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Fetal growth restriction at term: angiogenic factors versus Doppler

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Objective

To demonstrate if a management protocol based on angiogenic factors is non-inferior to Doppler criteria to prevent perinatal complications in small fetuses at term.

Methods

This is a multicentre, randomised, open-label, clinical trial conducted in 20 maternity hospitals across Spain between 2019 and 2022. Pregnancies with estimated fetal weight (EFW) ≤10th percentile betwen 36 and 37^{+6} weeks of gestation were recruited and randomly assigned to the control group (management based on Doppler studies) or the intervention group (management based on angiogenic factors). In the control group, cases with EFW <3rd percentile or with abnormal fetal or maternal Doppler were classified as FGR, otherwise as SGA. In the intervention group, cases with sFlt-1/PlGF >38 were classified as FGR, otherwise as SGA. In both groups, elective delivery was recommended at ≥37 weeks for FGR and at ≥40 weeks for SGA. The primary outcome was the ocurrence of neonatal acidosis (umbilical artery base excess <-12mEq/L and pH<7.15) or Cesarean for nonreassuring fetal status. Non-inferiority would be demonstrated if the lower limit of the 95% confidence interval of the difference between incidences of pregnancies without the primary outcome is less than -8.5%.

Results

Among the 1,088 participants, 97.4% (528/542) of pregnancies in the control group and 97.1% (530/546) in the intervention group did not present the primary outcome (absolute difference, 0.30 [95%CI, -1.6 to 2.3%]), indicating noninferiority. Additionally, compared with the control group, the rate of deliveries at <39 weeks was reduced by 51% (RR 0.49, 95% CI: 0.43-0.57), the rate of composite adverse perinatal outcomes was reduced by 32% (RR 0.68, 95%CI: 0.47-0.98), the rate of neonates with birthweight <2,500g was reduced by 15% (RR 0.85, 95%CI: 0.73-0.98), and the rate of preeclampsia and other related disorders was reduced by 52% (RR 0.48, 95%CI: 0.23-0.96).

Conclusion

Management of FGR and SGA after 36 weeks of gestation based on sFlt-1/PlGF was noninferior to a protocol based on Doppler to prevent neonatal acidosis and Cesarean section for nonreassuring fetal status. Additionally, the new approach could reduce perinatal complications, the rate of early-term deliveries and of neonates with birthweight below 2,500g.