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Re-evaluating fetal scalp pH thresholds: An examination of fetal pH variations during labor

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Abstract

Introduction: Since the 1970s, fetal scalp blood sampling (FSBS) has been used as a second-line test of the acid–base status of the fetus to evaluate fetal well-being during labor. The commonly employed thresholds that delineate normal pH (>7.25), subnormal (7.20–7.25), and pathological pH (<7.20) guide clinical decisions. However, these experienced-based thresholds, based on observations and common sense, have yet to be confirmed. The aim of the study was to investigate if pH drop rate accelerates at the common thresholds (7.25 and 7.20) and to explore the possibility of identifying more accurate thresholds.

Material and methods: A retrospective study was conducted at a tertiary maternity hospital between June 2017 and July 2021. Patients with at least one FSBS during labor for category II fetal heart rate and delivery of a singleton cephalic infant were included. The rate of change in pH value between consecutive samples for each patient was calculated and plotted as a function of pH value. Linear regression models were used to model the evolution of the pH drop rate estimating slope and standard errors across predefined pH intervals. Exploration of alternative pH action thresholds was conducted. To explore the independence of the association between pH value and pH drop rate, multiple linear regression adjusted on age, body mass index, parity, oxytocin stimulation and suspected small for gestational age was performed.

Results: We included 2047 patients with at least one FSBS (total FSBS 3467); with 2047 umbilical cord blood pH, and a total of 5514 pH samples. Median pH values were 7.29 1h before delivery, 7.26 30 min before delivery. The pH drop was slow between 7.40 and 7.30, then became more pronounced, with median rates of 0.0005 units/min at 7.25 and 0.0013 units/min at 7.20. Out of the alternative pH thresholds, 7.26 and 7.20 demonstrated the best alignment with our dataset. Multiple linear regression revealed that only pH value was significantly associated to the rate of pH change.

Conclusions: Our study confirms the validity and reliability of current guideline thresholds for fetal scalp pH in category II fetal heart rate.

Abbreviations: CTG, cardiotocography; FHR, fetal heart rate; FSBS, fetal scalp blood sampling.

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KEYWORDS

abnormal fetal heart rate, fetal monitoring, fetal scalp blood sampling, labor, scalp pH

1 | INTRODUCTION

Accurate risk prediction of neonatal acidosis is important for facilitating timely and informed decisions for labor management. Predicting the risk of acidosis, commonly defined as an arterial cord pH <7.10 at birth, can help healthcare providers to intervene promptly and appropriately, potentially reducing adverse neonatal outcomes associated with acidosis.¹

The management of labor relies on the interpretation of fetal well-being through cardiotocography (CTG) analysis. For many decades, the assessment of pH levels via fetal scalp blood sampling (FSBS), has served as a secondary diagnostic measure particularly in cases of category II fetal heart rate (FHR).^{2,3} According to the American College of Obstetricians and Gynecologists' classification, category II FHR tracings are abnormal but not predictive of abnormal fetal acid–base status and do not require immediate resuscitation and preparation for delivery (category III).³

While an ongoing debate surrounds the utilization of FSBS, guidelines in numerous developed countries have consistently established thresholds for defining normal, subnormal and pathological pH levels, along with the corresponding recommended course of action.^{2,4–8} A pH level above 7.25 is categorized as normal, permitting the ongoing course of labor. In such cases, a pH retest is warranted within 1 h, only if still indicated by the cardiotocograph trace. A pH level between 7.25 and 7.20 is considered subnormal or borderline and guidelines agree that it is recommended to repeat sampling within 30 min. When the pH level drops below 7.20, a critical threshold is breached, indicating the need for delivery.^{2,4–7,9} These recommendations are based on clinical observations, common sense and the interpretation of studies published between 1964 and 1967.^{10–14} The recommendations to repeat the FSBS within 30 min for a pH level between 7.25 and 7.20 and to expedite the birth for a pH level below 7.20 rest on the presumption that, given an abnormal FHR, a pH drop of a maximum of 0.10 units/30 min can be anticipated.¹¹ Nevertheless, this supposition, rooted in clinical intuition, remains unvalidated by direct evidence. A study repeating measurements of FSBS pH during labor in fetuses with suspicious heart rates is of course ethically untenable due to the invasiveness of scalp pH testing. Understanding how fetal pH changes during labor, particularly in the presence of abnormal FHR patterns, is crucial to improve risk assessment and decision-making.

