

Risk Stratification of Foetuses based on Estimated Foetal Weight less than the 40th Percentile and Evaluation of Perinatal Outcomes using Third-trimester Obstetric Ultrasound: A Prospective Cohort Study

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ABSTRACT

Introduction: Perinatal mortality and morbidities constitute a burden on society and healthcare system. One of the major identifiable causes of these conditions in India is Low Birth Weight (LBW) and preterm births. Small for Gestational Age (SGA) infants account for almost 46.9% of LBW infants. They are prone to the morbidities of preterm birth and are the second major contributor to perinatal mortality. Recent studies have reported that higher screening performance for SGA can be achieved through ultrasonographic foetal biometry and Doppler studies during the third trimester.

Aim: To stratify foetuses with Estimated Foetal Weight (EFW) below the 40th centile, as determined by obstetric ultrasound, into three categories (low, intermediate, and high-risk), and study the perinatal outcomes in each category.

Materials and Methods: The present prospective cohort study was conducted in the Department of Obstetrics and Gynaecology at Vardhaman Mahavir Medical College and Safdarjung Hospital, New Delhi, India from November 2020 to April 2022. A total of 280 antenatal women, at a gestational period between 35 to 36+6 weeks with singleton pregnancies, were studied and based on the foetal biometry and Doppler parameters, women were classified into low (Group A), intermediate (Group B) and high risk (Group C) categories. Risk categorisation was based on EFW and Doppler indices. The low-risk group underwent an ultrasound Doppler scan after four weeks, the intermediate-risk group after two weeks, and the high-risk group was scanned weekly. The high-risk group was delivered at 39 weeks of gestation. Perinatal outcomes, neonatal weights, adverse neonatal outcomes [such as Neonatal Intensive Care Unit (NICU) admissions exceeding 48 hours], stillbirths, and neonatal deaths were recorded.

The Area under Curve (AUC) cut-off for EFW percentiles on ultrasonography was calculated as a predictor for SGA foetuses requiring NICU admissions. Concurrent admissions in the NICU of neonates delivered to unregistered pregnant mothers, who were not screened during the antenatal period, were also recorded. The Chi-square test was used to compare categorical data between groups. The receiver operating characteristic curve was used to determine the cut-off for foetal weight to predict NICU admission. A p-value of <0.05 was considered statistically significant.

Results: Among the study population, 231 (82.6%) were between 21-30 years of age, and 250 (88.87%) had a normal Body Mass Index (BMI) with a mean age of 25.78±3.90 years. On risk categorisation, 71 (25.1%), 82 (29%), and 127 (45.9%) women were in the high, intermediate, and low-risk categories, respectively. All the neonates in the high-risk group were classified as SGA according to the INTERGROWTH 21st growth chart. Among the neonates, 18 (6.4%) weighed below 2100 g, 35 (12.4%) weighed between 2101 to 2200 g, 62 (22.3%) weighed between 2201 to 2400 g, and 165 (59%) weighed above 2401 g. NICU admissions occurred in 25 (35.2%), 10 (12%), and 5 (3.8%) neonates in the high, intermediate, and low-risk groups, respectively (p-value <0.001). At a cut-off of EFW (g) less than or equal to 2122 g (between the 10th and 20th centile) during the first ultrasound, it predicted SGA neonates requiring NICU admissions with a sensitivity of 80% and a specificity of 70%. No stillbirths or neonatal mortality occurred in the study group.

Conclusion: A single third-trimester obstetric ultrasound, along with Doppler measurements, should be performed at 35 to 36 weeks as an important adjunct for identifying and stratifying the risk of singleton foetuses. Close monitoring and timely delivery can help reduce adverse perinatal outcomes in SGA foetuses.

