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Integration of clinical features in a computerized cardiotocography system to predict severe newborn acidemia

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ABSTRACT

Background: Cardiotocography (CTG), used during labor to assess fetal wellbeing, is subject to interobserver variability. Computerized CTG is a promising tool to improve fetal hypoxia detection. *Objective:* To assess if adding clinical features improves the performance of a computerized CTG system to predict

severe newborn acidemia (blood cord pH below 7.05).

Methods: A retrospective multicentric database was built using the data from two sources (the open-source CTU-UHB database and the data from Beaujon university hospital). Four CTG features were extracted from the fetal heart rate (FHR) signal (minimum and maximum value of the baseline, area covered by the accelerations and decelerations). Clinical features were also collected. Severe fetal acidemia was defined by arterial pH < 7.05 on umbilical cord sample. Risk factors for severe acidemia were sought by comparing cases with severe newborn acidemia to the rest of the cohort. We evaluated the accuracy of the model using both CTG and clinical features using area under the curve (AUC) in a cross-center, cross-validation approach.

Results: The datasets contained 1264 cases including 100 cases with severe acidemia. In univariate analysis, hypertensive disorders and other clinical features showed no significant difference, except for meconium-stained amniotic fluid (p = 0.03). Multivariate analysis revealed that a high deceleration area (OR = 1.09 [1.04-1.11]) and apparition of meconium amniotic fluid increased the risk of newborn acidemia (OR = 2.10[1.24-3.49]). In a k-fold cross-validation approach, DeepCTG®1.5 reached an AUC of 0.77, compared to 0.74 when using CTG features only.

Conclusion: The CTG features have a good accuracy to predict severe newborn acidemia, confirming existing literature. Integrating clinical features tends to enhance the accuracy. Further research will aim at using more advanced machine learning models to combine the features more efficiently.

Introduction

Fetal hypoxia is defined as a condition during the antenatal period in which the oxygen supply to fetal tissues is insufficient [1]. Fetal hypoxia affects 0.5 % to 1.0 % of deliveries worldwide, accounting for 23 % of primary causes of neonatal mortality [2]. Since direct access to the fetus is not possible during the antenatal period, we rely on measuring the umbilical cord pH after birth to assess and detect newborn acidemia [1,3]. Recognizing newborns at risk for neonatal acidemia and reducing

its occurrence remains a crucial priority. Cardiotocography (CTG) during labor aims to reach this goal as a non-invasive tool assessing fetal well-being [4]. CTG monitors uterine contractions (UC) and fetal heart rate (FHR). It helps professionals to detect newborn acidemia and allows them to intervene in a timely manner to prevent any damage by performing caesarean section or instrumental vaginal delivery. The interpretation of CTG is visual and, despite the existence of clinical guidelines offering a framework for assessing and managing intrapartum fetal monitoring patterns[5], it is subject to inter- and intra-observer

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variability [6,7]. In order to enhance the assessment of fetal well-being during labor, invasive second-line techniques such as fetal scalp blood sampling and ST analysis of the fetal ECG have been developed [8,9]. However, their effectiveness has been debated due to a lack of randomized studies demonstrating a reduction in fetal acidosis, and their use is not without any harm [10]. Recently, computerized CTG analysis systems based on state-of-the-art machine learning (ML) approaches have been developed to overcome the inter-observer variability [11,12].

In a previous work, we developed DeepCTG® 1.0 [13], a model able to predict fetal acidosis from CTG signals. DeepCTG® 1.0 is based on a logistic regression model fed with four features extracted from the last available 60 min of CTG signals (regardless of the mode of delivery, whether cesarean or vaginal): the minimum and maximum values of the FHR baseline, and the area covered by accelerations and decelerations. The Area Under the Curve (AUC) of the model is between 0.74 and 0.87 depending on the centers on which the model is validated. DeepCTG® 1.0 does not take into account clinical features, even if the probability of unfavorable neonatal outcomes is higher in cases of pathological pregnancies or vulnerable fetuses. Several studies have identified various maternal and fetal criteria as risk factors for neonatal acidemia such as fetal growth restriction (FGR), gestational diabetes or intra uterine infection [14–17].

In this study, we introduce DeepCTG®1.5, a computerized CTG system that predicts fetal acidemia from both CTG and clinical features. The primary objective of this study is to evaluate if adding clinical features improves the performance of the model.

