A Case for Fetal Oxygen Monitoring

July 26, 2011
Mallinckrodt Inc. Healthy Mother and Baby

A New Dimension in Intrapartum Obstetric Care

During birth, knowing the blood oxygenation level of the fetus is of paramount importance to the obstetrician, midwife and parents. Lack of oxygen in the baby's blood can result in brain damage and, in the worst cases, death. Although every unborn child has a reserve supply of oxygen (oxygen margin of safety) to draw upon during labor, exactly how large a margin and how long it will last is unknown.

Until now, there has been no reliable way to measure the oxygen saturation of a fetus during labor directly and continually. Traditionally, physicians assess the status of the fetus by monitoring fetal heart rate and uterine activity (contractions). Electronic fetal monitoring (EFM), the technology used to measure fetal heart rate, was first introduced in 1968, and has changed little since then. An ultrasound transducer is applied to the mother's abdomen during labor, or an electrode is attached to the baby's scalp, and the fetal heart rate is measured.

The rigors of labor - being squeezed by contractions, a temporary occlusion of the umbilical cord, placental insufficiency - stress the fetus and can cause changes in the heart rate recorded by the EFM. Certain abnormal patterns in heart rate activity are classified as "non-reassuring." What the EFM cannot reliably indicate is how well the fetus is tolerating labor and whether there is a dangerous change in oxygen level.

Approximately 30 percent of all births in the United States (1.17 million) are marked by a period in which a non-reassuring heart rate is present during labor. Without an accurate method to determine whether these patterns represent a situation in which the fetus' oxygen level is compromised and with low-tolerance for prolonging a situation in which fetal outcome is at stake, many physicians turn to an intervention as a first course of action. These interventions can include the administration of oxygen to the mother or more invasive procedures, such as the collection of a fetal scalp blood sample (FBS) or delivering the baby with the use of forceps, a vacuum extractor or via Cesarean delivery.

Limitation of Current Methods

The collection of a fetal scalp blood sample requires the insertion of a scalpel blade and a long glass blood sampling tube into the birth canal between contractions. A small amount of blood is removed from a cut made in the fetus' scalp and is quickly tested for the build-up of acid (pH) - not oxygen level. In addition to being invasive to both the mother and fetus, FBS only provides intermittent data and results can be inaccurate as a result of sample contamination or testing delays.

A fetal scalp electrode is also invasive to the fetus - a thin electrode wire is screwed into the fetal scalp. The fetal scalp electrode provides information only on the fetal heart rate - not on the pH or oxygenation of the fetus. Thus, the clinical team is still faced with the same questions about fetal well being when the pattern is not reassuring.

Forceps and vacuum extractors, while effective, can cause anxiety for parents who are concerned about the potential for injury to their baby.

The number of Cesarean births rose in the United States in 1997 and again in 1998 to top 21.2 percent. These were the first two increases in Cesarean birth rates since 1989. In addition, although the number of vaginal births after a Cesarean section (VBAC) have risen consistently over the past decade, almost 75 percent of mothers who have one Cesarean birth, deliver their subsequent children in the same manner. On a purely financial level, Cesarean births are much more costly than...
vaginal childbirth, and result in a longer length of stay for the mother. On an emotional level, the parents are not able to experience the childbirth they had hoped.

**The Promise of Fetal Oxygen Monitoring**

New fetal oxygen monitoring technology, developed by Mallinckrodt, the world’s leading provider of oxygen monitoring solutions, is designed to help reassure the obstetrical team that the baby is well oxygenated during periods of a non-reassuring fetal heart rate. By allowing continuous measurement the oxygenation level of the fetus during labor, obstetricians can monitor the status of the fetus in relation to the changes in heart rate, and intervene only when necessary.

A healthy air-breathing adult or child has a normal oxygen saturation range of 95 - 100 percent. A baby in the womb receiving oxygenated blood via the placenta and umbilical cord, is uniquely adapted to live at a much lower range, only about 30 - 70 percent oxygen saturation. These oxygen levels can now be accurately measured using the Mallinckrodt OxiFirst™ fetal oxygen monitoring system.

In a randomized, controlled clinical trial of more than 1,000 births conducted at nine sites throughout the United States, fetal oxygen monitoring proved to be safe and effective for measuring the oxygenation of a fetus during periods of non-reassuring fetal heart rate patterns. Use of the OxiFirst System as an adjunct to traditional FHR monitoring did not result in a reduction in the overall rate of deliveries by Cesarean-section. Cesarean deliveries for non-reassuring fetal status (NRFS) were reduced in the test group (FHR + OxiFirst) by 50 percent. For reasons not explained by the study data, Cesarean deliveries for dystocia were increased in the test group to offset the reduction in Cesarean deliveries for NRFS.

**How Fetal Oxygen Monitoring Works**

Research and development of fetal oxygen saturation monitoring has been underway for more than a decade. It was started by Nellcor Puritan Bennett (NPB), and has been completed under Mallinckrodt, which acquired NPB in 1997. The OxiFirst system adapts the core concept of adult oxygen monitoring (which has been available for almost two decades) with a form factor that can be utilized in utero during labor and delivery.

Blood oxygen saturation measurement is based on the color of the blood itself. Well-oxygenated blood is bright red, whereas poorly oxygenated blood becomes darker as the oxygen saturation decreases. By shining red and infrared light through the skin, and measuring the amount of the light at each wavelength that is reflected back, an oxygen monitor can calculate the oxygen saturation of blood on a percentage scale.

In adults and children, a sensor housing an LED light and photo-sensor is taped to a finger, earlobe, temple or toe - places where the skin is relatively thin and smooth and capillaries are close to the surface.

The OxiFirst™ system utilizes a single-use, fetal oximetry sensor, which is inserted through the birth canal during labor, after the amniotic membranes have ruptured and the cervix is dilated to at least two centimeters. It rests against a smooth patch of the baby's skin - a cheek, forehead, or temple - and is held in place by the uterine wall.

Red and infrared light shines into the skin and the reflected light is analyzed in order to derive the percent oxygen saturation of the baby's blood, which is displayed as a number on the monitor screen.

This data, when viewed in association with the EFM, gives the obstetrics staff quantitative information to assess fetal oxygen status and help manage the birthing process.

Because a fetus can move a great deal during labor, the monitor indicates when the sensor is no longer in contact with the fetal skin.
Mallinckrodt's OxiFirst fetal oxygen monitoring technology has been available in Europe since 1995 and in Canada since 1998. The technology is available as either the standalone N-400 fetal oxygen monitor sold by Mallinckrodt, or as an integrated feature in electronic fetal monitors sold by Agilent Technologies (Hewlett-Packard) and GE Medical Systems (Corometrics) - the world's two largest providers of maternal/fetal monitors. Both standalone and integrated systems require the FS-14 single-use fetal oxygen sensor. The N-400 is approved for sale in the United States. Agilent and Corometrics integrated solutions are currently the subjects of U.S. FDA Pre Market Approval applications (PMA).

The N-400 monitor can be connected to Agilent, Corometrics, Oxford Medical and other fetal monitors via a digital interface. Fetal oxygen values are annotated and recorded on the uterine activity scale of the fetal monitor chart paper. The Agilent and Corometrics systems both use Mallinckrodt FS-14 single-use fetal oxygen sensors exclusively.

Disclosures:

Source URL: http://www.physicianspractice.com/articles/case-fetal-oxygen-monitoring