Keywords: Foetal biometry and doppler, Perinatal mortality, Small for gestation foetus

INTRODUCTION

Perinatal morbidities constitute a significant burden on society and healthcare system. The World Health Organisation (WHO) defines the perinatal period as the period between 22 completed weeks of pregnancy and seven days after birth [1]. Sustainable development goals aim to reduce perinatal mortality to 12 per 1,000 live births in every country by 2030 [1]. One of the major identifiable causes of perinatal mortality and morbidity in the United Kingdom (UK) is LBW and preterm births. Approximately 30% of neonates in the UK are born with LBW (<2500 g), accounting for the highest (42%)

global burden [2]. Small for Gestational Age (SGA) infants make up almost 46.9% of LBW infants [2]. SGA infants have a birth weight between the 3rd and 10th percentiles of the mean body weight of infants of the same gestational age and gender with normal Dopplers [3]. Established management protocols exist for growth-restricted foetuses; however, there are no established protocols for SGA infants. These foetuses are at risk of being born as SGA neonates and are prone to morbidities such as preterm birth and complications of prematurity, contributing significantly to perinatal mortality after preterm births [4,5].

The traditional approach used for identifying SGA foetuses has been maternal abdominal palpation and serial measurement of symphysial-fundal height. However, this approach has a low detection rate (30%) [6]. Recent studies have reported that higher screening performance for SGA can be achieved through ultrasonographic foetal biometry and Doppler studies during the third trimester [7]. Prospective studies have shown that screening using Estimated Foetal Weight (EFW) at a cut-off below the 10th percentile does not identify all SGA foetuses, and the predictive performance improves to 85% when the cut-off is taken as the 40th centile [7]. They further reported that 85% of adverse perinatal events occur in the group between the 10th and 40th centiles, with most foetuses being SGA. Therefore, using the <10th centile cut-off on ultrasound does not predict all SGA neonates after delivery. To reduce perinatal morbidity, it is essential to predict SGA neonates in a timely manner and to monitor the group of foetuses between the 10th and 40th centiles, who are at risk, by performing follow-up ultrasound scans and delivering them at an optimal gestation [8].

The present study aimed to stratify foetuses with EFW below the 40th centile by obstetric ultrasound into three categories (low, intermediate, and high-risk) and study the perinatal outcomes in each category.

MATERIALS AND METHODS

The present prospective cohort study was conducted from November 2020 to April 2022 in the Department of Obstetrics and Gynaecology at Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, India which conducts 5000 to 6000 deliveries per year. A total of 280 antenatal women with a gestational period between 35 to 36+6 weeks and singleton pregnancy were studied after obtaining Institutional Ethical Clearance (IEC) (IEC/MMMC/SJH/Thesis/2020-11/CC-176).

Sample size calculation: The sample size was calculated with a 3.5% margin of error, 5% level of significance, and a study power of 80%, resulting in a required sample size of 224 women. Considering a potential loss to follow-up of 10%, the total sample size taken was 280. Women who met the inclusion and exclusion criteria were recruited from the antenatal Outpatient (OP)/ward after obtaining informed consent.

Inclusion criteria: Pregnant women with a gestational period between 35+0 weeks to 36+6 weeks and singleton pregnancy.

Exclusion criteria:

- Women with gestational diabetes mellitus and overt diabetes mellitus.
- All maternal and foetal conditions necessitating immediate delivery.
- Multiple pregnancy.
- Foetus diagnosed as growth-restricted. The Delphi consensus defines Foetal Growth Restriction (FGR) as EFW or Abdominal Circumference (AC) below the 3rd centile or at least two out of the following criteria: AC or EFW below the 10th centile, Umbilical Artery Pulsatility Index (UA-PI) above the 95th centile, or Cerebro-Placental Ratio (CPR) below the 5th centile, and third AC or EFW crossing more than two quartiles on growth charts [9].

Study Procedure

The gestational period was confirmed by comparing the reliability of the woman's Last Menstrual Period (LMP) with the earliest available ultrasound. Obstetric ultrasound biometry and Doppler measurements were performed using the Phillips Affinity 50 G machine with a curvilinear probe (3-5 Mhz). The following parameters were measured:

1. Estimated Foetal Weight (EFW) using the Hadlock formula [10] [Table/Fig-1,2].
2. Umbilical Artery Pulsatility Index (UA-PI) and Middle Cerebral Artery Pulsatility Index (MCA-PI) [Table/Fig-3,4].



