Intrapartum prediction of emergency delivery due to non-reassuring fetal status at 40 weeks' gestation in low-risk pregnancies: contribution of Doppler parameters, maternal history, and intrapartum clinical characteristics

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Running head: Prediction of emergency delivery

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Abstract

Objective: To assess the added value of Doppler parameters, maternal history, and intrapartum clinical characteristics for the prediction of emergency delivery due to non-reassuring fetal status in low-risk pregnancies.

Methods: This was a prospective cohort of low-risk pregnancies undergoing ultrasound assessment at 40 weeks' gestation within 7 days of delivery. The main outcome was emergency cesarean section due to non-reassuring fetal status. The association between Doppler parameters, intrapartum clinical characteristics, and maternal history was performed by logistic regression. The predictive performance of the constructed models was assessed by receiver operating characteristic (ROC) curve analysis and the area under the curve (AUC).

Results: From 403 included pregnancies, 18.6% (n= 75) underwent an emergency delivery due to non-reassuring fetal status. The mean gestational age at birth was 40.5 (SD 5) days. Middle cerebral artery pulsatility index (MCA) and cerebroplacental ratio (CPR) were lower in the emergency cesarean section group (1.16 *vs.* 1.30; p<0.001, and 1.61 *vs.* 1.78; p=0.001, respectively). There was a higher incidence of small-for-gestational-age neonates (20% *vs.* 10.1%; p=0.017), lower Apgar scores at the 5th minute (9.7 *vs.* 9.9; p=0.006), and NICU admissions (9% *vs.* 3%; p=0.016) in the emergency cesarean section group. The base model comprised nulliparity, and the finding of meconium-stained amniotic fluid during labor, achieving an AUC of 66%, while the addition of the MCA Z-score significantly improved the previous model (AUC: 73%; DeLong: p=0.008).

Conclusions: In low-risk pregnant woman at term, the addition of MCA Z-score to a previous model comprising maternal history and intrapartum clinical findings, significantly improves the prediction of emergency delivery due to non-reassuring fetal status.

Introduction

The identification of fetuses at risk of intrapartum complications in low-risk pregnancies is still challenging, and no widely accepted screening tests for this condition exists yet. No evidence supports the evaluation of the amniotic fluid index (AFI) [1] at labor admission, neither the use of cardiotocography (CTG) as a screening test for fetal compromise [2]. Moreover, during labor, continuous CTG is recommended only in those pregnancies at higher risk of hypoxia, while in women at lower risk intermittent monitoring should be more appropriate [3]. Nevertheless, the majority of intrapartum hypoxia occurs in low-risk pregnancies [4–6] .

Doppler assessment is nowadays considered essential in the evaluation and follow-up of small-for-gestational-age fetuses (SGA), but there is not enough information on its use for low-risk pregnancies at term. Over the last decade, several studies have suggested that Doppler assessment could be valuable in the detection of placental insufficiency in adequate-for-gestational-age fetuses (AGA). The rationale behind this hypothesis is that Doppler parameters could capture a subgroup of fetuses with placental insufficiency that has not reached an estimated fetal weight (EFW) below the 10th percentile. In these cases, the only sign of placental insufficiency would be a redistribution of the fetal circulation shown by a reduction in the middle cerebral artery (MCA) pulsatility index (PI) and cerebroplacental ratio (CPR)[7-9], which has been associated with an increased risk for emergency cesarean section and neonatal acidosis [10,11,12]. The objective of this study is to assess the added value of Doppler parameters combined with maternal history and intrapartum clinical characteristics for the intrapartum prediction of emergency delivery due to non-reassuring fetal status in low-risk pregnancies.

Methods

Study population

This is a blinded prospective cohort of low-risk pregnancies conducted in a third level reference hospital in Italy between October 2014 and December 2015. Criteria for inclusion were 1) low-risk pregnant woman (where low-risk was considered in the absence of any major maternal morbidity or pregnancy complication), 2) admitted for hospital evaluation at 40 weeks' gestation, 3) with history of an adequate-for-gestational age fetus (EFW ≥10th percentile) at third trimester ultrasound screening (30-34 weeks' gestation) according to local standards [13], 4) delivering within the next 7 days from evaluation. Exclusion criteria were multiple pregnancies, pregnancies complicated with neonatal chromosomal or structural abnormalities, intrauterine infection, and those fetuses without a cephalic presentation. The hospital ethics committee approved the study protocol, and written consent was obtained for the study from all recruited patients (*protocol #354_2014*).

