component in our sample. It was recorded in 85% of those identified as FGR according to ISUOG criteria. Moreover, we found that AC had good predictive value for ANO with best cut-off criterion is < 3rd centile with a sensitivity of 66.6% and specificity of 90.9%. The EFW had poor predictive value with the best cut-off criterion is < 3rd centile had a sensitivity of 85.7% and specificity of 52.9%.

In their meta-analysis Blue *et al*. [15] found that after 24 weeks gestation AC and EFW<10th percentile had similar ability to predict SGA. Instead, Baschat and Weiner found that AC percentile had the highest sensitivity (98.1%) for the diagnosis of FGR when compared with either estimated foetal weight (85.7%) or UA S/D ratio (67.3%) [16].

According to Marchand *et al*. [17], AC was proved to be the most suitable sonographic parameter in predicting FGR, especially in advanced weeks of gestation, as it reflects the size of the liver, which is affected early in the process of growth retardation due to glycogen depletion. It correlates with the degree of foetal malnutrition. Thus, it has the highest sensitivity for diagnosing FGR.

Abdominal circumference less than 3rd percentile rather than the 10th percentile was a good predictor of composite ANO according to Lees *et al*. [18].

Unterscheider and his colleagues [19] found that all foetuses with an EFW less than 3rd centile were at increased risk for either adverse perinatal outcome or NICU admission. In the same line, a large retrospective cohort study, found that the risk of stillbirth was inversely proportional to the percentile of birthweight for gestational age. The risk for stillbirth in those < 3rd percentile was as high as 58 per 10,000 at-risk foetuses, and 26.3 for < 10th percentile compared to 5.1 for non-SGA gestations [20].

In the era of molecular medicine, different biomarkers were investigated for predicting pre-eclampsia, FGR and stillbirth such as microRNAs, endothelial progenitor cells (EPCs) and natural killer (NK) cells with promising results [21, 22]. These advances can be used for future verification of ISUOG criteria for FGR identification.

The main limitation of our study was the relatively small sample size, and the use composite adverse neonatal outcomes instead of individual components as outcomes such as IVH, neonatal anaemia, NEC, neonatal seizures or stillbirth because they were rare or absent. Moreover, NICU admission policies as regard the age of viability were major obstacles in studying early-onset FGR.

A main strength of this study is that ISUOG adopted a definition obtained through a Delphi procedure that is usually useful in topics that cannot be answered by clinical research through a series of sequential rounds of questions to reach consensus between a panel of experts, yet. It might introduce new definition parameters based on opinions into clinical practice. So, this study was an attempt to provide evidence to support ISUOG definition.

CONCLUSIONS

As evident from the current study, ISUOG definition for foetal growth restriction can accurately identify foetuses at risk of adverse perinatal outcomes.

COMPLIANCE WITH ETHICAL STANDARDS

Authors contribution

M.H.: Data curation, formal analysis, investigation. G.E.: Conceptualization, formal analysis, methodology. M.S., R.A.: Conceptualization, methodology, resources, supervision, validation, visualization. M.S., M.H., G.E.: Writing – review & editing. R.A.: Writing – original draft.

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Study registration

Clinical trials.gov: NCT04933396.

Disclosure of interests

The authors declare that they have no conflict of interests.

Ethical approval

The study was approved by the Ethical and Research Committee of the Council of Obstetrics and Gynecology Department, Faculty of Medicine Ain Shams University Ethical Research Committee (FMASU ERC) (FMASU MS 254/2021) on 17/4/2021 and Ethical Committee of the Council of Obstetrics and Gynecology Department and an informed consent was obtained from all subjects involved in the study.

Informed consent

Informed consent for data collection for research purposes was obtained from all subjects involved in the study.

Data sharing

Data are available under reasonable request to the corresponding author.

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