

OBSTETRICS

Monitoring and timing of delivery in suspected late fetal growth restriction at term



Piyanga Athauda, MB BChir, MRCOG, MSc, MA (Cantab); Zonglun Li, PhD, MSc, BSc;
Ruth MacSwan, MBChB, MRCOG, MSc; Roise Dudley, MBBS, BSc; Jenny Stokes, MB BCh BAO, MRCPI, MRCOG;
Christina Ammari, MD, MRCOG, PGCert, MSc, MD(Res); Davide Casagrandi, MD, MSc; Alexey Zaikin, PhD, MSc;
Raffaele Napolitano, MD, PhD

BACKGROUND: Infants affected by late fetal growth restriction are at risk of adverse perinatal outcomes, either due to placental insufficiency or the consequences of late iatrogenic prematurity. There is no randomized trial reporting the optimal timing of delivery, and recommending delivery at 37 weeks can cause harm. Antenatal ultrasound parameters can be used to risk-stratify these pregnancies into low-risk cases, which are associated with a lower likelihood of adverse outcomes and are thus suitable for full-term delivery, and high-risk cases, which may benefit from early-term delivery.

OBJECTIVE: This study aimed to prospectively evaluate the performance of an antenatal risk stratification and management protocol in reducing severe adverse perinatal outcomes in fetuses with late fetal growth restriction.

STUDY DESIGN: This was a prospective study of singleton pregnancies with nonanomalous fetuses at ≥ 32 weeks of gestation with suspected late fetal growth restriction managed between 2018 and 2022 at University College London Hospital, United Kingdom. Pregnancies with unknown outcome or diagnosis of a structural, chromosomal, or genetic abnormality were excluded (but women with placenta previa were included). At 36 weeks, fetuses were classified as low-risk if the estimated fetal weight was between the third and 10th centiles with normal Doppler findings and no abdominal circumference drop, or if the estimated fetal weight was >10 th centile with an abdominal circumference drop ≥ 50 centiles from previous scans and/or a cerebroplacental ratio below the fifth centile. The high-risk group included all fetuses with an estimated fetal weight below the third centile, fetuses of any size with an umbilical artery Doppler pulsatility index >95 th centile, and fetuses with an estimated fetal weight between the third and 10th centiles with at least one of the following features: a mean maternal uterine artery Doppler pulsatility index >95 th centile, an abdominal circumference drop ≥ 50 centiles, or a cerebroplacental ratio below the 5th centile. Delivery was advised at 40 to 41 weeks of gestation in the low-risk group or 37 to 38 weeks in the high-

risk group. The primary outcome was a composite of severe adverse perinatal outcomes (perinatal mortality and severe morbidity including acidosis at birth, mechanical ventilation, encephalopathy, use of inotropes, and infections). Based on expert consensus and targeting a clinically meaningful 5% difference between the 2 groups, our sample size calculation determined that 372 patients were required in each group (alpha, 0.05; power, 85%). Adverse maternal outcome was defined as operative delivery due to abnormal intrapartum fetal heart rate. Multiple logistic regression analysis and modeling to estimate the risk of severe adverse perinatal outcome at different gestational ages were performed.

RESULTS: After exclusions, 1002 of the original 1065 patients were included (594 in the low-risk and 408 in the high-risk groups). There was a significant difference in gestational age at delivery between the low- and high-risk groups: 39^{+4} (interquartile range, 38^{+6} – 40^{+3}) vs 38^{+0} (37^{+2} – 38^{+5}) weeks ($P<.001$). Neonates from pregnancies classified as low-risk were less likely to have severe adverse perinatal outcomes (3.2% vs 8.3%; adjusted odds ratio, 2.1; 95% confidence interval, 1.2–3.9; $P=.02$). There was no difference in adverse maternal outcome between the low- and high-risk groups (20.5% vs 24.8%; adjusted odds ratio, 1.2; 95% confidence interval, 0.9–1.6, $P=.23$). There were no cases of extended perinatal mortality (including stillbirth, neonatal death, and infant death up to 6 months) in the low-risk group (4 cases in the high-risk group).

CONCLUSION: Our study demonstrated that appropriate risk stratification of singleton nonanomalous fetuses with late fetal growth restriction enables conservative term management for pregnancies at low risk of adverse perinatal outcomes, with lower adverse perinatal outcomes compared with high-risk late fetal growth restriction cases, without an increase in perinatal mortality and maternal interventions.

Key words: antenatal ultrasound, fetal growth restriction, infant death, pregnancy outcomes, prematurity, stillbirth

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Introduction

Fetal growth restriction (FGR) can be defined as a fetus not reaching their inherent biological growth potential in utero.^{1,2} Fetuses with FGR are at risk of stillbirth and neonatal morbidity and mortality; however, these risks are small when FGR occurs late in gestation.³ There is no universal consensus on how to diagnose late FGR or the optimal delivery strategy in late FGR.^{1,4–6}

Randomized trials investigating optimal timing of delivery after 32 weeks failed to demonstrate any benefit in early vs delayed delivery.^{7–11} Some of those results are due to lack of risk stratification between fetuses at high risk of stillbirth and those at low risk, for which delivery at term is possible.¹² If appropriately timed delivery is not undertaken, severe consequences such as stillbirth can occur; however, late prematurity can be associated with short-

AJOG at a Glance

Why was this study conducted?

Randomized trials have not shown any benefit of early or late term delivery in fetuses with late fetal growth restriction, likely because of the absence of subgroup risk classification.

Key findings

We report the performance of a risk stratification protocol for the management of singleton nonanomalous fetuses with late fetal growth restriction. Antenatal ultrasound parameters were used to identify low-risk fetuses who could be delivered after 38 weeks of gestation vs high-risk fetuses delivered at 37 to 38 weeks. Severe adverse perinatal outcome as a composite of perinatal mortality and morbidity was reduced in the low-risk cohort.

