FDA Approves Fetal Heart Monitor; ACOG Balks

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Contributing Writer

A fetal heart monitor that provides an analysis of the fetal ECG during labor has won Food and Drug Administration approval almost 4 years after it was originally rejected for use in the United States.

The American College of Obstetricians and Gynecologists is standing firm, however, in its refusal to endorse the STAN S31 fetal heart monitoring system "until it's proved efficacious" in everyday clinical use.

The device, which is used in 22 countries, is now labeled for use in the United States as an adjunct to standard electronic fetal monitoring (EFM) for determining "whether obstetric intervention is warranted when there is increased risk of developing metabolic acidosis." Physicians who use the device, the labeling says, must be certified and credentialed in its use.

The new system monitors the fetal ECG and heart rate via a scalp electrode, automatically identifying and analyzing T-wave and ST-segment changes, which reflect myocardial ability to respond to hypoxia. When the STAN system was first reviewed in 2002, members of the FDA's Obstetrics and Gynecology Devices Panel agreed that findings from a randomized Swedish trial of almost 5,000 women in labor demonstrated its safety and effectiveness.

Among women who were monitored with both the STAN monitor and conventional monitoring, as opposed to conventional monitoring alone, metabolic acidosis was reduced by 54%, and operative deliveries for nonreassuring fetal heart rate were reduced by 19%. Moderate and severe neonatal encephalopathy were also significantly reduced.

The panel recommended nonapproval, however, citing concern about differences between Sweden and the United States in labor management and medical terminology. The FDA asked the manufacturer to conduct bridging studies to show that U.S. clinicians could learn the STAN system.

Last June, satisfied with the results of the two bridging studies, the panel unanimously recommended approval. Panelists voiced hope that the device could decrease its false-positive rate and thus reduce the rate of unnecessary cesarean sections. But at the same time they expressed concern that it could do the opposite and increase the cesarean section rate.

Dr. Gary D.V. Hankins, who chairs ACOG's Committee on Obstetric Practice, said he and others on the committee share this concern. For ACOG to endorse use of the device, it has to know "if it does indeed prevent injury without inordinately increasing operative delivery" once it is used in U.S. institutions. "Other technologies that were going to 'get rid of the neurologically impaired baby' haven't delivered on their promises," said Dr. Hankins of the University of Texas, Galveston. "It's a responsible position to be conservative and not endorse any technology until it's proved efficacious—that is, it provides something that's worth the cost."

Dr. Julia Carey-Corrado, the FDA's clinical reviewer of the device application, said the FDA is requiring the manufacturer to submit annual reports that address a specified list of adverse events, including rates of perinatal death, neonatal encephalopathy, acidemia, and acidosis; the rate of device malfunction; the number of monitors sold; the number of institutions using the monitors; the proportion of patients monitored with STAN as opposed to standard EFM; and the number of physicians credentialed.

"The reports [will provide for] a more systematic, intense review" than normally occurs through the FDA's standard adverse event reporting requirements, Dr. Carey-Corrado said.

"The approval is unique in that we have been very explicit [in our conditions]," she said. "And having a denominator [on the extent of the device's use] will allow us to interpret the significance of outcomes."

The FDA will not, however, require the manufacturer to submit data on operative delivery rates, which is something its advisory panel recommended in June.

According to Colin Pollard, chief of the FDA's ob.gyn. devices branch, the agency decided not to require collection of these data, largely because it felt the issue of operative delivery rates had been addressed in the pivotal study.

In the pivotal Swedish randomized trial, the rate of operative delivery decreased significantly with the use of the STAN system. The rate of cesarean section for fetal distress was not significantly lower when all enrollees were included (the intent-to-

