New Methods For The Assessment of Fetal Well-Being: Fetal Oxygen Pulse Oximetry

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ABSTRACT

Background: The use of non traumatic fetal pulse oximetry - enabling the continuous monitoring of oxygen saturation - has recently been introduced in order to increase the detection rate of intrapartum asphyxia. We have tested a new pulse oximeter and sensor (to be positioned on the fetal back) with the aim to validate its efficacy and applicability.

Methods: The prospective trial included 18 term pregnancies fulfilling the criteria: an ultrasound scan in pregnancy for the confirmation of gestational age and placental location, spontaneous labor and absence of pharmacologic interference. We have used the fetal oxygen monitor OBS-500 (OB Scientific, Inc., USA), a compact pulse oxymetry device that simultaneously detected the signal of Sat O_2 and the fetal cardiac frequency by means of a flexible sensor (OBS-900) to be positioned on the back of the fetus during labor. Umbilical cord blood was obtained at birth, after double clamping of the cord before the first neonatal breath, and subsequently submitted for blood gas analysis (UBGA).

Results: The mean gestational age at birth was 39.7 ± 1.1 (37- 42 weeks), the mean neonatal weight was 3370 ± 437 g. The probe was inserted to laboring women, with a dilation between 4 and 9 cm (mean 6.0 ± 1.6 cm). In 7 cases the probe was inserted with intact membranes, under ultrasound guidance (for checking the location of the placenta). The mean umbilical artery pH was 7.28 ± 0.08, and the mean umbilical artery pO_2 15.9 ± 4.5 mmHg. The mean Sat O_2 to 5, 15 and 30 minutes before birth were 47.5%, 52.6% and 52.5%, respectively. The median of Apgar scores at 1 and 5 min was 8 and 9, respectively. From our data it emerges that a value of Sat O_2 > 50.0% corresponds to an Apgar score and to UBGA values at birth within normality.

Comment: These are preliminary results to ascertain the reliability of the method in one cluster of normal pregnancies at term. New cases are being recruited, including alterations of CTG tracing in labor, with the aim to evaluate the utility of pulse oxymetry in the decision of the modality of birth.

A number of important observations, have provided further insight into our understanding of intrapartum fetal physiology and intrapartum fetal assessment.

Regarding in-labor intrapartum surveillance, three different clinical patterns of acute fetal distress may be observed: a persistent nonreactive and "fixed" fetal heart rate (FHR) on admission to the hospital, a progressive intra-partum asphyxia manifested by a substantial rise in baseline heart rate, a loss of variability and repetitive severe variable or late decelerations, and finally, as a result of a catastrophic event, a sudden prolonged FHR deceleration to approximately 60 beats per minute lasting until delivery(1). Among all techniques tested for the evaluation of fetal hypoxia intrapartum (continuous recording of the fetal electrocardiogram or computed-assisted EFM, fetal pulse oximetry or fetal scalp sampling with immediate determination of blood gases/lactates), fetal pulse oximetry (SpO_2) has undergone a remarkable evolution since its conception over 10 years ago (2-4). An impressive development of sensors, hardware and software was necessary to convert the optical signals of reflected red and infrared light into saturation values (5). The purpose of this paper is to va-

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lidate the reliability of the method in one cluster of normal pregnancies at term with the use of a flexible sensor.

MATERIALS AND METHODS

The study was designed as an observational prospective study, guaranteeing that patient management was independent from SpO_2 readings. The saturation readings could not induce any further diagnostic means or interventions. The study was carried out in the obstetric unit of a university hospital.

Patient management was based substantially on continuous FHR monitoring. Only fetuses non showing a risk of fetal hypoxia were included in the trial. Suspicion of hypoxia during delivery, based on the occurrence of variable decelerations in the FHR tracings or meconium-stained amniotic fluid or any other circumstance requiring fetal blood sampling, were exclusion criteria such as the presence of documented uterine malformations or placenta previa. Thus, eighteen normal pregnancies were recruited on the basis of: ultrasound scans in pregnancy for the confirmation of gestational age and placental location, spontaneous labor and absence of pharmacologic interference. After an informed written consent was obtained from the laboring women, the oxisensor was positioned. We used for this study the fetal oxygen monitor OBS-500 (OB Scientific, Inc., USA), a compact pulse oxymetry device that simultaneously detects the signal of Sat O_2 and the fetal cardiac frequency by means of a flexible sensor (OBS-900) to be positioned on the back of the fetus during labor.

Total monitoring time ranged from 40 min to 4h (median 80 min). In all cases a cord blood sample was taken after double clamping of the umbilical cord before the first neonatal breath. Blood samples immediately underwent analysis in a commercial blood gas analyser (Radiometer ABL 625, Copenhagen, Denmark). The SpO_2 obtained from the blood samples were compared with the hemoximetry measurements. These couples of values were evaluated concerning mean and median of relative and absolute differences, the 95% CI and their correlation coefficients. A further aspect of evaluation focussed on the distribution of saturation in a certain time window preceding each individual fetal blood sample. This approach takes into account that SpO_2 is a method that determines the oxygen saturation levels continuously. For this purpose, the median and distribution of the saturation (SpO_2) percentiles in the chosen time frame were determined. The chosen time frames of observation were the 5, 15 and 30 min preceding the sampling.