What does this add to what is known?

Optimizing the timing of delivery in late fetal growth restriction requires risk stratification based on multiple ultrasound parameters. The current study can provide feasibility data for future trials exploring different timings of delivery in low- or high-risk late fetal growth restriction.

term neonatal morbidity,¹³ long-term abnormal neurodevelopment,¹⁴ and special education needs.¹⁵

Previous observational studies have demonstrated that with appropriate risk stratification, low-risk late FGR infants delivered at full term (≥ 40 weeks of gestation) had better perinatal outcomes.^{3,12,16,17} None of these studies were adequately powered to detect a substantial difference in severe adverse perinatal outcomes, including stillbirth, neonatal/infant death, and need for advanced resuscitation. Our hypothesis was that antenatal risk stratification together with specific timing of delivery can impact neonatal outcome.

The objective of the present study was to prospectively evaluate the performance of a risk stratification protocol for late FGR management by classifying fetuses as low- or high-risk for adverse perinatal outcomes, aiming to demonstrate a reduction in severe adverse perinatal outcomes in the low-risk group.

Materials and Methods

This was a prospective study of patients with a singleton pregnancy, from University College London Hospital, United Kingdom, between February 2018 and March 2022. All pregnancies were dated using crown–rump length in the first

trimester,^{18,19} head circumference (HC) in the second trimester,²⁰ or the date of embryo transfer. Patients were referred for screening scans at 28, 32, or 36 weeks of gestation in the presence of risk factors for FGR or abnormal uterine artery (UtA) Doppler findings at 20 weeks. Patients were included if they had a singleton, nonanomalous fetus with suspected late FGR confirmed at ≥ 32 weeks of gestation² and the following conditions were met:

1. estimated fetal weight (EFW) ≤ 10 th centile on either a customized²¹ or population-based²² fetal growth chart; or
2. EFW > 10 th centile with either an umbilical artery (UA) Doppler pulsatility index (PI) > 95 th centile²³ with positive end-diastolic flow, a cerebroplacental ratio (CPR) below the fifth centile,²⁴ or a decrease in fetal abdominal circumference (AC) ≥ 50 centiles according to Chitty et al,²⁵ compared with a previous ultrasound scan.

Customized charts were used only as a temporary tool during participation in the DESiGN (DEtection of Small for Gestational age Neonate) trial. Ultrasound parameters were prespecified on

the basis of expert consensus, drawing from established guidelines and previous studies.

Pregnancies were excluded if the outcome was unknown or if a structural, chromosomal, or genetic abnormality was diagnosed. Other obstetrical risk factors, such as breech presentation or placenta previa, were not considered exclusion criteria. Data on risk factors associated with FGR were collected. Medical risk factors included smoking, alcohol and drug use, chronic hypertension, type 1 or 2 diabetes, hyper- and hypothyroidism, ulcerative colitis, Crohn's disease, celiac disease, chronic liver disease, nephrectomy, complicated renal disease, sleeve gastrectomy, HIV, sickle cell disease, protein S deficiency, homozygous factor V Leiden thrombophilia, thalassemia, antiphospholipid syndrome, complex or cyanotic cardiac conditions, rheumatoid arthritis, and scleroderma. Gynecologic risk factors were multiple fibroids, a single fibroid (≥ 5 cm), uterine anomalies, and previous surgery for a uterine anomaly or myomectomy. Past obstetrical risk factors included a newborn with birthweight (BW) < 10 th centile or a placental abruption. Current obstetrical risk factors included preeclampsia, pregnancy-induced hypertension, gestational diabetes mellitus, and antepartum hemorrhage.

During each visit, patients' blood pressures were measured. Preeclampsia and pregnancy-induced hypertension were diagnosed according to international consensus.^{26,27} Ultrasound examinations were performed by sonographers competent in performing growth scans and trained in a dedicated 2-year clinical training or master's program in obstetrical ultrasound and fetal medicine.²⁸ Ultrasound measurements of fetal biometry, amniotic fluid and fetomaternal Dopplers (including UA, CPR, and UtA) were performed according to specific ultrasound methodology and in line with local, national, and international standards.^{29–34} The EFW in grams was calculated using biparietal diameter, HC, AC, and femur length, according to the Hadlock formula.²⁰ A quality control strategy was used, including reproducibility assessment as described previously.^{35–37}

The detailed management protocol was described previously.¹² Patients were classified into 2 groups based on ultrasound findings at 36 weeks of gestation or at the time of the last scan.

Low-risk FGR was categorized as follows:

- 1A: EFW $\geq$ 3rd and $\leq$ 10th centile with normal UA PI, UtA PI,^{24,38} CPR,^{24,38} and no AC drop
- 1B: EFW $>$ 10th centile with normal UA PI and any of the following: AC drop $\geq$ 50 centiles or CPR below the fifth centile

In cases of low-risk FGR, delivery was recommended between 40 and 41 weeks of gestation, or between 39 and 40 weeks in subgroup 1B.

High-risk late FGR was categorized as follows:

- 2A: EFW below the third centile
- 2B: EFW $\geq$ 3rd and $\leq$ 10th centile and any of the following: third-trimester mean maternal UtA PI $>$ 95th centile, AC drop $\geq$ 50 centiles, or CPR below the fifth centile
- 2C: any-size fetus with an UA PI $>$ 95th centile

Delivery of high-risk cases was recommended between 37 and 38 weeks.

Patients initially classified as low-risk but subsequently meeting high-risk criteria had their delivery expedited and were reclassified as high-risk for data analysis.