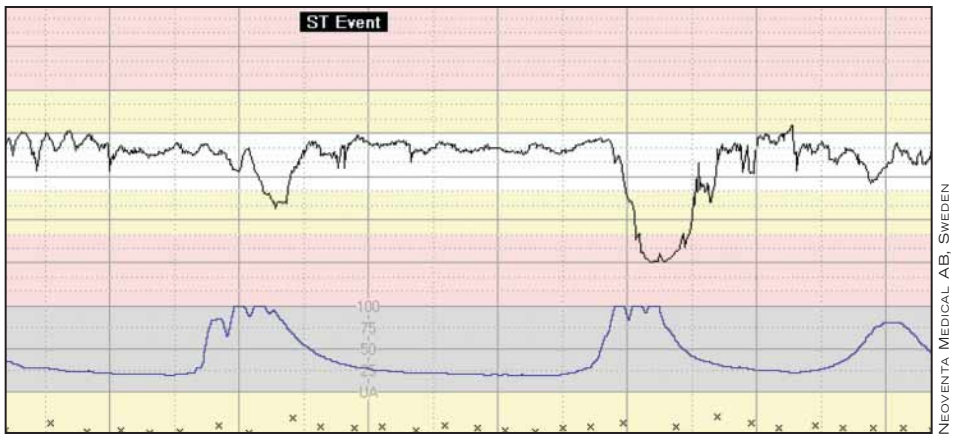
treat analysis), but it was significantly lower when only those with adequate recordings were included.

Under the FDA's requirement for training, clinicians must be certified based on a written test and credentialed based on an oral exam that is administered after successful completion of at least five "practice cases," according to Dr. Carey-Corrado.

Physician certification is something the FDA's advisory panel called for in June, and the FDA deliberately structured its training requirement to resemble the training that was required of clinicians in the U.S. bridging studies, she said.

Dr. Hankins questioned how such a requirement could be enforced and said that training is ultimately "under local purview." When asked about enforcement, the FDA's Mr. Pollard acknowledged the validity of the question and said that the agency's authority "does not extend beyond the labeling."

The STAN S31 system is indicated for use in patients with planned vaginal delivery, greater than 36 weeks of gestation, a singleton fetus, vertex presentation, and ruptured amniotic membranes. Simon Grant, CEO of Neoventa, the monitor's Swedish manufacturer, said the company intends to partner with a U.S. company to introduce the device to the U.S. market this year. ■



NEOVENTA MEDICAL AB, SWEDEN

The upper trace of this STAN S31 recording is the fetal heart rate, the bottom shows uterine contractions. The black flag above marks an ST-segment event.

GERD Overlooked, Undertreated in Pregnant Women

SCOTTSDALE, ARIZ. — Gastroesophageal reflux disease may be underreported and undertreated in pregnant women, according to a poster presented at the annual meeting of the Central Association of Obstetricians and Gynecologists.

Dr. Houmam Al-Hakeem and his coinvestigators at Southern Illinois University in Springfield diagnosed the condition in 72 of 111 pregnant women screened with the Gastrointestinal Symptom Rating Scale Questionnaire, a measure validated in published studies.

The poster reported that a 2-week trial of conservative management, described as "the first line of treatment in pregnant women," failed to improve the cumulative scores of the women who had symptoms of gastroesophageal reflux disease (GERD).

GERD "is very common in pregnancy but at the same time it is very overlooked," Dr. Al-Hakeem said in an interview.

Conservative management, as prescribed in the study, includes not lying down after meals, avoiding certain foods, raising the head of the bed, and taking antacids. Physicians know this does not work, and prescribe drugs as a first-line treatment in GERD patients who are not pregnant, according to Dr. Al-Hakeem, who now practices in San Antonio.

"Why are we waiting during pregnancy?" he asked. "Because we are afraid to give medicine."

He said the investigators have begun the second phase of the study: a double-blind crossover trial of GERD treatments in a pregnant population. The study will look at fetal outcomes and reflux symptoms in patients treated with conservative management, the drugs Zantac and Prevacid, and a placebo. Dr. Al-Hakeem anticipated results would be available in about a year.

The 111 patients in the first phase were in good health in a pregnancy of at least 24 weeks' gestation. Patients with documented history of GERD, esophageal disorders, Zollinger-Ellison syndrome, hiatal hernia, peptic ulcer syndrome, and irritable bowel syndrome were excluded.

The investigators found no significant differences in ethnicity, education, tobacco use, or alcohol and drug use between the 72 women deemed to be GERD positive and the 39 women who were not.

—Jane Salodof MacNeil