It is well known that as the oxisensor may not continuously achieve good contact with the fetus, the amount of signal loss reduces data quality. In such instances, the 'posting time' indicates the quality of signal out-put: it describes the percentage of provided SpO_2 values during the period of time that the oxisensor was placed. The fact that the signal algorithm processes only high-quality signals and leads to reduced signal output is accepted. Data was then coded and a work-sheet created form statistical purposes.

Statistical analysis

The accuracy of SpO_2 compared with hemoximetry was calculated considering hemoximetry as the reference method. We performed for statistical differences between the groups the Wilcoxon's and Fisher's exact test. The correlation between the instantly measured saturation values of both methods was calculated by the Spearman correlation coefficient. A ROC curve (receiver operator curve) was performed in order to find a suitable limit for SpO_2 values.

RESULTS

The mean gestational age at birth was 39.7 ± 1.1 (37-42 weeks), the mean neonatal weight was 3370 ± 437 g.

The percentage signal loss rose and the posting time declined with the degree of decreasing pH in the umbilical artery. All cases underwent vaginal delivery, and an average of 10 min passed between the sensor being removed and the babies being born.

We have inserted the probe to laboring women, when the cervix showed a dilation between 4 and 9 cm (mean 6.0 ± 1.6 cm). In 7 case the probe has been inserted with intact membranes, under ultrasound guide (for diagnosisng the location of the placenta).

Data analysis focussed on the absolute and relative difference between hemoximetry and pulse oximetry of fetuses. The median disagreement between SpO_2 and umbilical artery Sat O_2 ranged between 6 and 10%. The mean umbilical artery pH was 7.28 ± 0.08, and the mean umbilical artery pO_2 15.9 ± 4.5 mmHg. The mean SpO_2 at 5, 15 and 30

minutes from birth were 47.5%, 52.6% and 52.5%, respectively. The median of Apgar scores to 1 and 5 min was 8 and 9, respectively.

We have correlated SpO_2 values to umbilical artery pH > 7.2 and Apgar score > 7 at 5 min by means of a ROC curve in order to find a significant threshold of SpO_2. From our data it emerged that a value of SpO_2 > 50.0% corresponds to an Apgar score and to UBGA values at birth within normality.

DISCUSSION

SpO_2 has been developed to a stage where it is a safe and accurate indicator of intrapartum fetal oxygenation. In general, the SpO_2 devices have been developed to a stage where it is a safe and accurate indicator of intrapartum fetal oxygenation. In general, sliding the SpO_2 sensor along the examiner's fingers and through the cervix, to lie alongside the fetal back is easy (6). The validity of our study lies on the fact that only normal pregnancies with no complications have been considered and hemoximetry from umbilical artery performed immediately. In this physiology trial we have observed that values of SpO_2 above 50.0% are related to good neonatal conditions at birth. It has been described that when fetal oxygen saturation ($FSpO_2$) values are <30%, prompt obstetric intervention is indicated, such as fetal scalp blood sampling or delivery.

Conventionally, SpO_2 may be used during labor when the electronic fetal heart rate trace is nonreassuring or when conventional monitoring is unreliable, such as with fetal arrhythmias. Reflectance pulse oximetry, which is harmless to mother and fetus (7), appears useful for fetal monitoring because it provides almost continuous information about fetal oxygenation during birth (8). Reassuring saturation and good outcome in cases of suspicious FHR traces (9) suggests that this technology provides predictive values sufficiently.

However, the disappointing experiences of the increased rate of operative deliveries after the introduction of electronic fetal monitoring in the clinical routine indicates that further evaluation of pulse oximetry is needed. We agree with the concept of a blinded-randomized data collection indispensable for the evaluation of SpO_2 in the future. Unfortunately, SpO_2 techniques may suffer the impact of artifacts (10). Possible sources of artificially low oxygen saturation readings may be meconium, which behaves in a similar manner to a red light filter (660 nm) (11). Consequently, the ratio of red/infra-red light is altered towards artificially low values. It has been published that the distance to the pressure of contraction (12) or to caput succedaneum formation (13) may lead to errors in saturation measurements. $FSpO_2$ monitoring should not form the sole basis of intrapartum fetal welfare assessment. Rather, the whole clinical picture should be considered.

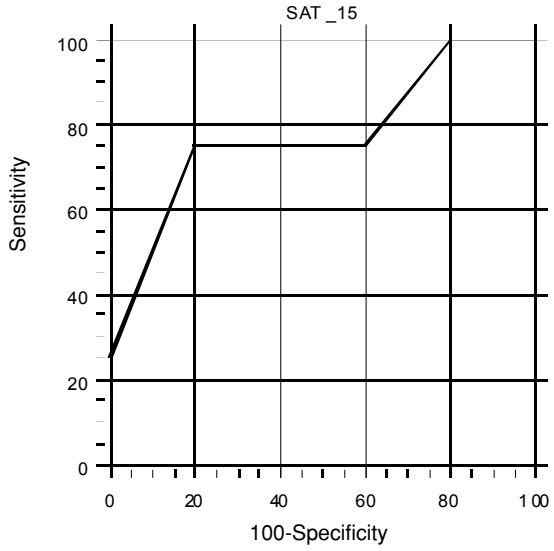

Figure 1. *ROC analysis of $FSpO_2$ readings at -15 min from delivery (SAT_15) vs. Apgar scores at 1 min >7 . Best compromise between sensitivity and specificity is $FspO_2$ = 50 %*

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