Scans were performed every 2 weeks or more frequently if clinically indicated. The set of outcomes was established according to international consensus and expert consultation.^{12,39} Infant BW centiles were calculated using INTERGROWTH-21st Project charts.^{40,41} Adverse maternal outcome was defined as operative delivery for abnormal fetal heart monitoring in labor, including either instrumental assisted vaginal delivery or emergency cesarean delivery.

The primary outcome was a composite of severe adverse perinatal outcomes including any of the following: stillbirth, neonatal or infant death up to 6 months,

advanced cardiac or respiratory neonatal resuscitation requiring chest compression, inotropes or mechanical ventilation, an Apgar score <7 at 5 minutes, severe metabolic acidosis (UA pH <7 or umbilical vein pH <7.1), sepsis (clinical sepsis and positive blood cultures, necrotizing enterocolitis, or meningitis), and severe cerebral, respiratory, or circulatory morbidity. Severe cerebral morbidity included need for therapeutic hypothermia, abnormal postnatal brain imaging, intracerebral hemorrhage grade 3 or 4, periventricular leukomalacia grade 2 or 3, hypoxic-ischemic encephalopathy (HIE), or seizures. Severe respiratory morbidity included respiratory distress syndrome requiring treatment, bronchopulmonary dysplasia, mechanical ventilation, meconium aspiration syndrome, and persistent pulmonary hypertension of the newborn. Severe circulatory morbidity included hypotensive treatment, ductus arteriosus treatment, and disseminated intravascular coagulation.

The secondary outcome was a composite of mild adverse neonatal outcomes, including any of the following: hypoglycemia (serum glucose <2.5 mmol/L), hypothermia (temperature $<36.5^{\circ}\text{C}$), jaundice requiring phototherapy treatment or exchange transfusion following the bilirubin treatment threshold defined by the National Institute for Health and Care Excellence (NICE), suspected infection (≥ 48 hours of antibiotic treatment with negative microbiological results), feeding difficulties, Apgar score <7 at 1 minute, admission to the neonatal unit (NNU), and readmission to hospital for FGR-related complications or weight loss $\geq 10\%$.

Our late FGR protocol was approved by the hospital clinical governance team and implemented as part of routine clinical service. The study was approved and registered with the hospital governance team as a quality improvement project before commencement. Therefore, requirements for ethical approval and individual patient consent were waived. Data were analyzed in an anonymized fashion.

Induction of labor (IOL) was recommended as the initial approach if

delivery was expedited. However, mode of delivery was individualized according to local and national guidelines, patient preference and history, contraindications to vaginal birth, and ultrasound findings.

Labor was induced by administration of prostaglandins. If onset of labor did not occur, oxytocin induction was initiated after artificial rupture of membranes. Indication for operative delivery for abnormal fetal heart rate followed NICE criteria,⁴² adapted for the local protocol. Intervention was prompted by abnormal cardiotocography findings if any major concerning feature was present, including bradycardia <110 beats per minute (bpm) for >10 minutes; a single deceleration (15 bpm drop for >15 seconds) lasting >3 minutes; tachycardic fetal heart rate of >160 bpm or >20 -bpm increase; variability <5 bpm for >50 minutes; presence of late decelerations for >30 minutes; or variable decelerations with concerning features for >30 minutes. Intervention for abnormal fetal heart rate was also prompted if there was a combination of ≥ 2 minor features on the cardiotocograph, including variability <5 bpm for >30 minutes and variable decelerations with concerning features <30 minutes. Operative delivery was also indicated in cases with lack of progress in labor, defined as the inability to perform artificial rupture of membranes after administration of 2 doses of prostaglandins or absence of progress in cervical dilatation after >4 hours of oxytocin administration.

The study design, analysis, and reporting adhered to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) recommendations.⁴³

The Python software (Python Software Foundation, Wilmington, DE) was used for data analysis. Continuous data were presented using medians and interquartile ranges, and distributions in the low- and high-risk groups were compared using the nonparametric Mann–Whitney U test. Categorical data were presented using frequencies and percentages, and the distributions were compared using the chi-square test,

TABLE 1
Maternal and pregnancy characteristics

Characteristics	Low-risk FGR (n=594)	High-risk FGR (n=408)	P value
Age (y)	33 (30–37)	33 (29–36)	.61
BMI (kg/m ²)	22.9 (20.5–26.2)	22.9 (20.4–27.4)	.61
Conception via ART	26 (4.4)	36 (8.8)	.006 ^a
Nulliparous	277 (46.6)	209 (51.2)	.17
Current smoker	31 (5.2)	29 (7.1)	.26
Recreational drug user	1 (0.2)	8 (2.0)	.004
Medical risk factor	55 (9.3)	46 (11.3)	.35
Gynecologic risk factor	38 (6.4)	26 (6.4)	>.99
Past obstetrical risk factor	150 (25.2)	106 (26.0)	.85
Preeclampsia	12 (2.0)	37 (9.1)	<.001 ^a
Pregnancy-induced hypertension	16 (2.7)	13 (3.2)	.79
Gestational diabetes	58 (9.8)	43 (10.5)	.77
Gestational age at diagnosis (wk ^{+d})	31 ⁺⁵ (28 ⁺² –34 ⁺⁰)	30 ⁺⁰ (28 ⁺¹ –32 ⁺⁶)	<.001

Values are reported as absolute number (percentage) or median (interquartile range). A P value <.05 was deemed statistically significant.

ART, assisted reproductive technologies; BMI, body mass index; FGR, fetal growth restriction.

^a Adjusted for at multiple regression analyses.

