Toshiyuki Uchida, Naohiro Kanayama*, Mari Mukai, Naomi Furuta, Hiroaki Itoh, Hikaru Suzuki and Masatsugu Niwayama

Examiner's finger-mounted fetal tissue oximetry: a preliminary report on 30 cases

Abstract

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Objective: To describe preliminary experience with a finger-mounted fetal tissue oximetry probe during the 2nd stage of labor.

Materials and methods: A total of 30 term pregnant women without pregnancy complications were recruited. We measured fetal tissue oxygen saturation (FtO₂) by using a finger-mounted fetal tissue oximetry during cervical examinations in the 2nd stage of labor. The data capturing rate of FtO₂ and the interclass correlation coefficient were also examined. The mean FtO, was compared to the neonatal condition assessed by the levels of umbilical cord blood.

Results: FtO, was obtained in all cases, regardless of wetness, hair color, the part of the fetal head that was exposed, rotation of the fetus, color of amniotic fluid, and caput succedaneum. The mean FtO, was 65.5%±8.58% in normal neonates [Apgar score >7 (1 min), n=25]. The mean FtO, was significantly correlated with umbilical cord arterial pH (r=0.52, P=0.0030, n=30), but not with umbilical cord arterial partial pressure of oxygen. The interclass correlation coefficient was 0.94.

Conclusions: Tissue oxygen saturation of the fetal head was obtained easily by the examiner's finger-mounted fetal tissue oximetry.

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Keywords: Examiner; fetal tissue oximetry; fetal tissue

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Introduction

The best approach to evaluate fetal well-being is to measure fetal blood pressure and oxygen status, which cannot be achieved non-invasively using currently available techniques. Therefore, fetal heart rate (FHR) is the gold standard for evaluating fetal status. However, FHR monitoring has shown to have low false-negative and high false-positive rates [1]. Thus, obstetricians have attempted to use fetal oxygen status, by itself or in addition to FHR monitoring, to improve diagnostic ability [2-4].

There have been many reports describing the development of fetal pulse oximetry, and subsequent clinical trials investigating the technique [5–7]. Several researchers have reported that oxygen dynamics can be measured using a pulse oximetry probe applied transvaginally to the fetal head [8-10]. In addition, an intravaginal optical probe using near-infrared spectroscopy (NIRS) to measure fetal oximetry has also been reported [11, 12]. However, East et al have reported that every method has a significant rate of signal loss during the active phase of labor, and sensor contact is lost during oximetry in up to 64% of attempts [13]. The markedly low rate of data capture inherent in these approaches remains one of the most significant barriers in adopting these procedures. Other drawbacks include the invasiveness of the probe, patient discomfort, and interference with the obstetrician performing cervical examinations. Although many clinical trials investigating fetal pulse oximetry have been performed, its clinical utility remains controversial [10].

Recently, we developed a new approach to fetal tissue oximetry [14], which changes the placement of the sensor to overcome these issues. We attached an NIRS probe to the doctor's finger, rather than the fetal head or cheek. Here we report the characteristics of this oximetry technique and clinical data obtained during labor.

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Materials and methods

Probe

Q4: Please supply the manufacturer's name, city, and country for all reagents, devices, and software mentioned throughout. The wavelengths of the light sources were 770 nm and 810 nm, and the sensitivity of the photodiodes (PD2501, Epitex) was high in the near-infrared band. The bare chips of the light-emitting diodes (LEDs) and photodiodes were mounted on the substrate with a wire bonding. The detectors were located 6 mm and 8 mm away from the LEDs to determine the absolute value of hemoglobin concentration using the spatially resolved NIRS (Figure 1A).

Patients

Pregnant women who were at term and had not experienced any complications during their pregnancy were recruited for the present study. Informed consent was obtained from the subjects, and the protocol was approved by the Ethics Committee of Hamamatsu University School of Medicine.

Measurement protocol

We measured fetal tissue oxygen saturation (FtO_2) in the late 2^{nd} stage of labor until delivery. The probe was attached to the fetus head during

the delivery. Each measurement lasted at least 1 min after the attachment of the sensor. For the measurement, transparent vinyl gloves were prepared in collaboration with Utsunomiya Seisaku Co., Ltd. (Higashi Osaka-shi, Japan). Figure 1 (B, C, and D) shows the examiner's finger with the optical probe the method for data capture. To calculate the interclass correlation coefficient, the measurement was also performed for three cases, that is, three different obstetricians measured FtO₂ in each patient. The umbilical artery pH and partial pressure of oxygen (PaO₂) were measured at the time of the delivery. Statistical significance was calculated by Spearman's correlation coefficient. The value of P<0.05 was considered to be statistically significant.

Results

A total of 30 women were recruited in the study. The characteristics of the participants are presented in Table 1. FtO_2 was obtained in all cases, regardless of wetness, hair color, the part of the fetal head that was exposed, rotation of the fetus, color of amniotic fluid, and caput succedaneum. After attachment of the sensor to the fetal head, we obtained FtO_2 within 10 s in all the cases. The measurement was performed between one and five times during each delivery, and FtO_2 was obtained at every



Figure 1: Scheme (A) and photograph (B) of the oximeter probe attached to the examiner's finger pulp. Flexible substrate-mounted two light-emitting diodes (LEDs) and two photodiodes are adhered to a black rubber sheet. (C) The outlook of the measurement. (D) The measurement of the newborn.

Age (years)	32 (24–42)
Parity	0 (0-1)
Gestational age (days)	281 (261–293)
Birth weight (g)	3143 (2276–3970)
Umbilical artery pH	7.305 (7.054–7.382)
Apgar score (1 min)	8 (5–10)
Apgar score (5 min)	9 (7–10)
Measurement time (min)	4.54 (1–15.3)
Time of second stage (min)	114 (3–969)

Table 1: The characteristics of the subjects.

