UT SOUTHWESTERN MEDICAL CENTER NEWS

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Measuring fetal oxygen does not reduce Caesarean rate, researchers find

DALLAS – Nov. 22, 2006 – Measuring the amount of oxygen in the blood of a fetus during labor has no bearing on whether a Caesarean section is performed and does not affect the health of the newborn baby, researchers at UT Southwestern Medical Center have found in a multicenter study.

In the study, appearing in this week's edition of the *New England Journal of Medicine*, researchers tested whether doctors' knowledge of fetal blood-oxygen levels – measured through fetal pulse oximetry – made a difference in the rate of Caesarean section or condition of the newborn infant.

The device used to measure oxygen levels, called OxiFirst, was conditionally approved by the Food and Drug Administration in 2000. That approval was conditional because of questions regarding the impact of the device on the rate of Caesarean delivery, said Dr. Steven Bloom, chairman of the department of obstetrics and gynecology at UT Southwestern.

"We didn't find a device that could help us, but I think the good news is that these results have served to protect pregnant women from being exposed to equipment and a technology that appears to provide no benefit," Dr. Bloom said.

Obstetricians would like to find better ways to measure the fetus' health during labor, he said.

The current *NEJM* study involved 5,341 first-time mothers at 14 university hospitals. Specialized oximetry sensors were fed through the cervix and positioned against the fetus's face to measure the level of oxygen in its blood.

With computers recording the data, the women in the study were randomly placed into one of two groups – in one, the clinicians could see the oxygen readings, and in the other, they couldn't.

The rates of Caesarean section or forceps or vacuum delivery were very close in both groups, as was the overall health of the babies. There also was no difference in labor complications between the two groups.

In 507 cases, the devices were removed because of technical problems or at the request of the mother or doctor.

The study was originally planned to involve 10,000 women, but was stopped early because "the results were conclusive at that point, conclusive that knowledge of fetal oxygen saturation did not

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improve Caesarean rates or fetal condition," Dr. Bloom said.

The FDA originally approved the device in the wake of a study of 1,010 women in labor with "non-reassuring fetal heart rates," such as speeding up or slowing down of the heart rate. In that study, oximetry greatly reduced the Caesarean section rate due to non-reassuring fetal heart rate patterns, but unexpectedly also greatly increased the number of Caesareans due to other labor complications.

Because those data were inconclusive, and researchers wanted to see in a larger group whether it was safe to withhold Caesarean sections when oximetry showed normal blood oxygen levels but heart monitors showed abnormal heart rate, and to find whether oximetry improved the baby's health.

Other participants in the current study were the National Institute of Child Health and Human Development, the Food and Drug Administration, George Washington University, University of Utah, University of Alabama at Birmingham, UT Health Science Center at Houston, University of Pittsburgh, Northwestern University, Wayne State University, Drexel University, Brown University, Case Western University, University of North Carolina, Columbia University, Wake Forest University, Ohio State University and UT Medical Branch at Galveston.

The work was supported by the National Institute of Child Health and Human Development.

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UT Southwestern Medical Center, one of the premier medical centers in the nation, integrates pioneering biomedical research with exceptional clinical care and education. Its more than 1,400 full-time faculty members – including four active Nobel Prize winners, more than any other medical school in the world – are responsible for groundbreaking medical advances and are committed to translating science-driven research quickly to new clinical treatments. UT Southwestern physicians provide medical care in 40 specialties to nearly 89,000 hospitalized patients and oversee 2.1 million outpatient visits a year.

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