Intrapartum management of nonreassuring fetal heart rate patterns: A randomized controlled trial of fetal pulse oximetry

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Objectives: We tested if fetal pulse oximetry in addition to electronic fetal monitoring (CTG) and scalp blood sampling improves the accuracy of fetal assessment and allows safe reduction of operative deliveries (−50%) and scalp blood sampling (−50%) performed because of nonreassuring fetal status.

Study design: A randomized controlled trial was conducted in 146 patients with term pregnancies in active labor and abnormal fetal heart rate patterns: 73 had electronic fetal heart rate monitoring (CTG) and fetal scalp blood sampling (control group), 73 had CTG, fetal scalp blood sampling, and continuous fetal pulse oximetry (study group).

Results: There was a reduction of −50% in operative deliveries and fetal scalp blood sampling performed because of nonreassuring fetal status in the study group: operative deliveries, study versus control 25/49 (P < .001); fetal scalp sampling, study versus control 32/64 (P < .001). An increase in cesarean sections because of dystocia in the study group did not change the net number of operative deliveries. There was no difference between the 2 groups in adverse maternal or neonatal outcomes, as well as for the end points of metabolic acidosis and need for resuscitation.

Conclusion: There was a safe reduction in operative deliveries (−50%) and scalp blood sampling (−50%) performed because of nonreassuring fetal status. The increase in cesarean sections because of dystocia in the study group was a well-documented arrest of labor, but it did not change the total number of operative deliveries in this group.

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**KEY WORDS**
Fetal pulse oximetry
Fetal oxygen saturation
Nonreassuring fetal heart rate patterns
Intrapartum triple fetal surveillance

Electronic fetal heart rate monitoring (FHR) is the routine first-line method for assessing fetal oxygenation in labor. However, it is a nonspecific tool to identify fetal hypoxia and acidosis because of its bad specificity of 40% to 50% and sensitivity of 85%.1,3 There is a high number of nonreassuring FHR patterns, even though the fetus is in good condition.

In case of 40% to 50% prediction of fetal hypoxia and acidosis, electronic FHR monitoring is associated with increased cesarean section and assisted vaginal delivery rates.4-6

Until now, there has been only fetal scalp sampling adjacent to FHR monitoring as the so-called gold
standard to evaluate the fetal status. But this procedure is invasive and traumatic for the fetus, it is only intermittent concerning the fetal assessment; a caput succedaneum or amniotic fluid contact could falsify the analytic results. Normal pH shows an adequate fetal oxygenation and fetal acidosis can be excluded, especially in case of nonreassuring FHR; however, unnecessary operative deliveries could not be avoided in this connection.7-10 Fetal pulse oximetry gives rise to hope.11

The use of special far-infrared (735 nm) and near-infrared (890 nm) wavelengths12 and the transcervical placement of the sensor FS 14 C lodged against the fetal cheek have largely made it possible to overcome the difficulties of inaccessibility and physiologic differences of the fetus.

Fetal pulse oximetry is nearly noninvasive and nontraumatic for the fetus; continuous registration of fetal oxygenation (FSPo2) is possible in real time; only a lot of vernix and dark hair could make it difficult to get a sufficient signal for FSPo2 registration.

In the study performed, we wanted to test for an improvement in fetal assessment by evaluating whether fetal pulse oximetry adjacent to FHR and fetal scalp sampling allows a significant and safe reduction in operative deliveries and in numbers of fetal scalp sampling performed because of nonreassuring fetal status without increasing rates of adverse maternal or neonatal outcomes, as well as for the end points of metabolic acidosis and need of resuscitation (Table I).

| Table I | Metabolic end points of the study and need of resuscitation8,13 |
|-----------------------------------------------|
| Study successful | Study unsuccessful |
| pH-umbilical artery | > 7.20 (Saling) | pH-umbilical artery | ≤ 7.20 |
| Base excess | ≤ -8 mmol/L (Berg, Kubli) | Base excess | > -8 mmol/L |
| Lactate | ≤ 4.5 mmol/L (Westgren) | Lactate | > 4.5 mmol/L |
| Apgar score (5 min) | ≥ 7 | Apgar score (5 min) | < 7 |

Material and methods

A randomized prospective trial of 146 patients with nonreassuring FHR patterns sub partu (International Federation of Gynecology and Obstetrics [FIGO] score <8) (Table II) was done. The hypothesis to be tested is as follows. In patients in labor with a nonreassuring FHR, the addition of fetal pulse oximetry to FHR and fetal scalp sampling, compared with electronic FHR monitoring combined with fetal scalp sampling alone, reduces the rate of operative deliveries (cesarean section and assisted vaginal delivery) and of fetal scalp sampling without increasing adverse outcomes for the mother, fetus, or newborn. Study protocol (Table III) was approved by the local ethical committee.