Given the limited knowledge on how quickly fetal pH drops over the course of labor, particularly in fetuses with a category II FHR, the aim of our study was to fill this knowledge gap by observing and quantifying these variations. The objective of this study was to assess whether the pH drop rate accelerates at the commonly used thresholds (7.25, 7.20) and whether more accurate thresholds can be identified for clinical practice.

Key message

The fetal scalp pH intervention thresholds during labor were defined empirically 50 years ago. This study provides a scientific basis for using those thresholds by confirming their validity and reliability for fetal scalp pH in category II fetal heart rate.

2 | MATERIAL AND METHODS

We included all patients at term (≥ 37 weeks), who had at least one FSBS during labor for a category II FHR³ and an arterial cord pH at delivery of a singleton cephalic infant between the June 29, 2017 and July 9, 2021 at a tertiary maternity unit in Paris. All women giving birth at the study center were informed that their data were computerized and could be used to evaluate medical practices. Our study was retrospective in a clinical setting.

According to the local protocol, a FSBS was indicated when a category II FHR tracing persisted for more than 60 min. FSBS is only performed when the fetus is in a cephalic presentation with ruptured membranes, and cervical dilation of at least 2 cm, allowing the introduction of the amnioscope. If these conditions are met, 20 μ L of blood is sampled from the fetus's scalp by Ob-Gyn residents. This is done using a capillary tube, after cleaning the scalp with betadine, drying it, and applying paraffin. In cases of category II FHR at full dilation, the standard practice of the department is to obtain a sample, even if the fetal presentation is advanced. This helps assess the potential duration of pushing before considering instrumental delivery. The sample is then immediately analyzed on a pH-meter in the delivery room. If its result is between 7.25 and 7.20 another sample is performed within 30 min regardless of the FHR tracing. The local protocol aligned with the national guidelines.¹⁵ For all deliveries a neonatal arterial cord pH is performed at birth regardless of neonatal status.

Patients with missing data on FSBS or arterial cord pH results or for whom CTG recording was unavailable were excluded from the analysis.

All data were extracted from the computerized medical records and individually reviewed for consistency. This included cross-checking the timing of FSBS during labor with corresponding CTG tracing to ensure the accurate representation of FSBS indications, rather than questioning the initial determination of the indications. Pre-existing maternal characteristics, age, prepregnancy body mass index (BMI), parity, pre-existing medical condition; pregnancy characteristics, obstetrical pathology, suspected small for gestational age (SGA, defined by a <5th percentile estimated fetal weight for

gestational age) or large for gestational age; and delivery characteristics, gestational age, mode of onset of labor, drugs during labor, type of membrane rupture and color of amniotic fluid were recorded.

We first described the characteristics of the population. Then, quartiles of pH values were calculated for each 10-min interval before delivery, up to 5 h before delivery, and represented in a box plot graph.

For each patient, the rate of change in pH value (r_i) was calculated between two consecutive samples as $r_0 = (pH_{t_{i0}} - pH_{t_{i-1}}) / (t_{i0} - t_{i-1})$. Rates for all consecutive pairs and all patients were plotted on a graph as a function of the pH value (to two decimal places). Median, mean, and standard deviation of the rate of change in pH value were also plotted. Both FSBS and umbilical cord arterial pH measurements were utilized to assess the rate of change in pH values during labor. FSBS provided real-time measurements from the fetal scalp, while umbilical cord arterial pH measurements were performed at birth. This comprehensive approach allowed us to gain a more complete understanding of fetal acid-base status throughout labor and delivery.

In order to model the evolution of the rate of pH drop in our study population, we utilized linear regression models between the commonly used action thresholds for scalp pH values of 7.25 and 7.20. We estimated the slope and standard errors for the three pH intervals (7.35–7.25, 7.25–7.20, and 7.20–7.10) while assuming residual normality.