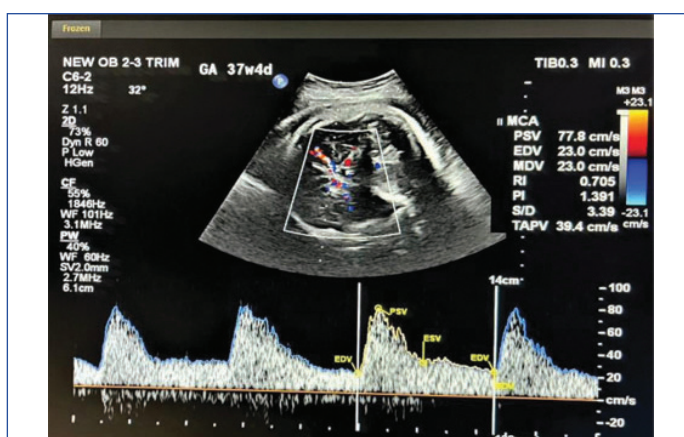
[Table/Fig-1]: Measurement of Head Circumference.



[Table/Fig-2]: Measurement of abdominal circumference.



[Table/Fig-3]: Measurement of umbilical artery pulsatility index.



[Table/Fig-4]: Measurement of middle cerebral artery pulsatility index.

Based on the foetal biometry and Doppler parameters, women were classified into low, intermediate, and high-risk categories as specified below:

Low-risk (Group A): EFW between the 20th and 40th centiles with normal Doppler.

Intermediate-risk (Group B): EFW between the 10th and 20th centiles or with UA-PI ranging from the 90th to 95th centile and MCA-PI ranging from the 5th to 10th centile.

High-risk (Group C):

- EFW > 3rd centile and <10th centile with normal Doppler.
- EFW between the 10th and 40th centiles with UA-PI >95th centile and MCA-PI < 5th centile.

Follow-up for the low-risk group was done through an ultrasound Doppler scan every four weeks, the intermediate-risk group was followed-up fortnightly, and the high-risk group was followed-up weekly.

Outcome measures: All women were followed until delivery. Adverse neonatal outcomes, defined as NICU admissions lasting more than 48 hours, stillbirths, and neonatal deaths, were recorded. The AUC cut-off for EFW percentiles on ultrasonography, which served as a predictor for SGA foetuses requiring NICU admissions, was calculated.

STATISTICAL ANALYSIS

The data was entered into an MS-Excel spreadsheet, and analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 21.0. Categorical variables were presented as numbers and percentages (%), while continuous variables were presented as mean±SD and median. The Chi-square test was used for group comparisons of categorical data. The receiver operating characteristic curve was used to determine the cut-off for foetal weight to predict NICU admission. A p-value of <0.05 was considered statistically significant.

RESULTS

The majority of the study population, 231 (82.6%), were between 21-30 years of age, with a mean age of 25.78±3.90 years. Among the 280 antenatal women, the majority, 250 (88.87%), had a normal Body Mass Index (BMI) [Table/Fig-5].

Demographic parameters	Mean±SD Median (IQR) Min-Max Frequency (%)
Age (years)	25.78±3.90 26.00 (23.00-28.00) 18.00-35.00
Age group (years)	n (percentage) (N=280)
15-20	22 (7.8%)
21-25	118 (42.0%)
26-30	113 (40.6%)
31-35	27 (9.5%)
>35	0 (0.0%)
BMI (kg/m ²)	20.35±1.27 20.10 (19.90-21.00) 17.00-24.00
BMI	
<18.5 kg/m ²	11 (4.9%)
18.5-22.9 kg/m ²	250 (88.7%)
23.0-24.9 kg/m ²	16 (6.4%)
≥25 kg/m ²	3 (1.07%)
Gravida	
Primigravida	133 (47.9%)
Multigravida	2.1%)

[Table/Fig-5]: Demographic characteristics of study population.

In present study, 71 (25.1%), 82 (29%), and 127 (45.9%) of the women were categorised as high-risk, intermediate-risk, and low-risk, respectively, and were followed according to the study protocol.

Among the intermediate-risk group, 77 (93.9%) women had a follow-up scan after two weeks, while 5 (6.1%) were delivered before the scheduled scan. In the low-risk group, 36 (27.7%) women had a follow-up scan after four weeks, and the remaining 91 women (72.3%) were delivered before the scheduled scan. Among the high-risk group, most of the women, 52 (73%), had their first growth scan performed between 35 to 35+6 weeks, while 44 (53%) of women in the intermediate-risk group and 70 (55.4%) in the low-risk group had their first growth scan performed between 35-35+6 weeks.