In case of nonreassuring FHR defined as FIGO score <8, all patients underwent fetal scalp blood sampling. After informed written consent for study inclusion, the patients were randomized to the control group (n = 73), FHR and fetal scalp sampling, or to the study group (n = 73), FHR, fetal scalp sampling, and fetal pulse oximetry.

The study was limited to patients ≥ 36 weeks 0 days’ gestation and in active labor with a nonreassuring FHR, single fetus in a cephalic presentation with the cervix dilated to at least 2 cm and at the −2 station or below. All patients had ruptured membranes; amniotomy was also permitted. Exclusion criteria included the following: planned cesarean section, placenta previa, need for immediate delivery, active genital herpes, or known human immunodeficiency virus infection, which precluded internal monitoring, multiple pregnancy, and gestational age <36 weeks. For patients in the study group, a Nellcor FS 14 C fetal oxygen sensor (Pleasanton, Calif) was placed and connected to a Nellcor N-400 monitor. The flexible FS 14 C sensor can be inserted transcervically until it rests against the fetal cheek. The N-400 monitor was connected to a conventional electronic fetal monitor that continuously prints the fetal oxygen saturation, averaged over 45 seconds, superimposed on the lower contraction channel of the fetal monitor, which is calibrated at 0 to 100.

Management of the patient according to group assignment was as follows: for both groups, the FHR was defined as nonreassuring if FIGO score was <8 (Table II). Then all patients underwent fetal scalp blood sampling for baseline assessment of the fetus (including pH, Po2, Pco2, base excess, lactate).
After informed written consent for study inclusion, the patients were randomized. Concerning the control group we did as follows: if cardiotocography (CTG) was suspicious and fetal blood analysis (FBS) had a pH > 7.25, we continued CTG and tried vaginal delivery. If scalp pH was ≤ 7.25, clinical intervention was necessary (tocolysis for intruterine resuscitation, cesarean section, or assisted vaginal delivery). In case of pathologic CTG, patients were delivered immediately. Concerning the study group we had the following management: if CTG was suspicious and pH-FBS > 7.25 and FSPo$_2$ > 30%, we continued CTG and fetal pulse oximetry and tried vaginal delivery. If CTG was suspicious and pH-FBS > 7.25, but FSPo$_2$ < 30% for ≥ 10 minutes or repeatedly < 30%, we continued CTG and fetal pulse oximetry; in case of FSPo$_2$ < 30%, we did a follow-up FBS. If scalp pH was ≤ 7.25, clinical intervention was necessary. If CTG was pathologic, patients were also delivered immediately (Table III).

The use of fetal pulse oximetry was based on the guidelines for the use of fetal pulse oximetry of the German Multicenter Study Group (Table IV). For both groups the study has been successful if pH-UA (= umbilical artery) was > 7.20, base excess was ≥ −8 mmol/L, lactate was ≤ 4.5 mmol/L, and 5-minute Apgar score was ≥ 7; the study was unsuccessful if pH-UA was ≤ 7.20, base excess was < −8 mmol/L, lactate was > 4.5 mmol/L, and 5-minute Apgar score was < 7 (Table I).

Statistical methods used were as follows: the Kolmogorov-Smirnov-test, the chi-square test, the Student t test, the Mann-Whitney U test, and the Spearman correlation. Each test is specified in connection to the evaluation and comparison of specific parameters and is mentioned in the legend of each table or figure.

The goal of the study was to determine if using fetal pulse oximetry adjacent to CTG and FBS in case of nonreassuring intrapartal CTG (FIGO score < 8) (Table II) can improve early detection of fetal preacidosis (pH-FBS ≤ 7.25; pH-UA ≤ 7.20), reduce fetal blood sampling rate −50%; reduce operative delivery rate −50% (vacuum extraction, forceps, cesarean section); and determine whether vaginal delivery can be performed without fetal hypoxic risk

### Results

Data acquisition was done anonymously for both groups. Concerning special items in patients’ history there are some differences. In the study group we had significantly more fetal risks (1 or more) than in the control group (chi-square test; $P = .023$), green amniotic fluid was especially significantly more abundant in the study group (chi-square test; $P = .02$), as well as meconium sub partu (chi-square test; $P = .030$).