Then, we aimed to identify more accurate thresholds. We systematically explored all possible combinations of alternative pH action thresholds while maintaining the assumption of three intervals

of interest. The goal was to pinpoint alternative thresholds that minimize standard errors, providing a more accurate data representation. A lower standard error signifies that our estimated pH drop rates are more consistent with our data and therefore reliable, whereas a higher standard error indicates greater variability and uncertainty in our estimates. Our constraints were as follows: the minimal threshold values ranged between 7.15 and 7.25, with a step size of 0.01; the maximal threshold values ranged between 7.20 and 7.35, with a step size of 0.01; and the top boundary values ranged between 7.26 and 7.36, with a step size of 0.01.

This systematic exploration enabled us to pinpoint the specific combination of pH thresholds that effectively minimized standard errors, ensuring a more accurate and reliable representation of the underlying pH drop rate dynamics. As before, we applied a linear regression to each 1035 possible combinations. We selected the best combination as the one that minimized the mean standard error. We then plotted the rate of change in pH values between the best combination of thresholds and evaluated the rate of change in pH between these thresholds.

In order to investigate the possibility of multiple notable changes in pH slope (i.e., >2 changes in the rate of pH change), we expanded our analysis to explore more complex scenarios. We did this by testing various combinations of alternative pH action thresholds. Instead of just having three pH ranges as before, we imposed four or five pH ranges on our data. This allowed us to look at the pH changes within a greater number of smaller ranges, providing a more detailed view of how pH changes could potentially vary at different points during labor.

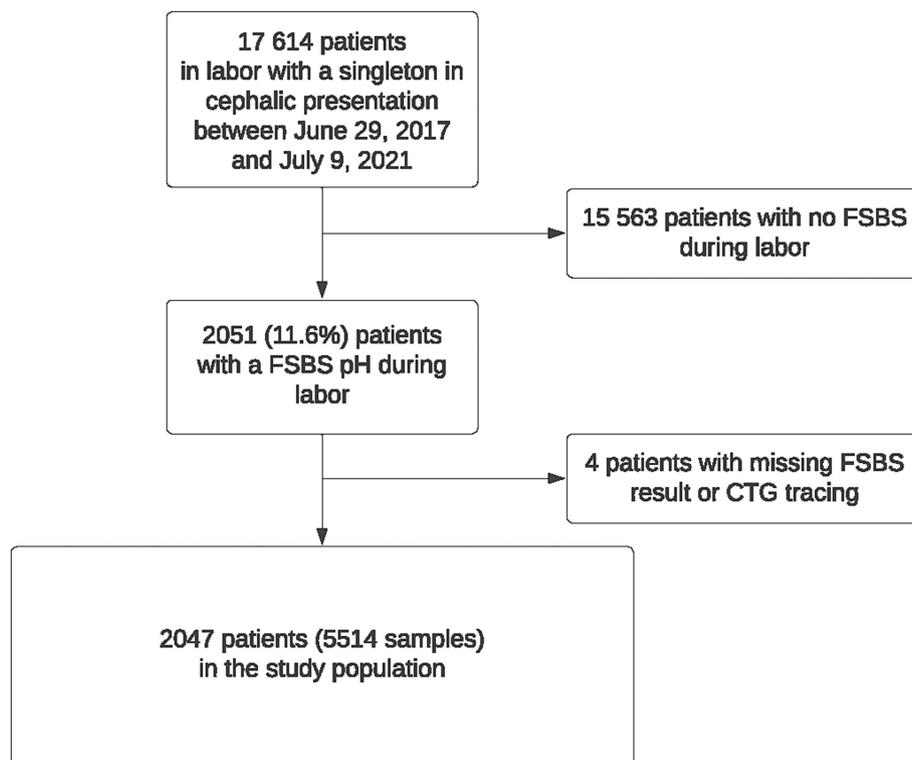


FIGURE 1 Flow chart.

Sensitivity analyses were performed by repeating these analyses while excluding the arterial cord pH and the cases with only one FSBS performed during labor ($n=830$ patients and 2250 FSBS samples).

