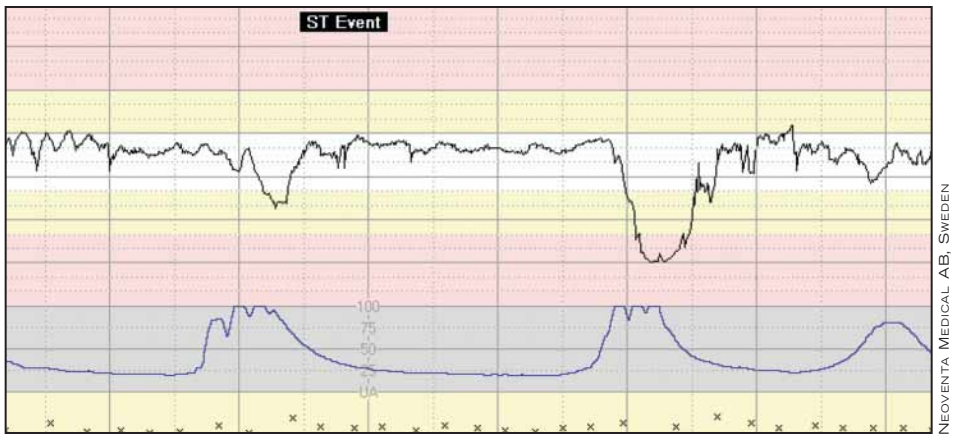
treat analysis), but it was significantly lower when only those with adequate recordings were included.

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