Fetal Pulse Oximetry Fails to Lower C-Section Rate

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MIAMI — Fetal pulse oximetry failed to significantly decrease the cesarean delivery rate or to improve neonatal outcomes in a randomized, multicenter study of more than 5,000 women, Dr. Steven L. Bloom said at the annual meeting of the Society for Maternal-Fetal Medicine.

"Unfortunately, the results of this study … suggest that fetal oximetry has not realized its promise of reducing cesarean births," said Dr. Bloom, who presented the findings on behalf of the National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network in Bethesda, Md.

Dr. Bloom and his associates randomized 2,629 nulliparous women at term in early labor to an "open oximetry" group; physicians delivering the babies of the women in this group could view fetal oxygen saturation values. For comparison, investigators randomized another 2,712 women to a "masked oximetry" group. The oximetry was an adjunct to continuous electronic fetal monitoring.

A total of 692 women in the open group and 747 women in the masked group delivered via cesarean section (26.3% vs. 27.5%). A nonreassuring fetal heart rate was the reason for cesarean section for 187 women in the open group and 214 women in the masked group (7.1% vs. 7.9%). Dystocia was the reason for 490 women in the open group and 521 women in the masked group (18.6% vs. 19.2%).

"The overall cesarean rate, as well as the rates of cesarean deliveries for specific indications, was not different," said Dr. Bloom, interim chair of the department of obstetrics and gynecology at the University of Texas Southwestern Medical Center, Dallas.

A study published in 2000 had shown that the rate of cesarean delivery for nonreassuring fetal heart rate was reduced significantly from 10% to 5% with the addition of fetal pulse oximetry. That study also showed a doubling of the rate of cesarean section due to dystocia, so there was no significant reduction in the overall cesarean rate—26% with fetal heart rate monitoring alone vs. 29% with fetal heart rate monitoring plus oximetry (Am. J. Obstet. Gynecol. 2000;183:1049-58).

Fetal pulse oximetry could 'escalate the cost of medical care without necessarily improving clinical outcome,' according to an ACOG statement.

Based on these earlier findings, the American College of Obstetricians and Gynecologists in 2001 issued a Committee Opinion stating that it did not endorse adoption of fetal pulse oximetry into clinical practice, citing concerns that the device could "escalate the cost of medical care without necessarily improving clinical outcome." ACOG also recommended further study of the device.

The U.S. Food and Drug Administration required additional research when it granted conditional approval for the fetal pulse oximeter device in 2000.

Results of the first large, randomized trial since 2000 are not encouraging.

Dr. Bloom and his associates designed the study to assess whether knowledge of fetal oxygen saturation values in the perinatal period would significantly change the overall cesarean rate. Any changes in cesarean rate for a nonreassuring fetal heart rate or dystocia, as well as any impact on maternal and infant safety, were secondary objectives.

Infant outcomes did not differ significantly: 0.7% of each group was intubated in the delivery room and 0.3% of each group had confirmed sepsis. In addition, 0.2% of the open group and 0.1% of the masked group had 5-minute Apgar scores of 3 or less; 0.6% of the open group and 0.5% of the masked group had an umbilical artery pH less than 7; and 4.8% of the open group and 5.4% of the masked group were admitted to the neonatal intensive care unit.

There was no significant difference in maternal morbidity between groups. In each group, 10.7% experienced chorioamnionitis; 4.3% of the open group and 4.4% of the masked group had postpartum endometritis; and 0.2% of the open group and 0.1% of the masked group had a wound complication. ■

Pages 34a—34b