Values are expressed as median (range).

measurement. The rate of continuous data capture was 100% during the initial 1 min, 63.3% during the sequential 3 min, and 46.7% during the entire 5 min. The interclass correlation coefficient was 0.94.

The mean FtO₂ was 65.5%±8.58% (n=25) when the 1 min Apgar score was >7 (correlation coefficient 0.25; P=0.19). The relationship between mean FtO₂ and umbilical artery pH is presented in Figure 2 (n=30), (correlation coefficient 0.52; P=0.0030). The relationship between mean FtO₂ and umbilical artery PaO₂ is presented in Figure 3 (n=30), (correlation coefficient 0.17; P=0.36). There was only one case in which the umbilical artery pH was <7.1. The mean FtO₂ in this case was 41.7%. Representative plots of cases with normal FtO₂ and low FtO₂ are shown in Figure 4A and B.

Discussion

We have developed a fetal tissue oximetry technique involving a probe mounted on the examiner's finger [14].



Figure 2: There is a significant relationship between umbilical cord arterial pH (UA-pH) and fetal tissue oxygen saturation (FtO₂).



Figure 3: There is no significant correlation between umbilical artery partial pressure of oxygen (UA-PaO₂) and fetal tissue oxygen saturation (FtO₂).



Figure 4: (A) Normal FtO₂ case. The patient was a 34-year-old primigravida who delivered her infant at the 38th gestational week. The infant had the Apgar score of 9 at 1 min and 9 at 5 min, and weighed 2870 g. The umbilical artery pH was 7.27. The mean FtO₂ was 64.4%. (B) Low FtO₂ case. The patient was a 31-year-old parous woman who had a delivery at the 38th gestational week. The infant had the Apgar score of 8 at 1 min and 8 at 5 min. The umbilical artery pH was 7.05. The mean FtO₂ was 41.7%.

During the present study, we succeeded in obtaining FtO₂ measurements in all cases. Previous research has revealed that the presence of dark, thick, curly hair makes sensor attachment difficult [15] and may be a source of artifact because it absorbs red light and affects the error/signal ratio; a signal was also difficult to obtain during the appearance and expression of the fetal head. In our study, we were able to obtain a signal promptly in all cases; this was not impacted by wetness, hair color, the part of the exposed fetal head, fetal rotation, amniotic fluid color, caput succedaneum, or fetal head expression. Previous fetal pulse oximetry (FpO₂) devices were found to have data capture rates of approximately 70% owing to inadequate contact between the sensor and fetal skin. Because our sensor was constantly attached to the fetal head, we obtained a data capture rate of 100% during the 1st min and then the signal gradually decreased owing to fatigue of examiner's finger.

Continuous O, monitoring may be beneficial if it enables prompt diagnosis and treatment of fetal asphyxia. Rapid measurements of oxygen saturation at multiple sites are needed to document asphyxia. Commercially available sensors are placed on one location of the fetal head for the monitoring period, whereas the finger-based probe that we developed can be moved to any location accessible to the obstetrician. In addition, the spatially resolved NIRS system that we used can detect tissue oxygenation in low-perfusion conditions, which may allow a signal to be obtained in more clinical scenarios than previous designs. Our sensor achieves this because it requires only spatial intensity slope and not the weak pulsation signals that a traditional pulse oximetry requires. We assessed the readings obtained by multiple examiners to determine whether the amount of pressure applied to the fetal head would influence the FtO₂ values. We found an interclass correlation coefficient of 0.94, which suggests that the amount of pressure has limited to no effect.

Many investigators have reported that FpO_2 in a typical 2^{nd} stage of labor was approximately 50%. Our FtO_2 was slightly higher (65.5%±8.58%) than that reported with FpO_2 , suggesting that our value is a mixed measurement of the scalp and the brain. We have previously reported that our FtO_2 reflects contributions of approximately two-thirds from the fetal brain and approximately one-third from the scalp, and we assume that this is the reason for our FtO_2 to be higher than previously published FpO_2 data. We believe that our findings are correct as they correlate well with published data on the cerebral tissue oxygen saturation in neonates (67%–80%) [16, 17]. The present study is the first to report data on tissue oxygen

saturation of the fetal head during labor. Because the information obtained using our technique provides information on both the scalp and the brain, we believe it may be useful in clinical practice.

Our FtO, data also correlated well with neonatal parameters. There was a significant correlation between FtO, and umbilical artery pH, whereas no correlation was observed between FtO, and umbilical artery PaO,. Because our tissue oxygen saturation measures reflect the peripheral oxygen status of the brain and scalp, we believe that the FtO₂ value should differ from PaO₂ value. We had one neonate with an umbilical artery pH <7.1, and a mean FtO₂ of 41.7% was recorded in this case. The woman was parous and without complications during her pregnancy. The labor was notable for severe recurrent variable deceleration during the second stage of labor. The FtO₂ trend was continuously <50% (Figure 4B). The Kristeller maneuver (fundal pressure) was performed to hasten delivery, and the Apgar scores were 8 at 1 min and 8 at 5 min. This case highlights the possible clinical significance of oximetry measures obtained using our technique.

Our study was limited only by its small size (only 30 cases), the exclusion of women with complications, and the lack of compromised fetuses. Despite these limitations, the present study demonstrates the ease and simplicity of our finger-based device to obtain quick and reliable FtO_2 measurements. We believe that our oximetry probe provides new information for fetal management. We are currently conducting multicenter studies in Japan to better assess the clinical utility of our approach for determining fetal oxygen saturation.

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