Materials and methods

Datasets

We performed a retrospective multicentric study on two datasets: CTU-UHB and Beaujon. CTU-UHB is an open-access database with 550 intrapartum CTG recordings that were carefully selected from 9164 recordings collected between 2010 and 2012 in the obstetrics ward of the University Hospital in Brno, Czech Republic [18]. The Beaujon dataset contains 714 CTG recordings collected at Beaujon-APHP University Hospital (Clichy, France). Every delivery with an arterial pH level below 7.15 that occurred from January 2020 to December 2022 was included in the study. Additionally, for each delivery with a pH below 7.15, the most recent delivery with a pH above 7.15 was also included. For both centers, the CTG signals were recorded continuously until birth for vaginal deliveries or until a decision was made to perform a cesarean section. The CTG signals were captured using a doppler ultrasound probe placed on the mother's abdomen and for some cases in the CTU-UHB cohort with a fetal scalp electrode. All deliveries were after 37 weeks of gestation (WG).

For each CTG recording, both maternal and fetal characteristics were collected. The maternal parameters included age, parity, gestational diabetes, and hypertensive disorders of pregnancy (i.e. pre-eclampsia or gestational hypertension). The clinical data for the newborn included sex, birth weight, gestational age, Apgar score < 7 at five minutes, umbilical cord arterial pH. Obstetric data included the occurrence of meconium-stained amniotic fluid and delivery mode. Growth restriction was defined by a birth weight was below the 10th percentile and macrosomia by a birth weight above the 90th percentile on our local chart [19].

Statistical analysis

The primary outcome was the presence of severe acidemia, as defined by an arterial umbilical cord pH below 7.05 at birth. A descriptive analysis of the clinical features was performed: for quantitative variables, we present the mean and standard deviation, and for discrete variables the counts and percentages.

Univariate analyses were performed on the clinical features to

compare both groups using parametric and non-parametric tests if appropriate. Secondly, a multivariate analysis was conducted with clinical features with p-values less than 0.20, as well as four CTG features extracted using the methodology described in DeepCTG® 1.0 [13] (minimum and maximum value of the baseline, area covered by accelerations and decelerations). These four variables were the best performing features in univariate analysis and were easily explainable. We did not incorporate uterine contractions because of the large rate of missing data in Beaujon dataset. Variables with p-values > 0.2, but with a widely recognized association with fetal hypoxia were kept in the model as well. The odds ratios are reported with their 95 % CI.

Prediction model DeepCTG®1.5

The prediction model DeepCTG® 1.5 is a logistic regression model fed with the CTG and clinical features in the multivariate analysis. We performed both a cross-center and a k-fold cross-validation. For the cross-center validation, we trained the model on a dataset (Beaujon or CTU-UHB) and validated it on the other. In the k-fold cross validation, all cases in both datasets were gathered and split into 5 folds. Then, for every fold, the model is trained on the 4 other folds and validated on it.

The performance of the model was assessed using the area under the curve (AUC) with a 95 % CI.

All the statistical analyses were performed on R 4.4.0 software.

Ethical approval

This work had the approval of Robert Debré hospital's Ethical committee (IRB 00006477).

Results

Description of datasets

The study included 1264 cases from two centers: CTU-UHB (550 cases) and Beaujon (714 cases). The overall prevalence of severe acidosis across both centers was 7.9 %. The average maternal age was 29.7 years in both centers. Gestational diabetes was more prevalent in Beaujon dataset (16.7 %) compared to CTU-UHB (6.7 %), while the incidence of hypertension disorder was 3.6 % in Beaujon dataset and 3.1 % in CTU-UHB. The average gestational age at birth was 39.6 WG in Beaujon dataset and 40.0 WG in CTU-UHB. The cesarean rate is higher in the CTU-UHB dataset (24 % vs 9 % in Beaujon dataset). Among the newborns, 17.9 % were classified as FGR in Beaujon dataset, compared to 13.3 % in CTU-UHB. 26.8 % of pregnancies had a meconium amniotic fluid in Beaujon dataset compared to 11.6 % for CTU-UHB. Table 1 summarizes the maternal and fetal characteristics in both datasets.