Main outcome

The main outcome was the indication of emergency cesarean or vaginal operative delivery for non-reassuring fetal status was based on abnormal fetal heart rate tracing [19]. In brief, fetal heart monitoring was carried out, and tracings were classified as normal, suspicious, or abnormal, according to the presence, type, and length of decelerations; bradycardia; tachycardia and the assessment of variability as reported elsewhere [19]. In cases with two or more criteria of indeterminate tracing and one or more criteria of abnormality, indication for emergency delivery was considered for non-reassuring fetal status. Obstetricians and midwives who carried out labor were blinded to the results of Doppler evaluation.

Ultrasound evaluation

Pregnancies were dated by first-trimester crown-rump length measurements [14]. The EFW was calculated using the Hadlock formula [15].

According to the hospital protocol for low-risk pregnancies, all patients were evaluated at 40 weeks of gestation for the assessment of fetal well-being, by the biophysical profile modified based on fetal movements and the measurement of amniotic fluid index (AFI). Ultrasound Doppler examinations were performed by one of three experienced operators (N.C., S.A., or S.D.), using a General Electric Voluson E6 (GE Medical Systems, Zipf, Austria) ultrasound machine equipped with a 6-2 MHz linear curved-array transducer. Doppler recordings were performed in the absence of fetal movements, voluntarily suspended maternal breathing, and maternal contractions. Spectral Doppler parameters were performed automatically from three or more consecutive waveforms, with the angle of insonation as close to 0° as possible. Umbilical artery PI was calculated from a free-floating cord loop, and it was considered abnormal if >95th centile [16]. Middle cerebral artery PI was measured in a transversal view of the fetal head, at the level of its origin from the circle of Willis; it was considered abnormal if below the 5th centile [16,17]. Finally, CPR was calculated as a ratio of the MCA PI to the UA PI, and its value was considered abnormal if below the 5th centile [17]. Three images were taken from each vessel, and the mean of them was used for subsequent analysis.

Management

No clinical decisions were based on Doppler results since Doppler examinations were blinded to the attending obstetrician. Indications for hospital admission were active labor, premature rupture of the membranes (PROM), oligohydramnios, vaginal bleeding, and 41+0 weeks' gestation if no signs of labor appeared according to the hospital protocol.

Active labor was defined as cervical ripening and dilatation ≥3 cm in the presence of at least 3 uterine contractions in 10 minutes recorded at cardiotocography [18]. Diagnosis of PROM was based on history and confirmed by the presence of pooled amniotic fluid on a sterile speculum or positive result from a prom-test. Oligohydramnios was defined if AFI was below 5 cm. Induction of labor was carried out by cervical ripening with a release vaginal prostaglandin E2 or oral prostaglandin E1. If the onset of labor did not occur within 18 hours, oxytocin induction was started.

Data collection and outcome measures

Data on maternal characteristics including age, ethnicity, body mass index, parity, smoking status, known chronic disease as hypertension, diabetes mellitus, renal disease, autoimmune disease, and previous maternal history were recorded in the hospital database at inclusion. In addition, data regarding pregnancy follow-up, complications developed during pregnancy, ultrasound evaluation and perinatal data were prospectively collected.

Neonatal metabolic acidosis was defined as the presence of UA pH less than or equal to 7.15 and base excess greater than 12 mEq/L at birth [20]. SGA was defined as birthweight was less than 10th centile, while large-for-gestational-age (LGA) was defined as birthweight was above the 90th centile, according to local standards [13].

Statistical analysis

Quantitative variables were assessed for normality using Shapiro-Wilk's test: normally distributed variables were compared using t-test and expressed as mean and standard deviation (SD). Non-normally distributed variables were compared using U-Mann-Whitney test and expressed as median and interquartile range (IQR). Qualitative variables were compared using $\chi 2$ or Fisher's

exact test. The association between Doppler parameters (UA, MCA, CPR) and emergency delivery was assessed by logistic regression, where the basal comparison was a model comprising maternal history and intrapartum, and the full model included the addition of Doppler parameters using a nested logistic regression[21]. Models were compared by assessing the improvement in their Naegelkerke R2 as a measure of goodness of fit (the proportion of uncertainty explained by the model) using a Wald $\chi 2$ test[22]. The predictive performance for the models was determined by receiver operating characteristic (ROC) curve analysis and the area under the curve (AUC)[23]. A Conditional Decision Tree Analysis was also performed to present the best combination of predictors for the main outcome [24,25]. Data were analyzed using STATA for Mac, v.14.1 (College Station, Texas) and R v15.1 (The R Foundation for Statistical Computing) [package "pROC" and "Party"] [26]. A p-value ≤ 0.05 was considered statistically significant.