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except when the frequency count was <5, in which case the Fisher exact test was used. Maximum likelihood estimation (MLE) logistic regression was used to study the association of the risk stratification with the neonatal and maternal outcomes, and significant maternal and pregnancy characteristics were adjusted for when fitting the regression. Odds ratios, 95% confidence intervals (CI), and P values were reported to indicate the direction of association and statistical significance. A P value <.05 was deemed statistically significant. Based on expert consensus and targeting a clinically meaningful 5% difference between the 2 groups, our sample size calculation determined that 372 patients were required in each group (alpha, 0.05; power, 85%). This study is ongoing, with preliminary data previously reported by Peasley et al.¹² The inclusion period was extended to 5 years to reach the required sample size powered to detect differences in severe adverse perinatal outcomes.

Using a model-based approach, we estimated the probability score of severe adverse perinatal outcome at different gestational ages (GAs).¹² On a scale from 0 to 1, 0 represented the lowest risk and 1 the highest risk of severe adverse perinatal outcome. We fitted a logistic regression model using data from the cohort with a specified combination of risk factors. Namely, GA (in weeks) was used as a continuous variable, and low- and high-risk patients were represented by a dichotomous variable. A nonlinear relationship with GA was captured by adding a quadratic term. Thus, this model illustrates the estimated risk that is conferred to low- and high-risk patients at different stages of pregnancy.

Results

After excluding pregnancies with major congenital abnormalities (n=20), 1045 underwent the protocol assessment. After exclusion of pregnancies with unknown outcome data (n=43), 1002 pregnancies were included in the data

analysis, with 594 classified as low-risk FGR (59%) and 408 as high-risk FGR (41%). Initially, 33% had an EFW <10th centile, which was not confirmed at the 36-week scan. However, these were still analyzed within the low-risk group.

All 170 fetuses with an EFW below the third centile (17%) were classified into the high-risk category. The percentage of fetuses reclassified from low- to high-risk after meeting the high-risk FGR criteria was 8.1% (n=81). A significant percentage (56%) of fetuses classified in the low-risk group had biometry centiles that increased by the last scan.

Most maternal and pregnancy characteristics were comparable between the groups, except preeclampsia and assisted conception, which were adjusted for (Table 1). The number of recreational drug users in the high-risk group was significantly higher. However, this factor was not adjusted for because of its low incidence, and it was confirmed that it did not affect the results according to our simulation. There was a significant difference in GA at diagnosis between the low- and high-risk groups: 31⁺⁵ (interquartile range, 28⁺²–34⁺⁰) vs 30⁺⁰ (28⁺¹–32⁺⁶) weeks (P<.01). Pregnancies in the high-risk group were more likely to display ultrasound parameters suggestive of placental insufficiency (Supplemental Table S1).

The maternal and delivery outcomes are summarized in Supplemental Table S2. Low-risk patients were less likely to require an IOL (38% vs 60%; adjusted odds ratio [aOR], 2.6; 95% CI, 2.0–3.4; P<.001) and an emergency cesarean delivery in labor (17% vs 32%; aOR, 2.0; 95% CI, 1.5–2.7; P<.001) compared with high-risk patients. However, there was no significant difference in adverse maternal outcome between the low- and high-risk groups (20% vs 25%; aOR, 1.2; 95% CI, 0.9–1.6; P=.23).

There was a significant difference in GA at delivery between the low- and high-risk groups: 39⁺⁴ (interquartile range, 38⁺⁶–40⁺³) vs 38⁺⁰ (37⁺²–38⁺⁵) weeks (P<.001) (Table 2). Overall, 7.7% (77/1002) of neonates were born preterm, with most being in the high-risk group (3.2% vs 14% in the low- vs high-risk group, respectively; P<.001). A

TABLE 2
Neonatal characteristics at birth

Characteristics	Low-risk FGR (n=594)	High-risk FGR (n=408)	P value
BW (g)	2945 (2740–3140)	2452 (2226–2660)	<.001
BW centile	20.8 (10.7–35.8)	7.0 (3.4–14.0)	<.001
Gestational age at delivery (wk ^{+d})	39 ⁺⁴ (38 ⁺⁶ –40 ⁺³)	38 ⁺⁰ (37 ⁺² –38 ⁺⁵)	<.001
<37 ⁺⁰	19 (3.2)	58 (14.2)	<.001
37 ⁺⁰ –38 ⁺⁰	45 (7.6)	155 (38.0)	<.001
38 ⁺¹ –39 ⁺⁰	120 (20.2)	122 (29.9)	<.001
39 ⁺¹ –40 ⁺⁰	207 (34.8)	56 (13.7)	<.001
40 ⁺¹ –41 ⁺⁰	142 (23.9)	15 (3.7)	<.001
>41 ⁺⁰	61 (10.3)	2 (0.5)	<.001
Male	250 (42.1)	180 (44.1)	.57
BW <3 rd centile	23 (3.9)	82 (20.1)	<.001
BW 3 rd –10 th centile	111 (18.7)	180 (44.1)	<.001
BW ≤10 th centile	134 (22.6)	262 (64.2)	<.001
BW >10 th centile	460 (77.4)	146 (35.8)	<.001
1-min Apgar <7	32 (5.4)	24 (5.9)	.85
5-min Apgar <7	4 (0.7)	1 (0.2)	.65
Umbilical artery pH	7.26 (7.21–7.31)	7.27 (7.22–7.31)	.51
Umbilical vein pH	7.34 (7.3–7.37)	7.33 (7.28–7.37)	.92

Values are reported as absolute number (percentage) or median (interquartile range). A P value <.05 was deemed statistically significant.

BW, birthweight; FGR, fetal growth restriction.

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significant number of patients delivered in the low-risk group before 40 weeks (60%; 358/594). However, neonates in the low-risk group were nearly 500 g heavier than those in the high-risk group, and were born an average of 11 days later. The BW of most neonates in the low-risk group was >10th centile (77%), whereas most infants in the high-risk group had a BW ≤10th centile (64%). Overall, the proportion of neonates with a BW below the third centile was low (3.9% vs 20% in the low- vs high-risk group, respectively; $P<.001$).