Risk factors of fetal acidemia

We classified the cases based on their acidemia status, resulting in 100 cases of severe acidemia and 1164 cases without hypoxia. Although the occurrence of hypertension disorders appeared higher in the severe acidemia group, the difference was not statistically significant (p = 0.22). The mean maternal age was 29.7 years in both groups (p = 0.82). Gestational diabetes was present in 15.0 % of cases with severe hypoxia and 12.2 % of cases without acidemia, showing no significant difference (p = 0.31). Newborns with severe acidemia tended to have a lower birth weight with 21.0 % classified as FGR compared to 15.5 % in the other group, but this difference was not significative (p = 0.12). The presence of meconium-stained amniotic fluid is only features that was significantly associated to newborn acidemia (p = 0.03). Additionally, there was no significant difference between the groups in terms of mean birth weight, incidence of macrosomia, sex distribution, or mean gestational age at birth. A detailed comparison of the maternal and fetal characteristics between the groups is presented in Table 2.

Table 1

Maternal and fetal features.

	CTU-UHB	Beaujon
Total number of cases	550	714
Maternal Clinical Data		
Age in years (std)	29.7 (4.5)	29.7 (5.2)
Primiparous	68.4 %	57.0 %
Gestational diabetes	6.7 %	16.7 %
Hypertension disorder	3.1 %	3.6 %
Meconium amniotic fluid	11.6 %	26.8 %
Delivery mode		
Vaginal	48 %	76 %
Operative	28 %	15 %
Cesarean	24 %	9 %
Fetal outcome		
pH < 7.05	7.8 %	8.0 %
$7.05 \leq pH < 7.15$	12.5 %	45.5 %
$pH \ge 7.15$	79.6 %	46.5 %
Apgar $5' < 7$	8.2 %	10.5 %
Birth weight (Kg): mean (std)	3.4 (0.5)	3.3 (0.5)
Fetal growth restriction	13.3 %	17.9 %
Macrosomia	7.1 %	5.9 %
Sex (rate of female)	46.8 %	48.4 %
Term (SA): mean (std)	40 (1.1)	39.6 (1.5)

Table 2

Comparisons of the maternal and fetal characteristics between groups.

	Severe acidemia (pH <7.05)	No severe acidemia (pH≥ 7.05)	p- value
Total number of	100	1164	
cases			
Maternal Clinical			
Data			
Maternal age (std)	30 (5.33)	30 (4.87)	0.82
Gestational diabetes	15.0%	12.2%	0.31
Hypertension	5.0%	3.3%	0.22
disorder			
Meconium amniotic	32.0%	19.1%	0.03
fluid			
Fetal outcome			
Birth weight(g):	3327 (471)	3313 (488)	0.79
mean (std)			
Fetal growth	21.0%	15.5%	0.12
restriction			
Macrosomia	4.0%	6.7%	0.59
Sex (rate of female)	48.5%	47.2%	0.89
Term (WG): mean	39.7 (1.15)	39.8 (1.40)	0.92
(std)			
WG week of gestation			

In the multivariate analysis, deceleration showed a significant association with newborn acidemia (OR = 1.09, 95 % CI 1.04 - 1.11, p < 0.001). Among clinical features, maternal age and diabetes did not significantly influence outcomes, while meconium in the amniotic fluid significantly increased the odds of adverse outcomes (OR = 2.10, 95 %

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Multivariate analysis of newborn acidemia risk fact

OR	CI 95 %	p-value
0.99	0.98 - 1.02	0.77
1.03	0.99 - 1.08	0.06
1.13	1.05 - 1.20	0.24
1.08	1.04-1.11	< 0.001
1.03	0.99-1.09	0.17
1.33	0.73-2.32	0.33
1.14	0.57 - 2.15	0.69
1.98	0.61-5.29	0.20
2.10	1.24-3.49	< 0.001
	OR 0.99 1.03 1.13 1.08 1.03 1.33 1.14 1.98 2.10	OR CI 95 % 0.99 0.98–1.02 1.03 0.99–1.08 1.13 1.05–1.20 1.08 1.04–1.11 1.03 0.99–1.09 1.33 0.73–2.32 1.14 0.57–2.15 1.98 0.61–5.29 2.10 1.24–3.49

FHR fetal heart rate.

CI 1.24–3.49, p < 0.001). Hypertension disorders were not significantly associated with the outcome (1.98, 95 % CI 0.61–5.29, p = 0.20) (Table 3.).