Results

Participants and baseline characteristics

A total of 428 pregnancies fulfilled the selection criteria, from these, 6 patients refused to participate in the study and 18 were excluded because of delivery after 7 days from initial evaluation, leaving 403 participants for analysis. Baseline maternal characteristics of the study population are shown in Table 1. The mean gestational age at admission was 40.4 weeks (SD 5 days) and the mean gestational age at delivery was 40.5 weeks (SD 5 days).

Labor results and perinatal outcome

Induction of labor was carried out in 194 women (48.1%); the remaining 209 patients (51.9%) had spontaneous onset of labor. During labor, 75 fetuses (18.6%) had an emergency delivery due to non-reassuring fetal status that required either an emergency cesarean section (n=57, 76%) or an

operative vaginal delivery (n=18, 24%). There were no cases of stillbirth or neonatal death. Details on perinatal outcome are shown in Table 2 and 3.

Doppler parameters

Doppler parameters at 40 weeks examination showed that all cases had a normal UA PI, whereas 19 (5%) of the fetuses had MCA PI <5th centile, and 44 (11%) had a MCA PI <10th centile. CPR PI <5th centile was found in 25 (6%) of the fetuses, while in 55 (14%) it was <10th centile. Both CPR and MCA PI measured within 7 days of delivery were significantly lower in fetuses requiring emergency delivery compared to the controls (Table 4). Table 5 shows the comparison in perinatal parameters between the two groups. Figure 1 shows the comparison in Doppler parameters between fetuses requiring emergency delivery and controls.

Prediction of emergency delivery

Step-wise logistic regression analysis was used to determine the significant contributors to emergency delivery. The only significant contributor regarding maternal history was nulliparity, showing an OR of 4.17 (95% CI: 2-8.7; p<0.001). For the intrapartum clinical characteristics, the presence of meconium-stained amniotic fluid was found significant (OR: 2.26; 95% CI: 1.26-4.1; p=0.006). Finally, a higher MCA Z-score was associated with a reduced probability for emergency delivery due to non-reassuring fetal status (OR: 0.49; 95% CI: 0.35-0.69; p<0.001).

The base model for the prediction of emergency delivery comprised nulliparity and meconium-stained amniotic fluid (Naegelkerke R2: 6.3%), yielding an AUC of 66% (95% CI: 60% - 72%), while the addition of the MCA Z-score to the base model show and AUC of 73% (95% CI: 67% - 79%), significantly improving the previous model (DeLong: p=0.008). Table 6 show all logistic regression analyses and comparisons between models. Figure 2 shows the AUC for the constructed models.

Clinical decision analysis

A Decision Tree Analysis was used to determine the best combination of parameters for the prediction of emergency delivery (Figure 3). We decided to include only dichotomous variables to improve clinical decision making. The best initial predictor, according to this analysis, was an MCA <10th percentile, which included 43% of the fetuses requiring emergency delivery. In those with an MCA ≥10th percentile, the second-best predictor was nulliparity, which determined 21% of cases, while the proportion of emergency deliveries in a multiparous woman with normal fetal Doppler was only 4%.

Discussion

Main findings

There is controversy on whether Doppler parameters are useful in low-risk pregnancies at term. In this study, we found that women requiring emergency delivery due to non-reassuring fetal status had fetuses with lower MCA and CPR and that the addition of Doppler MCA to a base model comprising maternal history and intrapartum clinical characteristics, significantly improved the prediction of emergency delivery.

During periods of either acute or chronic hypoxia, the fetus redistributes its cardiac output to ensure better perfusion of vital organs, such as the brain. A decrease in MCA PI is a consequence of these hemodynamic changes, and it is considered a manifestation of fetal compromise. The CPR represents the interaction of alterations in blood flow to the brain, as a result of cerebrovascular dilatation revealed by the MCA and increased placental resistance, resulting in a decreased diastolic flow of the UA. The CPR becomes abnormal earlier, showing a greater sensitivity compared to its individual components, but with less specificity [27]. In this scenario, if Doppler assessment of the UA is of primary importance in those cases of severe placental impairment, the evaluation of the CPR better reflects the oxygenation state in milder