The primary perinatal outcomes are presented in Table 3 and Figure 1. The rate of severe adverse perinatal outcomes was lower in the low-risk than the high-risk group (3.2% vs 8.3%; aOR, 2.1; 95% CI, 1.2–3.9; $P=.02$). The main contributor to this difference was a lower rate of advanced resuscitation in the low-risk group (1.2% vs 4.4%; aOR, 2.7; 95% CI, 1.1–6.8; $P=.03$).

There were 3 stillbirths and 1 infant death in the high-risk group. In all cases, UA PI and CPR were normal, with no evidence of AC drop. The EFW was below or at the third centile in all cases of stillbirth and occurred at 31⁺⁵, 36⁺³, and 38⁺⁴ weeks of gestation, respectively. The latter occurred in a patient who declined the recommended early term delivery between 37 and 38 weeks. The GA limits at inclusion are arbitrary. The stillbirth at 31⁺⁵ weeks was kept in the analysis because it was diagnosed on the day of the scan when the management protocol would have been applied. The infant death was classified as sudden infant death syndrome at 6 months.

There were 5 cases of cerebral morbidity. Three of these cases were classified as high-risk. Two of these, delivered preterm because of severe pre-eclampsia at 34 and 36 weeks, had abnormal postnatal cranial ultrasound findings, including periventricular flares

and subependymal pseudocysts; the third case required active therapeutic cooling. Both cases in the low-risk group only had mild HIE with normal cranial imaging.

Neonates in the low-risk group were also less likely to have mild adverse neonatal outcomes (31% vs 50%; aOR, 2.1; 95% CI, 1.6–2.8; $P<.001$), particularly regarding hypothermia, NNU admission, and feeding difficulties (Supplemental Table S3).

The best model fit for predicting severe adverse perinatal outcome as a function of GA at delivery was determined using the following equation: $\text{Logit}(p) = a_0 + a_1 \text{GA} + a_2 (\text{GA} - 38)^2 + a_3 \text{R}$, where the intercept was 13.6433 (95% CI, 0.726–26.561; $P=.04$), GA was -0.4566 (95% CI, -0.792 to -0.121 ; $P<.01$), and R was 0.5096 (95% CI, -0.349 to 1.368, $P=.245$). The low-risk group showed a consistently lower probability of severe adverse perinatal

TABLE 3
Severe adverse perinatal outcomes

Perinatal outcomes	Low-risk FGR (n=594)	High-risk FGR (n=408)	OR (95% CI)	P value	aOR (95% CI)	P value
Severe composite adverse perinatal outcome	19 (3.2)	34 (8.3)	2.8 (1.5–4.9)	<.001	2.1 (1.2–3.9)	.02
Stillbirth	0	3 (0.7)	—	—	—	—
Neonatal death	0	0	—	—	—	—
Infant death (up to 6 mo of age)	0	1 (0.2)	—	—	—	—
Stillbirth/neonatal/infant death	0	4 (1.0)	—	—	—	—
Advanced resuscitation	7 (1.2)	18 (4.4)	3.9 (1.6–9.4)	.003	2.7 (1.1–6.8)	.03
5-min Apgar score <7	4 (0.7)	1 (0.2)	0.36 (0.04–3.25)	.36	—	—
Umbilical artery pH <7	2 (0.3)	0	—	—	—	—
Umbilical vein pH <7.1	4 (0.7)	0	—	—	—	—
Sepsis	1 (0.1)	3 (0.7)	4.4 (0.5–42.4)	.20	—	—
Cerebral morbidity	2 (0.3)	3 (0.7)	2.2 (0.4–13.1)	.39	1.1 (0.2–8.0)	.93
Stillbirth/neonatal/infant death and cerebral morbidity	2 (0.3)	7 (1.7)	5.2 (1.1–25.0)	.04	4.1 (0.8–20.7)	.09
Respiratory morbidity	9 (1.5)	18 (4.4)	3.0 (1.3–6.7)	.008	1.8 (0.7–4.3)	.19
Circulatory morbidity	0	2 (0.5)	—	—	—	—
Severe adverse perinatal outcomes in infants with BW <10 th centile	5 (3.7)	24 (9.2)	2.6 (0.97–7.0)	.06	1.8 (0.64–5.0)	0.26

Values are reported as absolute number (percentage). A P value <.05 was deemed statistically significant.

aOR, adjusted odds ratio; BW, birthweight; CI, confidence interval; FGR, fetal growth restriction; OR, odds ratio.

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outcome compared with the high-risk group, but with an overlapping 95% CI. In both groups, the lowest risk of abnormal outcome was predicted between 37 and 40 weeks (Figure 2).

Comment

Principal findings

The present study demonstrates that prospective risk stratification of late FGR using antenatal ultrasound parameters can correctly distinguish low-risk fetuses that can be delivered after 38 weeks from high-risk fetuses requiring delivery at 37 to 38 weeks. The incidence of severe adverse perinatal outcomes was significantly lower among low-risk fetuses, with no increase in adverse maternal outcomes. There were no cases of extended perinatal mortality in the low-risk group, justifying a conservative management approach to reduce the risk of late prematurity. Fitted MLE logistic regression revealed that low-risk fetuses

showed a consistently lower probability of severe adverse perinatal outcome compared with the high-risk group at any GA, with the lowest risk of abnormal outcome predicted between 37 and 40 weeks of gestation in both groups.