In the study group intrapartal FHR monitoring was done more via scalp electrode (test vs control: 20/7; chi-square test; $P = .001$), in the control group FHR monitoring was done more via ultrasound (control vs test 66/53; chi-square test; $P = .005$) (see Table VI). FSE were placed before and after randomization. It was not because FPO was being used; the reasons were problems to get a proper signal of fetal heart rate registration or maternal obesity (in most cases a mixture of both). This did not affect the overall results.

Concerning nonreassuring FHR patterns there was no difference between both groups in the first and second stages of labor. The study group showed significantly more decrease of baseline (study vs control 21.8%/10.5%; chi-square test; $P = .03$) and the control group had more tachycardia (control vs study 9.5%/4%, not significant). The first scalp sampling for baseline assessment of the fetus before randomization had similar results of pH, Pco$_2$, Po$_2$, base excess, and lactate in both groups. A second or third fetal scalp blood sampling also showed no difference in results, but the number of follow-up scalp samplings was highly significantly lower in the study than in the control group (second FBS 25/45; third FBS 7/19; chi-square test; $P ≤ .001$).

<table>
<thead>
<tr>
<th>Table III</th>
<th>Study design: management of labor after randomization concerning control and test group</th>
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<tr>
<td>Control: CTG + FBA</td>
<td>Randomization</td>
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<td></td>
<td>CTG</td>
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<td>FBA: pH &gt; 7.25</td>
<td>I. Suspicious</td>
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<tr>
<td>Continue CTG and try vaginal delivery</td>
<td>Continue CTG and fetal pulse oximetry, try vaginal delivery</td>
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<tr>
<td>FBA: pH ≤ 7.25</td>
<td>II. Pathologic</td>
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<tr>
<td>Clinical intervention*</td>
<td>Deliver</td>
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<td></td>
<td>Deliver</td>
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* Tocolysis, amnioinfusion.
There was a reduction of than in the control group (chi-square test; fetal status was significantly lower in the study group operative vaginal delivery performed for nonreassuring fetal pulse oximetry). The study: can the number of FBS be reduced group only CTG and FBS were used (see objective of the study). For intrapartum fetal surveillance, whereas in the control group included CTG, FBS, and fetal pulse oximetry.

If there is no FSP O2 registration, adjust sensor placement.

If FSPO2 is to get FSPO2 information from the very beginning until the baby is born.

Fetal pulse oximetry is only an adjunct to conventional CTG and fetal scalp blood sampling (FBA). No clinical decision and intervention should be done by fetal pulse oximetry alone. The German Multicenter Study Group includes M. Kühnert, Dept of Obstetrics and Perinatology, University of Marburg; B. Seelbach-Göbel Woman’s Hospital, St Hedwig Hospital, Regensburg; M. Butterwegge Woman’s Hospital, Marienhospital, Osnabrück.

This was a reduction of −50% (Table VI). The study group included CTG, FBS, and fetal pulse oximetry for intrapartum fetal surveillance, whereas in the control group only CTG and FBS were used (see objective of the study: can the number of FBS be reduced –50% by using fetal pulse oximetry?).

The number of interventions by cesarean section or operative vaginal delivery performed for nonreassuring fetal status was significantly lower in the study group than in the control group (chi-square test; P ≤ .001). There was a reduction of −50% of operative interventions and an increase of +50% of normal deliveries in the study group (P ≤ .001) (Tables V and VI). The reasons for operative intervention can be seen in Table VII.

The control group had significantly higher numbers of nonreassuring FHR patterns than the test group (P ≤ .001). In case of nonreassuring CTG and operative intervention we did a scalp sampling before vacuum or cesarean section in 73% of the control group (n = 37); in the study group we had only 2 cases of vacuum extractions, only 1 patient had scalp sampling (= 50%), the other one was done in case of emergency. Comparing both study groups, there was no difference in transferring newborns to the neonatal intensive care unit.