Finally, to explore the independence of the association between pH value and rate of pH change, we performed multiple linear regression while adjusting for age, body mass index, parity, suspected small for gestational age, and meconial stained liquid. Given that multiple pH samples were obtained from the same patient, the interdependence of these measurements was accounted for by using standard errors clustered by patient. This approach acknowledges potential inpatient correlation, thus providing more robust statistical inference.

All analyses were performed using the Python 3.9.7.

3 | RESULTS

Among the 17 614 patients who delivered a singleton in cephalic presentation after a labor in the study center during the study period, 2047 (11.6%) had at least one FSBS (total FSBS 3467) and met our inclusion criteria, so with 2047 umbilical cord blood pH, we had a total of 5514 pH samples (Figure 1).

Median age of the study population was 33.5 years, interquartile range (30.5–37.2), median BMI 22 kg/m² (20–25), 75% of the patients were nulliparas and 9.2% had a scarred uterus (Table 1).

The rate of suspected small for gestational age fetus was 4.7% in the study population, and the rate of suspected large for gestational age 4.5%. Median gestational age at delivery was 40 weeks interquartile range (39–41), oxytocin was used in 71.0%, and artificial rupture of the membranes in 42.0% (Table 1). Most patients had one FSBS during labor (59.4%) and 22.8% had two FSBS during labor (Table 1).

Figure 2 shows the fetal pH values in the 5 h prior delivery, the last pH (time 0) value being the cord pH. One hour before delivery, median pH was 7.30 and 30 min before delivery median pH was 7.26.

Figure 3 and Table 2 report the rate of change in pH value between 7.35 and 7.10. Figure 3A describes the median, mean and standard deviation of change without any imposed regression model. The pH tended to drop steadily and slowly between 7.35 and 7.27, then the drop seemed more pronounced, reaching respectively a median and 95th percentile rate of 0.0005 units/min (0.0136 units/30 min) and 0.0045/min (0.1354 units/30 min) at 7.25; and 0.0013 units/min (0.0400 units/30 min) and 0.0095/min (0.2856 units/30 min) at 7.20.

Figure 3B shows the linear regression results after imposing the constraints of the thresholds described in literature to our data (i.e. 7.25 and 7.20). The median change of pH value was insignificant (0.0000/min) between 7.35 and 7.25, then the pH dropped by 0.0007 unit/min between 7.25 and 7.20 and dropped by 0.0020 units/min between 7.20 and 7.10; thus, confirming that the drop was more pronounced after 7.20.

TABLE 1 Pre-existing, obstetrical and labor characteristics of the study population.

	Study population N = 2047	
	n	(%)
Pre-existing maternal characteristics		
Age, year, median [IQR]	33.5	[30.5–37.2]
BMI, kg/m ² , median [IQR]	22	[20–25]
Parity		
Nulliparous	1536	(75.0)
Multiparous without a scarred uterus	323	(15.8)
Multiparous with a scarred uterus	188	(9.2)
Pre-existing medical condition		
At least one condition	262	(12.8)
Autoimmune pathology	185	(9.0)
History of thromboembolic disease	20	(1.0)
Diabetes	26	(1.3)
Hypertension	15	(0.7)
Obstetrical pathology		
Threatened preterm birth	42	(2.0)
Preterm premature rupture of the membranes	241	(11.8)
Gestational hypertension	53	(2.6)
Pre-eclampsia	52	(2.5)
Gestational diabetes	263	(12.9)
Suspected SGA	96	(4.7)
Suspected LGA	92	(4.5)
Gestational age at delivery	40	[39–41]
Labor characteristics		
Oxytocin use	1454	(71.0)
Antibiotics use	941	(46.0)
Type of membrane rupture		
Spontaneous during labor	497	(24.3)
Artificial	859	(42.0)
Meconial stained fluid	755	(36.9)
Number of FSBS		
1	1217	(59.4)
2	466	(22.8)
3	221	(10.8)
4	88	(4.3)
5	36	(1.8)
6	11	(0.5)
7	7	(0.3)
8	1	(0.05)
Median pH at delivery	7.21	[7.16–7.27]

Abbreviations: BMI, body mass index; IQR, interquartile range; LGA, large for gestational age; SGA, small for gestational age.