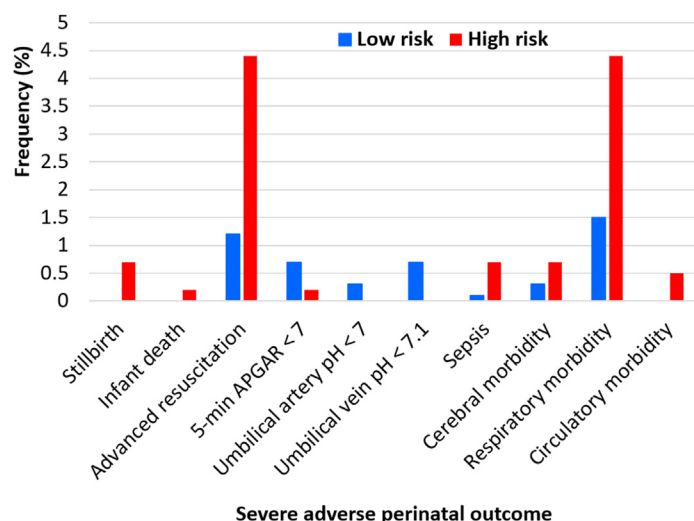
Results in the context of what is known

The DIGITAT study is the only randomized trial investigating the timing of delivery in cases of late FGR beyond term. It randomized 650 pregnancies with suspected FGR from 36 to 41 weeks of gestation to IOL within 48 hours or expectant management until delivery was indicated because of other obstetrical indications. It did not show any benefit of IOL in neonatal, maternal, and 2-year developmental outcomes.^{10,11} A Cochrane meta-analysis, which mainly included data from the DIGITAT trial, reported no significant differences between planned delivery and expectant

management at term in FGR.⁷ A possible explanation is the fact that fetuses in the DIGITAT trial were not risk-stratified for their suspected late FGR. Furthermore, there was a significant difference in the proportion of neonates with BW below the third centile between the 2 groups (12% vs 31%; $P<.001$), which could have skewed the results in the expectant management group, who could have benefited from earlier or later delivery.

There is a limited number of retrospective^{3,16,44–46} and prospective^{12,17} studies reporting on the risk stratification of late FGR. Figueras et al¹⁷ stratified patients prospectively, but their sample size was underpowered to detect differences in severe adverse perinatal outcomes. In Peasley et al,¹² we reported prospective findings similar to those of Figueras et al.¹⁷

Another difference from previous studies^{3,16,17} is that these studies did not incorporate as many ultrasound

FIGURE 1**Severe adverse perinatal outcomes in low- and high-risk late fetal growth restriction**

Frequency reported in percentages. Advanced resuscitation was defined as neonatal resuscitation requiring chest compressions, mechanical ventilation, or use of inotropes.

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parameters into their risk stratifications or include fetuses with EFW $>10^{\text{th}}$ centile with suspected FGR. We acknowledge that some comparisons might be affected by the charts used in each study.

However, overall, there is a general agreement in reporting that delayed delivery in low-risk FGR is associated with a lower risk of adverse perinatal outcome.

Clinical implications

Some professional bodies now advise delivery for high-risk late FGR with EFW below the third centile or abnormal fetal Doppler findings between 37 and 38 weeks, and between 38 and 40 weeks of gestation when the EFW is above the third centile and fetal Doppler findings are normal.^{4–6,47–49} The present study adds to the mounting body of evidence supporting this approach by providing a detailed management protocol. Furthermore, it demonstrates that appropriate risk stratification of late FGR can allow pregnancies at low risk of adverse outcome to be managed conservatively at term, reducing the risk of iatrogenic late prematurity. The present study was able to demonstrate that

adverse outcomes such as stillbirth, neonatal and infant death, and cerebral morbidity did not increase in low-risk FGR. This finding can aid in patient counseling and reassure clinicians who currently may recommend elective delivery of both FGR and small-for-GA fetuses at term because of concerns regarding stillbirth.

Research implications

Challenges in designing trials on late FGR are related to the fact that adverse neonatal outcomes can result from prematurity, hypoxia due to placental insufficiency, or both. Whether delivery at a later GA in the high-risk group improves outcomes by reducing prematurity, or delivery at an earlier GA in the low-risk group improves outcomes by reducing the effects of prolonged placental insufficiency, cannot be answered without a randomized controlled trial (RCT). Our results provide feasibility data, potentially informing the design of an RCT. Such an RCT should report long-term outcomes, akin to the secondary outcomes of the ongoing TRUFFLE 2 study.⁵⁰ In the meantime, we performed modeling to

estimate the probability of abnormal outcomes at different GAs in both groups. As previously observed, the nadir of abnormal outcomes occurred between 37 and 40 weeks in both groups, with overlapping 95% CIs (Figure 2). No sharp increase in adverse outcomes was observed thereafter in either group, corroborating the hypothesis that trials exploring different timings of delivery at term in low- and high-risk late FGR are feasible. Although this finding from the model does not definitively support the hypothesis that conservative management is appropriate in low-risk cases, it provides a basis for generating hypotheses for future trial designs.

Strengths and limitations

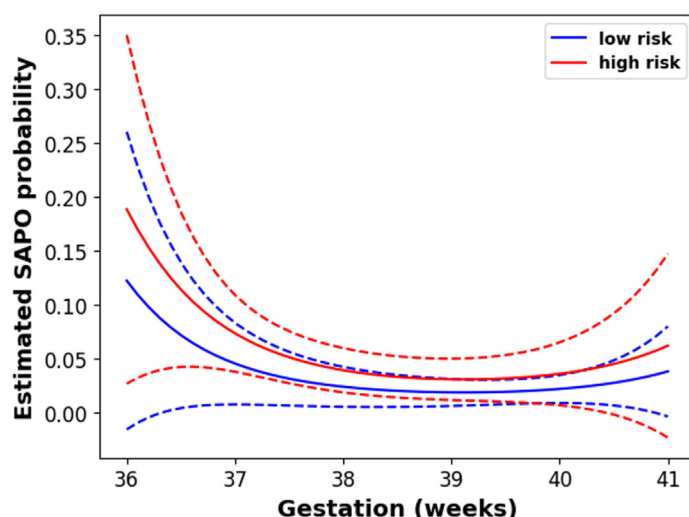
The strengths of this study include its prospective design, the large sample size, and reporting on important adverse outcomes.