For the study group we have found some special items. The amount of FSPO2 values ≤30% in comparison to the pH of the umbilical artery can be classified as follows: pH ≤ 7.20, >7.20 to 7.24, ≥7.25 = 4, 2, 1.

Fetal scalp pH and correlating FSPO2 values were demonstrated in a scatterplot (Figure 1). If the threshold of scalp pH was either ≤7.25 (= preacidosis) or ≤7.20 (= moderate acidosis) and the FSPO2 threshold was
Spearman correlation was significant in both cases ($P = .005$).

Umbilical artery pH in correlation to FSP02 values of the last 10 minutes immediately before delivery (average value) were highly significant ($P < .001$) and can be seen in Figure 2. The pH and the Sao2 values of the umbilical artery were nearly significant ($P < .020$) (Figure 3), but without clinical importance. The looser correlation of pH-UA and SaO2 could not be explained exactly in contrast to the excellent and highly significant correlation of pH-UA and FSP02 of the last 10 minutes immediately before delivery.

The mean values of FSP02 30 minutes before partus and the Sao2 of the umbilical artery were also nearly significant ($P < .011$), but also without clinical importance.

Concerning the rate of normal, preacidotic, and acidotic pH values of the umbilical artery, there were similar results (29/30) in both groups for normal pH (pH ≥ 7.25); preacidotic values (pH > 7.20-7.24) were slightly higher in the study group (24/19) and acidotic values (pH ≤ 7.20) were higher in the control group (25/19). Both items showed no statistical significance, and there was only a special tendency (Table VI). Bearing in mind the umbilical artery pH and the mode of delivery for both groups, there have been two categories defined: normal pH > 7.20 and suspicious pH ≤ 7.20.

There was no statistical significance comparing both groups, only a special tendency in the test group for a little bit more normal pH values for normal vaginal delivery and operative intervention than in the control group (test: normal vs operative = 36 vs 18; control: normal vs operative = 15 vs 32).

Sensitivity (identification of acidotic neonates and pH-UA ≤ 7.20 because of the study protocol) and specificity (identification of normal babies with pH-UA > 7.20 because of the study protocol) of the pH-UA in correlation to the mode of delivery showed that operative intervention was done earlier in the test than in the control group (specificity = 75 vs 62.5).

Sensitivity (acidotic babies) had a higher number in the control group (34.7 vs 28.0). Hence, it follows that intrapartum surveillance with CTG, scalp blood sampling, and fetal pulse oximetry led to a lower number of acidotic newborns, or in other words, in the study group there was a better management of choosing the adequate and optimal “mode of delivery” than in the control group.

There were no adverse maternal events in both study groups, as well as similar neonatal outcomes.

The fetal pulse oximeter sensor was successfully placed in all patients of the test group and FSP02 signal was obtained 98.5% of the time. All FPO registrations were done by one chief investigator, bearing in mind the guidelines in Table IV. “Time monitored” was defined as time from the application of the fetal sensor until it was withdrawn (minimum 33 minutes, maximum 482 minutes, median 96 minutes). The investigator was constantly at the bedside to make immediate adjustments.
Sensor adjustments were made 1 to 2 times for the test group every third patient.

Comment

FHR monitoring is generally good at detecting hypoxia, and adverse outcomes caused by intrapartum hypoxia are rare. It would take a prohibitively large sample size for fetal pulse oximetry to demonstrate benefit in reducing fetal or neonatal complications. We therefore chose to study whether fetal pulse oximetry improved the clinician’s accuracy of fetal assessment in deciding on operative intervention because of concern over potential fetal compromise. Therefore, this study was designed to test the hypothesis that the addition of fetal pulse oximetry to electronic FHR monitoring and scalp sampling would result in a lower rate of operative deliveries performed for nonreassuring fetal status, without any increase in adverse neonatal outcome. The study confirmed the primary hypothesis, demonstrating a 50% reduction in the rate of operative delivery for nonreassuring fetal status, and a reduction of fetal blood sampling rate −50%. Furthermore, it proved if early detection of fetal preacidosis could be performed without fetal hypoxic risk.