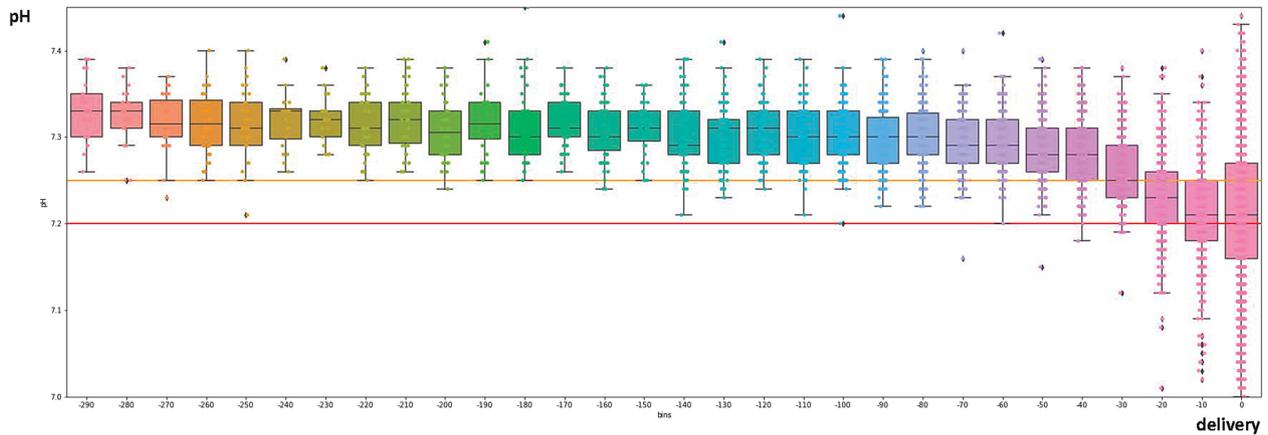


FIGURE 2 Fetal pH values in the 5h before delivery ($n=2047$ patients and 5514 samples).

Of the 1035 threshold combinations tested, the one that minimized the mean standard error was that with thresholds of 7.26 and 7.20. Figure 3C. shows the linear regression after imposing these thresholds. With these thresholds, the median change of pH value was insignificant (0.0000/min) between 7.35 and 7.26, then the pH dropped by 0.0005 unit/min between 7.26 and 7.20 and dropped by 0.0020 units/min between 7.20 and 7.10. The analyses testing more thresholds (4 and 5) did not show any change in the slopes of pH (data not shown).

The sensitivity analyses yielded similar results concerning the rate of change in pH value (Appendices S1 and S2) and the alternative thresholds.

The multiple linear regression model, which examined the relationship between pH change and various factors such as pH value, maternal age, body mass index, parity, oxytocin stimulation during labor, and suspected small for gestational age, revealed that only the pH value had a significant impact on the explained variance. The other variables did not demonstrate a substantial contribution to the model's power (Table 3).

4 | DISCUSSION

This observational study showed that in patients with a category II FHR during labor, the lower the fetal pH value, the faster it dropped. This underscores the need for proactive birth anticipation in order to reduce the risk of neonatal acidosis, when low scalp pH is detected. The commonly used pH thresholds of 7.25 and 7.20 showed a significant increase in the rate of pH change below these values. Our analysis identified a threshold combination of 7.26 and 7.20, which is closely aligned with the current guideline of 7.25, further reinforcing its validity in clinical practice. This slight difference in the threshold does not detract from the clinical relevance of our findings, but rather emphasizes the robustness of existing recommendations. Notably, the multiple linear regression model indicated that only the pH value significantly influenced the rate of fetal pH change in patients with a category II FHR tracing.

Most existing studies on pH values during labor have focused on normal values, defined as the pH values of fetuses born vaginally with normal Apgar scores, and comparisons between FSBS pH and continuous scalp tissue pH.^{10,11,14,16} The study by Weber et al. in 1979, included 64 newborns with an Apgar score of 9 or 10 at birth, and recorded the tissue pH values at 30, 60, 90, 120, 240, and 300 min before delivery. This study showed that 300 min before delivery mean pH value was 7.38 ± 0.12 decreasing to 7.30 ± 0.12 at delivery, resulting in a global drop by 0.0003/min. Although the tissue pH values reported were higher than previously described for scalp pH,^{11,14} the decrease appears to be lower than in our study. This difference is expected as the study by Weber et al. included only a small number of patients with good outcomes and lacked information on FHR during labor and labor duration.