However, this was a pragmatic study designed to reflect a real-world setting using patient-centered outcome measures.⁵¹ Limitations include the small sample size for mortality outcome analysis, the nonrandomized design, and lack of blinding of clinicians providing antenatal and intrapartum care. To reduce the loss to follow-up, the collection of outcome data stopped at 6 months of age, which poses a limitation on long-term infant safety data interpretation. Because clinicians and patients were able to individualize management depending on their clinical judgment and patient preference, the risk stratification and management protocol was not followed fully (Supplemental Table S4). However, because this was a pragmatic study, the final analysis was based on an intention-to-treat approach.

Furthermore, we cannot recommend on the basis of the results of the current study to exclude maternal comorbidities from the management protocol. Indeed, some patients delivered out of protocol because of preeclampsia. The diagnosis of suspected late FGR included a minority of fetuses with EFW $>10^{\text{th}}$ centile with AC drop or abnormal Doppler measurements. We acknowledge that those infants might not have been

FIGURE 2

Fitted MLE logistic regression indicating the estimated probability of severe adverse perinatal outcomes in low- and high-risk fetuses as a function of the gestational age



Bands (dashed blue and red lines) represent the standard deviation around the predictive posterior probability. Estimations are applied to the observed data. The scale of probability of severe adverse perinatal outcome ranges from 0 to 1, representing 0% to 100% probability of adverse outcome (Y axis) with advancing gestation (X axis).

MLE, maximum likelihood estimation; SAPO, severe adverse perinatal outcome.

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affected by late FGR at birth and may have had a low rate of adverse outcomes; however, because the above parameters are used in screening, we preferred to apply a conservative approach and include them in the low-risk group. Interestingly, in the subgroup of neonates with BW <10th centile, there was no substantial difference in the primary outcome, which confirmed that BW is not the only feature of the newborn affected by late FGR.

Conclusions

Appropriate risk stratification of late FGR enables conservative management at term for pregnancies at low risk of adverse perinatal outcomes, with lower rates of severe adverse perinatal outcomes compared with high-risk late FGR cases, and without an increase in perinatal mortality and maternal interventions. Current data can provide information for clinicians and patients on an evidence-based management protocol, and provide researchers feasibility data for designing a

trial on optimal timing of delivery in late FGR at term.

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Author and article information

From the Elizabeth Garrett Anderson Institute for Women's Health, University College London, London, United Kingdom (Athauda, MacSwan, Dudley, Ammari, Casagrandi, and Napolitano); Fetal Medicine Unit, Elizabeth Garrett Anderson Wing, University College London Hospitals NHS Foundation Trust, London, United Kingdom (Athauda, MacSwan, Stokes, Ammari, Casagrandi, and Napolitano); Department of Women's Cancer, Institute for Women's Health, University College London, London, United Kingdom (Li and Zaikin); and Department of Mathematics, University College London, London, United Kingdom (Li and Zaikin).

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Corresponding author: Raffaele Napolitano, MD, PhD. r.napolitano@ucl.ac.uk

SUPPLEMENTAL TABLE 1			
Ultrasound scan findings			
Ultrasound scan findings	Low-risk FGR (n=594)	High-risk FGR (n=408)	P value
EFW $\leq$ 10th centile ^a	174 (29.3)	368 (90.2)	<.001
EFW <3rd centile ^a	0	170 (41.7)	<.001
EFW 3rd–10th centile ^a	174 (29.3)	198 (48.5)	<.001
CPR <5th centile	16 (2.7)	93 (22.8)	<.001
AC drop $\geq$ 50 centiles	36 (6.0)	61 (15.0)	<.001
Umbilical artery Doppler PI >95th centile	9 (1.5) ^b	31 (7.6)	<.001
Values are reported as absolute number (percentage). A P value <.05 was deemed statistically significant. Oligohydramnios was not used as a management parameter. Some fetuses met >1 ultrasound criterion.			
AC, abdominal circumference; CPR, cerebroplacental ratio; EFW, estimated fetal weight; FGR, fetal growth restriction; PI, pulsatility index.			
^a EFW as plotted on the population growth chart; ^b Low-risk FGR cases that had abnormal Doppler measurements at or before 36 weeks, which had subsequently normalized prompting management as low-risk FGR.			
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SUPPLEMENTAL TABLE 2