Labour outcomes: Among the high-risk group, 60 (84.5%) women delivered between 37 to 37+6 weeks, and 11 (15.5%) women delivered between 38 to 38+6 weeks of gestation. None of the pregnancies in the high-risk group were carried beyond 39 weeks, as all women with growth-restricted foetuses were delivered between 37 to 37+6 weeks, and SGA foetuses were delivered between 38 to 38+6 weeks according to the Institutional protocol [Table/Fig-6].

POG at delivery (weeks)	Risk category				Chi-square test	
	High	Intermediate	Low	Total	χ ²	p-value
37-37+6 weeks	60 (84.5%)	34 (41.5%)	21 (16.5%)	115 (41.1%)	123.009	<0.001
38-38+6 weeks	11 (15.5%)	46 (56.1%)	55 (43.3%)	112 (40.0%)		
39-40 weeks	0	2 (2.4%)	51 (40.2%)	53 (18.9%)		
Total	71 (100.0%)	82 (100.0%)	127 (100.0%)	280 (100.0%)		

[Table/Fig-6]: Association between risk categories and Period of Gestation (POG) at delivery.

Neonatal outcomes: Authors observed that 18 (6.4%) neonates had a weight below 2100 g, 35 (12.4%) had a weight between 2101 and 2200 g, 62 (22.3%) had a weight between 2201 to 2400 g, and 165 (59%) had a weight above 2401 g.

All 71 neonates in the high-risk group were SGA according to the INTERGROWTH 21st growth chart used by the Paediatricians in study Institute [11]. Most of the neonates, 63 (76.8%), in the intermediate-risk group were also SGA [Table/Fig-7].

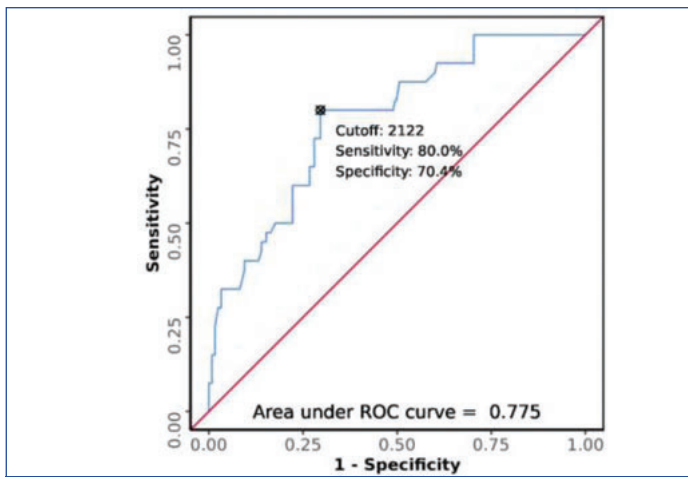
Size for age	Risk category				Chi-square test	
	High	Intermediate	Low	Total	χ ²	p-value
AGA	0 (0.0%)	19 (23.2%)	110 (86.9%)	129 (46.6%)	164.970	<0.001
SGA	71 (100.0%)	63 (76.8%)	17 (13.1%)	151 (53.4%)		
Total	71 (100.0%)	82 (100.0%)	127 (100.0%)	280 (100.0%)		

[Table/Fig-7]: Association between SGA neonates and risk categories.

The majority of SGA neonates, 124 (82.1%), were delivered within two weeks of the initial assessment since labour was induced between 37 to 38+6 weeks for all foetuses diagnosed as SGA (EFW <10th centile) on ultrasound, following the institute protocol. Most of the Appropriate for Gestational Age (AGA) neonates, 90 (69.8%), were spontaneously delivered after two weeks of the initial assessment.

The Area Under the Receiver Operating Curve (AUROC) for EFW (g) at the first scan during the study as a predictor of NICU admission was 0.775 (95% CI: 0.701-0.849), indicating a fair diagnostic performance. This result was statistically significant (p<0.001). At a cut-off of EFW (g) less than or equal to 2122 g (between the 10th and 20th centile) on the first ultrasound, it predicted SGA neonates requiring NICU admissions with a sensitivity of 80% and a specificity of 70% [Table/Fig-8].