Hurried performance of operative delivery, especially when there is no real indication, has the potential to result in suboptimal outcome, with possible increases in infection, hemorrhage, and anesthetic accidents. Operative delivery for nonreassuring fetal status was reduced by 50% with the addition of fetal pulse oximetry. Cut-off points (Table I) for newborn outcome, including parameters of newborn depression (low Apgar scores and need for resuscitation) and fetal acidosis (low umbilical cord arterial pH and high base excess), demonstrate that the addition of FSPO₂ monitoring provided a statistically significant improvement in appropriateness of operative delivery for the acidotic baby, and in the need for bag and mask resuscitation.

Fortunately, no baby died in either study group.

Fetal pulse oximetry did significantly improve the sensitivity and specificity of surgical intervention for nonreassuring fetal status. This has been also demonstrated in other clinical trials.¹⁻⁶⁻¹³⁻¹⁶⁻¹⁷

The rate of cesarean sections as a result of dystocia was similar in both groups of our study in comparison to the study of Garite et al., where it was significantly higher in the study group.

We also specified arrest of dilation for >3 hours and arrest of descent for >2 hours at complete dilatation as criteria for actual dystocia. So we could conclude that the use of fetal pulse oximetry besides CTG and scalp sampling could clearly “work out” and unmask a real dystocia. A normal FSPO₂ permits the obstetrician to allow labor to proceed through periods of nonreassuring FHR patterns. Ultimately, the patients in the study group with true dystocia were delivered by cesarean because of dystocia, whereas patients in the FHR monitoring and scalp sampling group more often underwent cesarean delivery because of nonreassuring fetal status.

In the control group there were 5 patients with dystocia who were delivered by cesarean section, in the test group we had 7 patients; in the study of Garite, there were 43 patients in the control group and 94 patients in the study group with dystocia.¹⁷

The most important single result of this study was that allowing labor to continue in the presence of a nonreassuring FHR but a reassuring FSPO₂ with the consequent reduction in operative delivery for nonreassuring fetal status did not result in an apparent increase in adverse neonatal outcome.

The number of fetal scalp blood sampling could be reduced in —50% (Table VI). Whereas our study included at least one scalp sampling for all patients in both groups, the American Multi Center Study had only a 5% rate for scalp sampling. The differences of both studies are¹⁷ as follows: our study was a single-center study with 146 patients, whereas the study of Garite was a multicenter study with 1010 patients. Furthermore, in Germany, FBS is a quality marker concerning obstetric management (part of balanced score card and perinatal statistics). FBS is the “gold standard” adjacent to CTG in case of nonreassuring heart rate patterns; indeed, the study results obtained were in a setting of heavy reliance on FBS (Saling education). In our study early detection of fetal preacidosis (scalp pH ≤ 7.25, pH-UA ≤ 7.20), could not be improved significantly in the test group.

Figure 3 Scatterplot of pH-UA in correlation to the SaO₂ values in the UA; Spearman correlation nearly significant, \( r = 0.349, P \leq .02 \).
Moderate acidosis (pH-UA 7.20-7.10) was similar in both groups (control vs test = 24:21), severe acidosis (pH-UA < 7.10) occurred n = 6 in the control, and n = 1 in the test group. This was only a tendency, but without statistical significance.

The use of intrapartum triple fetal surveillance (CTG + scalp sampling + fetal pulse oximetry) in case of nonreassuring FHR patterns (FIGO score <8) was accomplished without a demonstrable increase in adverse fetal or neonatal outcome, and vaginal delivery could be performed without fetal hypoxic risk.

The improvement in sensitivity and specificity of intervention by operative delivery for nonreassuring fetal status demonstrates that fetal pulse oximetry provides additional confidence that the clinician will have the capability to more accurately assess the well-being of the fetus in labor. The improved sensitivity for detecting true hypoxia and acidosis gives rise to hope to detect real distress sub partu in time.

Hence, if etiology and pathophysiology of fetal hypoxia is multifactorial, intrapartum fetal surveillance also must be multifactorial. Intrapartum triple fetal surveillance is necessary in case of nonreassuring CTG to continue vaginal delivery and to be sure of fetal well-being. By improvement in the technology of fetal pulse oximetry, the accuracy of fetal assessment can be improved even further.

Therefore, a better fixation of the fetal sensor is needed; technical details as well as the guidelines for the use of fetal pulse oximetry should be absolutely kept in mind. Then fetal pulse oximetry offers an opportunity to more accurately assess fetal oxygenation in labor, and may enable the obstetrician to act more appropriately for the fetus truly in need of intervention.

References