Maternal and delivery outcomes

Outcomes	Low-risk FGR (n=594)	High-risk FGR (n=408)	OR (95% CI)	P value	aOR (95% CI)	P value
Spontaneous onset of labor	258 (43.4)	85 (20.8)	0.34 (0.26–0.46)	<.001	0.35 (0.26–0.47)	<.001
Induction of labor	225 (37.9)	246 (60.3)	2.5 (1.9–3.2)	<.001	2.6 (2.0–3.4)	<.001
Unassisted vaginal delivery	282 (47.5)	165 (40.4)	0.75 (0.58–0.97)	.03	0.83 (0.64–1.1)	.15
Spontaneous onset of labor and unassisted vaginal delivery	114 (19.2)	122 (29.9)	1.8 (1.3–2.4)	<.001	2.0 (1.5–2.7)	<.001
Instrumental delivery	96 (16.2)	56 (13.7)	0.8 (0.6–1.2)	.29	0.8 (0.6–1.2)	.30
Elective cesarean delivery	108 (18.2)	55 (13.5)	0.70 (0.49–1.0)	.05	0.69 (0.48–0.99)	.04
Emergency cesarean delivery	104 (17.5)	130 (31.9)	2.2 (1.6–3.0)	<.001	2.0 (1.5–2.7)	<.001
Instrumental delivery for abnormal FHR	68 (11.4)	28 (6.9)	0.57 (0.36–0.90)	.02	0.55 (0.35–0.88)	.01
Emergency cesarean delivery for abnormal FHR	54 (9.1)	73 (17.9)	2.2 (1.5–3.2)	<.001	2.1 (1.4–3.0)	<.001
Adverse maternal outcome (operative delivery for abnormal FHR)	122 (20.5)	101 (24.8)	1.3 (0.9–1.7)	.12	1.2 (0.9–1.6)	.23
Operative delivery before 37 wk due to preeclampsia	1 (0.2)	21 (5.1)	32.2 (4.3–240.2)	<.001	—	—
Maternal infection ^a	22 (3.7)	19 (4.7)	1.27 (0.68–2.4)	.46	1.36 (0.72–2.6)	.34
Postpartum hemorrhage >500 mL	169 (28.5)	92 (22.5)	0.73 (0.55–0.98)	.04	0.68 (0.50–0.92)	.01
Massive obstetrical hemorrhage >2000 mL	2 (0.3)	1 (0.2)	0.73 (0.07–8.0)	.80	0.65 (0.06–7.5)	.73
Obstetrical anal sphincter injury	4 (0.7)	1 (0.2)	0.36 (0.04–3.3)	.36	—	—

Values are reported as absolute number (percentage). A *P* value <.05 was deemed statistically significant.

aOR, adjusted odds ratio; CI, confidence interval; FGR, fetal growth restriction; FHR, fetal heart rate; OR, odds ratio.

^a Maternal infection includes intrapartum and postnatal pyrexia and/or sepsis, chorioamnionitis, endometritis, wound infection, and mastitis.

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SUPPLEMENTAL TABLE 3

Mild adverse neonatal outcomes

Neonatal outcomes	Low-risk FGR (n=594)	High-risk FGR (n=408)	OR (95% CI)	P value	aOR (95% CI)	P value
Mild composite adverse neonatal outcome	184 (31.0)	206 (50.5)	2.3 (1.8–2.9)	<.001	2.1 (1.6–2.8)	<.001
Hypoglycemia	25 (4.2)	29 (7.1)	1.7 (1.0–3.0)	.04	1.5 (0.8–2.6)	.16
Hypothermia	37 (6.2)	53 (13.0)	2.2 (1.4–3.5)	<.001	2.3 (1.5–3.6)	<.001
Jaundice requiring treatment	14 (2.4)	14 (3.4)	1.5 (0.7–3.1)	.31	1.4 (0.6–3.0)	.42
NNU admission	34 (5.7)	69 (16.9)	3.4 (2.2–5.2)	<.001	2.8 (1.8–4.4)	<.001
NNU admission ≥ 5 d	30 (5.1)	64 (15.7)	3.5 (2.2–5.5)	<.001	2.8 (1.7–4.4)	<.001
Suspected infection	56 (9.4)	55 (13.5)	1.5 (1.0–2.2)	.05	1.4 (0.9–2.1)	.10
Feeding difficulties	50 (8.4)	83 (20.3)	2.8 (1.9–4.1)	<.001	2.5 (1.7–3.6)	<.001
1-min Apgar score <7	32 (5.4)	24 (5.9)	1.1 (0.6–1.9)	.74	0.9 (0.5–1.6)	.81
Hospital readmission	27 (4.5)	26 (6.4)	1.4 (0.8–2.5)	.21	1.5 (0.8–2.6)	.19
Jaundice (with or without treatment)	86 (14.5)	63 (15.4)	1.1 (0.8–1.5)	.67	1.0 (0.7–1.5)	.86

Values are reported as absolute number (percentage). A *P* value <.05 was deemed statistically significant.

aOR, adjusted odds ratio; CI, confidence interval; FGR, fetal growth restriction; NNU, neonatal unit; OR, odds ratio.

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SUPPLEMENTAL TABLE 4
Subgroup analysis of patients who delivered out of protocol

Contributory factors	Low-risk FGR	High-risk FGR
	Delivery <40 wk ^a (n=358)	Delivery >38 wk (n=195)
Spontaneous onset of labor	153 (43)	51 (26)
Elective cesarean delivery	98 (27)	16 (8)
Delivery expedited because of other obstetrical complications	90 (25)	0
Maternal request	2 (1)	10 (5)
Meeting high-risk criteria >38 wk ^b	0	81 (42)
Procedural delays ^c	0	68 (35)
Other reasons	15 (4)	36 (18)

Values are reported as absolute number (percentage).

FGR, fetal growth restriction.

^a Four low-risk pregnancies were excluded from this cohort despite delivery at <40 weeks of gestation because the deliveries were conducted in accordance with the protocol for delivery between 39 and 40 weeks for subgroup 1B (estimated fetal weight >10th centile and a normal umbilical artery Doppler pulsatility index with an abdominal circumference drop ≥50 centiles and/or a cerebroplacental ratio below the fifth centile); ^b This cohort includes pregnancies that were initially classified as low-risk but subsequently met the high-risk criteria and delivery was expedited; ^c Cases wherein delivery was delayed several days beyond the recommended delivery window of 37 to 38 weeks in the high-risk group despite the delivery plan being made according to the protocol. In most of these cases, induction of labor was commenced within the recommended delivery window, but the delivery was delayed beyond 38 weeks because of the length of the induction of labor process.

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