The study by Bretsher and Saling in 1967 involved 306 cephalic term infants born in a vigorous state, with no cases of fetal distress during labor among 1500 studied fetuses.¹⁰ The indication for FSBS were passage of meconium and/or alteration of the FHR with a fall below 120bpm or an acceleration above 150bpm. The normal pH at onset of labor was 7.33 ± 0.066 and the normal pH at birth 7.27 ± 0.073 , resulting in a global drop of 0.06. However, labor duration was not mentioned, preventing us from obtaining the rate of pH drop. The lower pH described at birth was 7.20, whereas 25% of children in our study were born with a pH below 7.16. Our results are not directly comparable, as we are addressing a different question: Bretsher and Saling aimed to define normal pH in fetuses, while we sought to describe the actual rate of pH drop in fetuses with a category II FHR during labor. Understanding pH change during labor in fetuses with suspicious FHR is important as it can impact labor and delivery management, unlike in fetuses with a normal FHR.

Our study results reinforce the current guidelines and thresholds used in clinical practice. We found that the pronounced drop in pH occurs at a threshold of 7.26, which is very close to the widely accepted threshold of 7.25. This close alignment between our findings and existing guidelines provides additional evidence supporting the validity and reliability of the current recommendations. The fact that

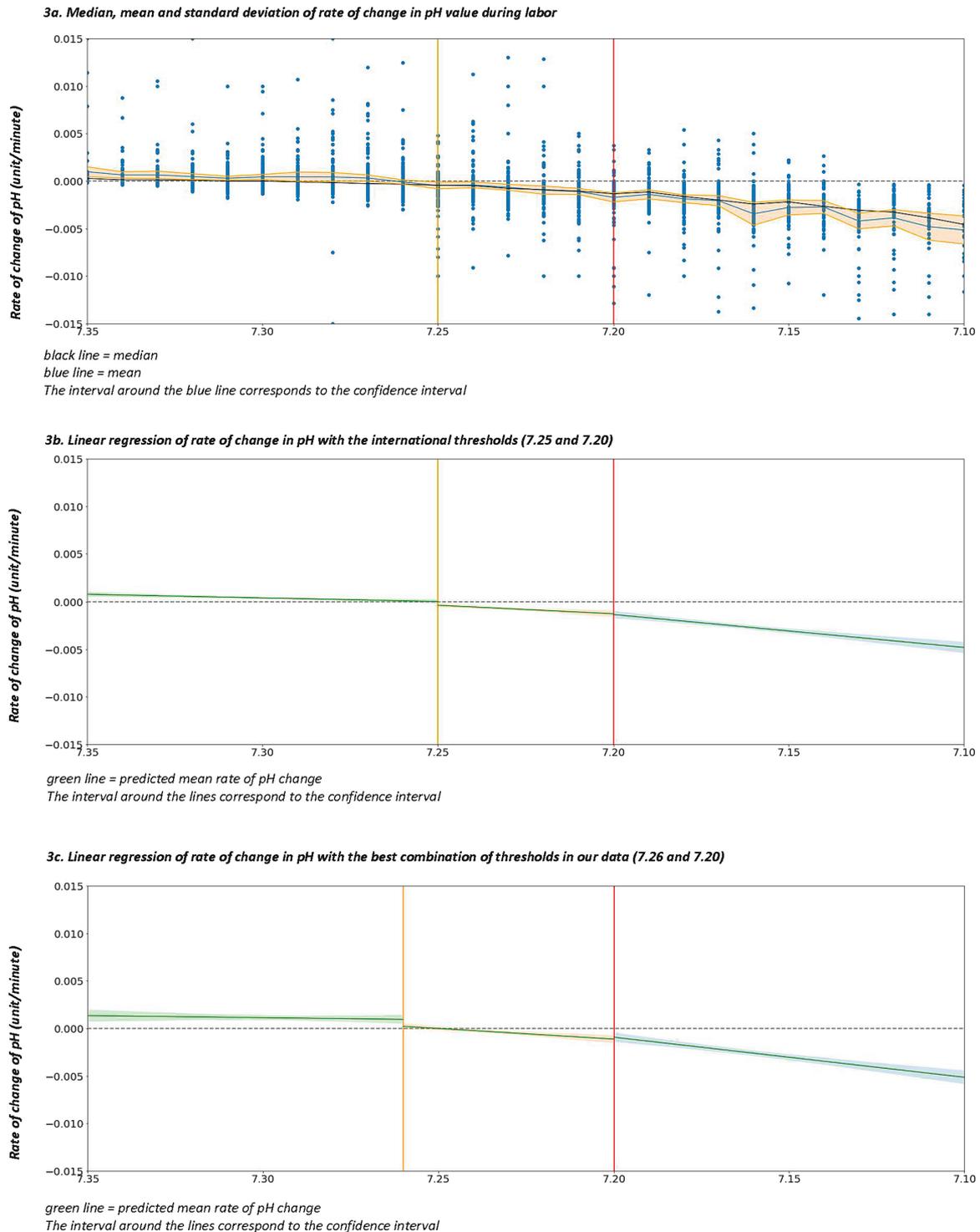


FIGURE 3 Rate of change in pH value during labor. (a) Median, mean and standard deviation of rate of change in pH value during labor. (b) Linear regression of rate of change in pH with the international thresholds of 7.25 and 7.20. (c) Linear regression of rate of change in pH with the best combination of thresholds in our data.