In the cohort, authors observed NICU admission for more than 48 hours in 40 (14.1%) of the neonates. NICU admissions occurred in 25 (35.2%), 10 (12%), and 5 (3.8%) of the neonates in the high-risk, intermediate-risk, and low-risk groups, respectively (p-value <0.001). There were no stillbirths or neonatal deaths in the study group [Table/Fig-9].



[Table/Fig-8]: AUC cut-off for estimated fetal weight percentiles on ultrasonography as a predictor for SGA foetuses requiring NICU admissions.

NICU admission	Risk category				Chi-square test	
	High	Intermediate	Low	Total	χ^2	p-value
Yes	25 (35.2%)	10 (12.2%)	5 (3.8%)	40 (14.1%)	37.580	<0.001
No	46 (64.8%)	72 (87.8%)	122 (96.2%)	240 (85.9%)		
Total	71 (100.0%)	82 (100.0%)	127 (100.0%)	280 (100.0%)		

[Table/Fig-9]: NICU admissions in different risk categories.

DISCUSSION

The women in the study group ranged in age from 18 to 30 years, with a mean age of 25.78 ± 3.90 years. Authors observed a lower mean BMI in the high-risk group, which had the highest proportion of SGA foetuses. Similar observations were made by Akolekar R et al., in their study, where the mean weight was 79.9 kg in the non SGA group and a lower mean weight of 73.4 kg was found in the SGA group. The mean height was also lower in the SGA group compared to the non SGA group, with values of 163 cm and 165 cm, respectively [8].

In another study by Ciobanu A et al., which included 67,836 women, lower mean maternal weight and height were observed in the SGA group. The mean maternal weight and height in the SGA group were 73.4 kg and 163 cm, respectively, compared to 79.9 kg and 165 cm in the non SGA group [12]. In contrast to these findings, Tarca A et al., who included 3,440 women in their study, reported a prevalence of BMI over 30 in 28% of women in the SGA group [13].

The Pregnancy Outcome Prediction (POP) study evaluated 3,977 women and compared the prediction of SGA (birth weight <10th centile) in the routine ultrasound group, where the detection rate was 57%, versus the clinically indicated ultrasound group in the third trimester, where the detection rate was only 20% [14].

Ciobanu A et al., reported that the prediction of SGA neonates with a birth weight <10th percentile, born at any stage after screening at 35-36+6 weeks, is more than 85% when using screening by EFW <40th percentile. However, if screening by EFW <10th percentile is done at the same gestation, the prediction of SGA neonates with a birth weight <10th percentile is found to be only 70% [7]. Therefore, in this current study, the screening cut-off for EFW <40th percentile was used, and the prediction rates for SGA with screening by ultrasonography and foetal Doppler measurement were 100%, 76.8%, and 13.1% in the high, intermediate, and low-risk groups, respectively.

Akolekar R et al., stratified the study population into high, intermediate, low, and very low-risk groups based on EFW and Doppler parameters. Among them, 12%, 10%, 15%, and 63% of women belonged to the high, intermediate, low, and very low-risk groups, respectively, similar to the present study. These groups were monitored at specific intervals from initial assessment to delivery [8].

In the current study, all (100%) foetuses in the high-risk group were SGA neonates (<10th percentile), and among these, 30 (41.79%) foetuses progressed to FGR (<3rd percentile) and were delivered within two weeks of the initial assessment, following the Institute protocol (p-value <0.001). Akolekar R et al., reported that 89%, 71%, and 47% of foetuses below the 3rd percentile and 75%, 52%, and 36% of SGA foetuses below the 10th percentile in the high-risk group were delivered within two, 2.1 to 4, and more than four weeks, respectively [8].

Among the intermediate-risk group in the present study, 63 (76.8%) foetuses were SGA (p-value <0.001), and 8 (17.7%) progressed to FGR. Among these SGA foetuses, 41 (65.08%) were delivered within two weeks, and 22 (34.92%) were delivered after two weeks of the initial assessment. Akolekar R et al., reported that 7%, 15%, and 26% of SGA neonates below the 3rd percentile and 12%, 22%, and 26% of SGA neonates below the 10th percentile were delivered within 2, 2.1 to 4, and more than four weeks, respectively [8].