191 cases. In SGA fetuses, the MCA Doppler and CPR are the best in identify those pregnancies at risk
192 for emergency delivery in labor [27,28], allowing to better assist the decision-making process
193 regarding timing and mode of delivery in these fetuses.
194 Over the last few years, great interest has arisen on the role of Doppler parameters for the
195 prediction of adverse perinatal outcome in AGA fetuses. Firstly, Prior *et al.* [7] prospectively
196 evaluated 400 AGA fetuses at term, reporting a lower CPR in women undergoing cesarean delivery
197 for non-reassuring fetal status, especially for a CPR was <10th centile, in which there was a 6 times
198 higher risk of cesarean section due to intrapartum fetal compromise. A few years later, Bligh *et al.*
199 [29] in a blinded prospective study with a cohort of 437 low-risk pregnancies, evaluated CPR within
200 two weeks of delivery as a predictor of intrapartum fetal compromise and composite adverse
201 neonatal outcome, finding a fair predictive utility of CPR for cesarean section. Similarly, our study
202 suggests that CPR and MCA Dopplers are lower in women undergoing emergency delivery for non-
203 reassuring fetal status but most important, the addition of MCA in a clinical setting would
204 significantly improve the prediction of emergency delivery.
205 Morales-Rossellò *et al.* [30] conducted a retrospective cohort of 11,576 AGA term fetuses finding a
206 relationship between a lower CPR and lower birthweight, suggesting an increasing prevalence of
207 fetal hypoxemia in AGA fetuses. They proposed the CPR as a tool to identify AGA fetuses that are
208 failing to reach their growth potential. These findings are in accordance with other studies
209 showing the potential role CPR has to identify term AGA fetuses at risk of neonatal acidemia [9], [31],
210 and NICU admission [32,34].
211 With the rationale to show the potential role of Doppler parameters as indicators of fetal
212 hypoxia, rather than low estimated fetal weight, Bakalis *et al.* [11] and Akolekar *et al.* [12] evaluated
213 the performance of a low CPR at 33 and 36 weeks' gestation, finding a lower CPR in fetuses with
214 adverse outcome.

The optimal gap between Doppler assessment and labor has not been determined[35]. Prior *et al.*[7] demonstrated that an abnormal CPR measured within 72 hours of labor among AGA neonates, was significantly associated with emergency delivery due to non-reassuring fetal status. Recently Dell'Asta *et al.*[10], reported that a reduced CPR in low-risk term woman undergoing labor, was associated with a two-fold higher risk of fetal compromise and three-fold higher incidence of composite adverse perinatal outcome. Our data suggest that Doppler evaluation may be useful to predict those fetuses at risk of intrapartum fetal compromise in a context of clinical decision analysis, and regardless of the type of labor, which emphasizes the benefit of induction in comparison with expectant management at the end of pregnancy. [33,34]

The strengths of our study are first, the prospective design, whereas a substantial proportion of the data on this topic comes from retrospective studies. Secondly, we recruited a cohort of low-risk pregnancies that underwent Doppler assessment within 7 days of delivery, potentially minimizing Doppler changes between the first assessment and the intrapartum management. And finally, this is one of the few studies in which attending obstetricians and midwives were blinded to Doppler results, reducing potential bias the management of these patients. The main limitation of this study is the relatively small sample size. Therefore, larger studies, ideally clinical trials, would be needed to add quality information on the usefulness of Doppler assessment in low-risk pregnancies.

In conclusion, in low-risk pregnancies at term, the addition of Doppler parameters such as MCA Z-score to a base model comprising maternal history and intrapartum clinical characteristics, significantly improves the intrapartum prediction of emergency delivery due to non-reassuring fetal status. This study adds evidence on the possible usefulness of Doppler evaluation in low-risk pregnancies. Meanwhile, there is still not enough quality information to support the use of

Doppler examination for clinical decision making in this type of population outside the context of a clinical trial.

Disclosure Statement

The authors have no conflicts of interest to declare.

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Author Contributions

All the authors had a substantial contribution with specific responsibilities.

Francesca Crovetto was responsible of conception and design of the work, analysis and interpretation of data, critically revision and final approval; Nicola Cesano, Federica Rossi, Stefano Acerboni, Stefano De Marinis had a substantial role in the acquisition of data; Annachiara Basso, Raigam Jafet Martinez Portilla, Rosalia Pascal Capdevila had a substantial contribution for writing and drafting of the work and analysis of data; Barbara Acaia, Luigi Fedele, Enrico Ferrazzi, Nicola Persico were responsible of the final revision and approval of the version to be published.

Any part of the work was appropriately investigated and approved by the authors.

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Figure 1. Doppler comparisons between normal fetuses and those requiring emergent delivery due to non-reassuring fetal status.

Figure 2. Performance of the predictive models for emergency delivery due to non-reassuring fetal status: model 2 based on nulliparity and meconium-stained amniotic fluid, and model 3 comprising the previous model plus Doppler parameters.

Figure 3. Decision tree analysis on emergency delivery due to non-reassuring fetal status: black bars represent the percentage of cases requiring emergency delivery among each subgroup.