our study confirms the threshold of 7.25 for significant pH drop is crucial, as it lends further credence to the use of this value in clinical decision-making. Our results, therefore, underscore the importance of adhering to established guidelines and provide valuable insights for practitioners when managing labor and delivery in cases of suspicious FHR.

Future studies should continue to examine and validate these thresholds to ensure optimal care for both the mother and the fetus during labor and delivery. The problem of insufficient scientific evidence for thresholds is also present for scalp lactates.^{17,18} Thus, it seems crucial to conduct similar studies in populations where scalp lactates are performed. Future research should also aim to validate

TABLE 2 Median, 5th and 95th percentile rate of pH value change per minute according to pH value.

pH value	Median rate of pH value change per minute	Fifth percentile of rate of change per minute	95th percentile of rate of change per minute
7.35	0.0010	0.0080	0.0000
7.34	0.0006	0.0040	-0.0003
7.33	0.0006	0.0042	-0.0004
7.32	0.0005	0.0034	-0.0009
7.31	0.0003	0.0030	-0.0011
7.30	0.0004	0.0041	-0.0011
7.29	-0.0004	0.0042	-0.0013
7.28	-0.0004	0.0069	-0.0014
7.27	-0.0003	0.0070	-0.0018
7.26	-0.0001	0.0040	-0.0021
7.25	-0.0005	0.0035	-0.0045
7.24	-0.0004	0.0052	-0.0040
7.23	-0.0007	0.0022	-0.0031
7.22	-0.0010	0.0035	-0.0050
7.21	-0.0011	0.0033	-0.0054
7.20	-0.0017	0.0016	-0.0095
7.19	-0.0014	0.0018	-0.0052
7.18	-0.0019	0.0016	-0.0068
7.17	-0.0021	0.0027	-0.0086
7.16	-0.0035	0.0027	-0.0192
7.15	-0.0028	0.0020	-0.0082
7.14	-0.0027	0.0015	-0.0069
7.13	-0.0042	-0.0011	-0.0124
7.12	-0.0039	-0.0006	-0.0113
7.11	-0.0048	-0.0005	-0.0139
7.10	-0.0051	-0.0008	-0.0140

TABLE 3 Linear regression and multiple linear regression models analyzing the association between pH change and pH value, maternal age, body mass index, parity, oxytocin stimulation and suspected small for gestational age.