Among the low-risk group in present study, 17 (13.1%) neonates were SGA (p-value <0.001), of which 12 (70.58%) were delivered within two weeks, and 5 (29.42%) were delivered after two weeks of the initial assessment. Akolekar R et al., reported that 3%, 8%, and 15% of SGA neonates with EFW below the 3rd percentile and 8%, 14%, and 20% of SGA neonates with EFW below the 10th percentile were delivered within 2, 2.1 to 4, and more than four weeks of the initial assessment in their low-risk group [8].

All 71 neonates in the high-risk group were SGA. The majority of neonates, 63 (76.8%), in the intermediate-risk group were also SGA. Therefore, it is important to monitor this category (EFW between the 10th-20th centile at initial assessment) and conduct timely delivery to prevent adverse perinatal outcomes. Among the 280 neonates studied, 40 (14.1%) required NICU admission for more than 48 hours. Akolekar R et al., reported 52 stillbirths, 11 neonatal deaths, and 3400 NICU admissions. They also reported adverse perinatal outcomes of 31%, 13%, and 7% in the high-risk group delivered within 2 weeks, between 2.1 and 4 weeks, and after four weeks, respectively. For the intermediate-risk group, they reported adverse perinatal outcomes of 7%, 9%, and 9%, respectively, and 8%, 10%, and 13% in the low-risk group [8]. No stillbirths or early neonatal deaths occurred in the current study.

During the study period, there were 1796 NICU admissions of neonates born to unbooked/unregistered antenatal women over six months at Institute hospital. Out of these, 504 were preterm neonates, and 1292 were term neonates. Among the admissions, 745 (41.4%) were SGA neonates. Out of the 276 neonatal deaths during study period, 106 (38.4%) were SGA neonates. Therefore, authors emphasise screening for SGA foetuses with a single third-trimester ultrasound scan and following up with repeat ultrasounds to monitor and timely deliver, as this can reduce adverse perinatal outcomes.

Routine third-trimester obstetric ultrasound between 35 and 36+6 weeks of gestation should be done in all pregnant women for the measurement of EFW and Doppler indices. It should be used as an important screening tool for small-for-gestational-age (SGA) foetuses. A risk stratification-based approach should be followed for monitoring foetuses between the 10th and 40th centile, especially those between the 10th and 20th centile, and they should be closely followed according to defined protocols. Close monitoring and

timely delivery can reduce adverse perinatal outcomes in SGA foetuses. A foetal weight cut-off of 2,122 g or less should be used as a predictor for NICU admissions, and these foetuses should be diligently monitored.

Future studies with a larger sample size will strengthen the current study findings. Further research is needed to determine the appropriate gestation for screening, whether it should be at 35-36 weeks or earlier in the third trimester. The question of whether all SGA foetuses should be delivered at 39 weeks needs to be addressed in future studies.

The strength of the study was that it was a prospective cohort study conducted on a relatively large group of low-risk antenatal women at a tertiary care center. It was conducted by a single investigator, thus negating inter-observer bias. The study was not influenced by the physical examination parameters assessed by the care providers, and a routine ultrasound was performed on all antenatal women meeting the inclusion criteria. The findings can be applied to any low-risk antenatal woman with a singleton foetus.

Limitation(s)

Women in whom labour was induced at early term, according to the institutional protocol, were unavailable for the follow-up scan, thereby marginally reducing the number of follow-up scans. Ultrasound is a skill-based procedure that may not benefit women receiving antenatal care at small centers where the facility may not be available.

CONCLUSION(S)

A single third-trimester obstetric ultrasound, along with Doppler measurements, should be done at 35 to 36 weeks as an important adjunct for the identification and risk stratification of singleton foetuses. The group of foetuses between the 10th and 20th percentile (intermediate group) comprises an important cohort that requires timely monitoring and delivery. The high-risk cohort (EFW <10th percentile or abnormal Doppler in higher percentiles) needs to be closely monitored and delivered by 37 weeks. An EFW cut-off of 2122 g or lower can be used as a predictor for NICU admissions, and these foetuses should be diligently monitored.

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