Logistic regression DeepCTG®1.5

The model fed with clinical features only (maternal age, FGR, diabetes, hypertension disorder, and meconium amniotic fluid) reached an AUC of 0.61 (0.50–0.67) when trained on CTU-UHB and tested on Beaujon and of 0.53 (0.44–0.62) when trained on Beaujon and tested on CTU-UHB. CTG features demonstrated a better predictive performance with an AUC of 0.73 (0.65–0.79) and 0.70 (0.60–0.80) under similar cross-validation conditions. In cross-center validation, the integration of all features has a limited impact on the AUCs (0.71 on both datasets). In k-fold validation, the AUC increased from 0.74 (0.68–0.80) to 0.77 (0.71–0.83) when integrating the clinical features (Table 4, Fig. 1). The 95 % confidence intervals on the AUCs are wide.

Discussion

In this study, we introduced DeepCTG®1.5, a logistic regression model that combines both clinical and CTG features to predict severe fetal acidemia during labor. In a cross-center validation, the AUC was 0.71 on Beaujon dataset and 0.71 on CTU-UHB dataset, and in a k-fold validation approach it reached 0.77 (compared to 0.74 with a model using the CTG features only). The integration of clinical variables in the model tends to increase the AUC, but this improvement is not significant given the width of the confidence intervals on AUC values.

Most existing studies related to computerized CTG build prediction models based on CTG features only, and a large part of them validate the model on the open-source CTU-UHB dataset, enabling a comparison of the results. For example, Gatellier et al.[23] used a multivariate logistic regression to predict pH below 7.10, finding an AUC of 0.72. However, the same dataset was used for evaluation and testing, which could introduce a bias. Abry et al [24] used another machine learning algorithm to predict pH < 7.05, achieving an AUC of 0.70. The SisPorto and OxSys computerized CTG models [20–22] are built and evaluated on private datasets. The model by Petrozziello et al. [25] is trained on a significantly larger dataset of over 35,000 cases and is based on more advanced deep learning methods. It reports an AUC of 0.82, but those results are biased because cases of moderate acidemia are excluded from the dataset.

One main identified limit of those approaches is that they do not integrate clinical parameters such as maternal and obstetrical factors, that are known to influence newborn outcome and thus CTG interpretation [26]. For instance, gestational diabetes mellitus and mean blood glucose are significantly correlated with an increase in baseline and a decrease in short-term variability [27]. The presence of hypertension disorder and other placenta –mediated complication such us FGR has also been identified as a risk factor for fetal acidosis [14,17,22]. Fetuses

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Evaluation and validation of DeepCTG[@] 1.5. AUC with 95% confident intervals.

	Validation dataset			
	Beaujon	CTU-UHB	All datasets (k-	
	(trained on	(trained on	fold cross-	
	CTU-UHB)	Beaujon)	validation)	
Clinical features (maternal age,FGR, diabetes, hypertension disorder, meconium amniotic fluid)	0.61 (0.50–0.67)	0.53 (0.44–0.62)	0.61 (0.54–0.68)	
Cardiotocography features	0.73	0.70	0.74	
	(0.65–0.79)	(0.60–0.80)	(0.68–0.80)	
CTG + Clinical features	0.71	0.71	0.77	
	(0.65–0.80)	(0.61–0.80)	(0.71–0.83)	

FGR fetal growth restriction. CTG Cardiotocography.



Fig. 1. Receiver-operating characteristic curves of DeepCTG $^{@}$ 1.5 on all cases, k-fold cross-validation (outcome: pH < 7.05).

with FGR had less acceleration and increase risk of late decelerations [28]. Nulliparity is also a risk factor with prolonged duration of labor and delivery and that increases the fetus' exposure to the risk of hypoxia [14,29]. A few studies aimed at building prediction models based on clinical parameters only. A large multi-center retrospective study in China developed a model using both antenatal and delivery features and demonstrated good accuracy to predict fetal asphyxia defined by APGAR score < 7 with pH < 7.05 (AUC = 0.73) [17]. However, the model included visual detection of abnormal FHR in the logistic regression, which had the highest odds ratio 4.75 (3.74–5.8). Similar results were reported in a large retrospective study with 5667 newborns using antepartum and intrapartum features and identified key predictors including gestational age, nulliparity, previous cesarean delivery, maternal diabetes, spontaneous labor onset, and meconium-stained amniotic fluid (AUC = 0.66) [29]. A. Houzé de l'Aulnoit et al. developed a multivariate model incorporating clinical features (nulliparity, term, sex, time between the end of recording and delivery) and automatically selected CTG features. Their model's discriminant ability (AUC = 0.79) is comparable to ours [30].