Variables	Coefficient	[95% CI]	Coefficient	95% CI
pH value	-0.024	-0.026 to -0.022	-0.024	-0.025 to -0.022
Age			1.1×10^{-5}	-1.3×10^{-5} to 3.42×10^{-5}
BMI			-2.0×10^{-5}	-4.6×10^{-5} to 0.6×10^{-5}
Multiparity			10×10^{-5}	-6.6×10^{-5} to 0.000
Oxytocin stimulation			-10×10^{-5}	-0.000 to 0.000
Suspected SGA			6.4×10^{-5}	-0.001 to 0.001
AIC	-26 418		-26 414	

Abbreviations: AIC, Akaike information criterion; BMI, body mass index; CI, confidence interval; SGA, small for gestational age.

the identified threshold combination of 7.26 and 7.20 in larger and more diverse populations, as well as in various clinical settings. Moreover, future investigations should examine the potential influence of these identified thresholds on clinical decision-making (i.e., cesarean delivery rate, consequences of retesting pH levels), and patient outcomes.

To our knowledge, it is the first study that presents a scalp pH curve during labor in patients with category II FHR. It is also the first to give rates of fetal pH drop according to its value. It presents data from a large number of patients and over 5000 samples. All medical records were reviewed individually for consistency, and all FHR patterns were visualized to verify the FSBS indication.

Nevertheless, our study had several limitations. To obtain a fully interpretable curve of pH change during labor, it would be necessary to have FSBS pH at regular intervals in all patients. However, this was not ethically feasible as FSBS is an invasive method. The number of FSBS per patient was heterogeneous with some patients having only one and some having more than eight during labor. Furthermore, after an FSBS pH of less than 7.25, the obstetrician can decide to either allow labor to continue or perform an instrumental extraction or cesarean delivery. This limits data on low scalp pH and explains the sharp drop in pH close to childbirth.

Furthermore, the evolution of pH levels, especially after 7.25, is influenced by the management of labor following FSBS, which can vary by country, maternity center, and practitioners. This indication bias affects the external validity of our findings. Nevertheless, delivering a healthy newborn is the ultimate goal of an ObGyn, and this indication bias cannot be overcome.

The indication for FSBS was a category II FHR, which includes a variety of changes. While these indications may seem broad, they reflect the reality of clinical practice, and it was important to describe the overall pH change during labor with standard practices. Additionally, intra- and interobserver reliability for FHR classification was low, making the production of multiple pH curves according to abnormal FHR classification questionable.

Whilst we had data on oxytocin administration during labor, we did not have detailed information on whether and when it was discontinued due to abnormal FHR, which could have explained some improvement or deterioration in pH value and its rate of change.

Linear regression may seem like a strong assumption, but when observing the data without imposing a type of regression, it appears to be a valid method when applying three thresholds. Furthermore, we tested imposing more thresholds on our data, but the results were similar to those with three thresholds. Although our sample size was relatively large, it was also insufficient to fit another type of regression model.

5 | CONCLUSION

Our study provides valuable insights into the rate of fetal pH drop during labor in patients with category II FHR and reinforces the current guideline thresholds used in clinical practice. The close alignment of our identified thresholds with existing recommendations supports their validity and reliability, emphasizing the importance of adhering to established guidelines for optimal management of labor and delivery in cases of category II FHR tracing.

AUTHOR CONTRIBUTIONS

Aude Girault: Collected the data and performed the first analyses. Xavier Tannier and Aude Girault: planned the analyses, performed them, and drafted the first version of the manuscript. François Goffinet, Charles Garabedian and Camille Le Ray: edited the manuscript, and reviewed the final version of the manuscript.

CONFLICT OF INTEREST STATEMENT

Charles Garabedian carried out consultancy work for Bioserinity and was a lecturer for General Electrics and Bayer in the previous 3 years. The other authors report no conflict of interest.

ETHICS STATEMENT

This study was approved by the National Data Protection Authority (Commission Nationale de l'Informatique et des Libertés, CNIL n° 1755849) on October 1, 2021. Under 'French regulations, this study was exempt from IRB review because it was an observational study using anonymized data from medical records. The European General Data Protection Regulation (GDPR) compliance was carried out by a data protection officer.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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