In our study, we found no maternal or fetal criteria associated with severe acidosis except for meconium amniotic fluid, as described in literature [14,15,17,22,29]. Thus, a prediction model using clinical features only has a poor performance. One possible explanation for this finding is the limited data available [31]. The combination of antepartum risk factors and intrapartum CTG features improved slightly the performance of the model (AUC = 0.77) compared with CTG features only (AUC = 0.74) in the k-fold cross-validation approach. This result does not hold in the cross-center validation approach, suggesting that further work will be needed to build a model that integrates clinical features and generalizes well to new centers. Surprisingly, we found that a higher acceleration area is linked to an increase in the risk of fetal hypoxia (even if this link is not statistically significant), which was the opposite of what we expected [5]. We hypothesize that the high instability of the FHR signal during the last phase of delivery harms the quality of the baseline estimate.

No RCTs have validated algorithms using both clinical and signal features, though some target CTG-only systems. The largest RCT, the INFANT study [32] with over 47.000 deliveries, showed no improvement in neonatal outcomes. Meta-analyses suggest that computerized CTG systems do not affect outcomes like acidosis or APGAR scores [33,34], raising questions about their clinical integration and the

suitability of RCTs for such validations due to cost and duration.

Our work had several limitations. First it was built on two datasets that are both biased: the CTU-UHB dataset is formed with cases extracted from a larger cohort, and in Beaujon dataset half of the cases have a pH lower than 7.15. A validation of the system on another retrospective cohort would be needed to confirm the performance of the system. Secondly, several features known to be linked to newborn acidemia are not included in the study. The uterine contractions are not used in the set of CTG features. Regarding the clinical features, the set of features integrated in the study is limited because we had to include variables that are available in the two datasets. We could not then evaluate other blood gas parameters or other clinical characteristics that are involved in a poor neonatal outcome, such as BMI, history of caesarean or intrauterine infection [14,29,35]. We also did not consider the use of oxytocin during labor, which can contribute to adverse fetal conditions if the uterus does not relax properly [36]. Also, on a physiological point of view, the different stages of labor should be analyzed separately. However, we showed in a previous work [13] that on our cohort, training and validating according to the mode of delivery did not impact the performance of the model, suggesting that both stages could be analyzed in the same way. Automatic detection of the labor stage from the signal is challenging too. This point could be investigated further in future work. Another limitation is the relatively small sample size of the training datasets as well as the small number of cases of severe acidemia, given the low arterial pH threshold (7.05) we used to define this group, following other publications [24]. Because of this, we only defined a training and a validation set and we did not define an independent test set, possibly introducing a bias in the evaluated performance. The small sample size also limited the complexity of machine learning or deep learning methods. The logistic regression employed is a powerful tool for developing prediction models, but it might not effectively capture complex interactions between features. More advanced methods like deep learning models can learn more complex nonlinear relationships, however they require large datasets to be trained in a robust way [12,37]. By incorporating clinical parameters into these powerful automated models their ability to screen for fetal hypoxia and newborn acidemia might be enhanced. Further work aims also to define the desired outcomes, other than pH, [38] and determining the optimal threshold for intervention. Practitioners must establish a target false positive rate, which will inherently dictate an acceptable true positive rate, to avoid unnecessary interventions.

Conclusion

While CTG features alone show strong predictive power, integrating clinical features improves the model accuracy for predicting newborn acidemia, although slightly. Future research will focus on deploying more sophisticated machine learning techniques to effectively combine clinical and cardiotocography features, a process that will necessitate large training datasets.

Authorship

The conception and design of the study EM, IB, JS, EL; Acquisition of data JV, IB, IA; Writing – Original Draft Preparation, EM, IB; Project Administration JM; Drafting the article or revising it critically for important intellectual content EM, IB, IA, EH, JV, JS, EL. All the authors gave their final approval of the version to be submitted.

CRediT authorship contribution statement

Elena Menzhulina: Writing – review & editing, Writing – original draft, Conceptualization. Juliette Vitrou: Writing – review & editing, Investigation, Data curation. Jade Merrer: Writing – review & editing, Project administration, Methodology, Investigation. Emilia Holmstrom: Writing – review & editing, Methodology, Investigation. Erwan Le Pennec: Writing – review & editing, Visualization, Validation, Supervision, Software, Methodology, Investigation, Conceptualization. Julien Stirnemann: Writing – review & editing, Validation, Supervision, Software, Methodology, Investigation, Formal analysis, Conceptualization. Imane Ben M' Barek: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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