NAAT Outperforms Antepartum GBS Culture

BY SUSAN LONDON

FROM THE ANNUAL MEETING OF THE SOCIETY FOR MATERNAL-FETAL MEDICINE

SAN FRANCISCO – A rapid intrapartum test for group B streptococcus may improve identification of colonized pregnant women, according to study results reported at the meeting.

When the rapid test – a nucleic acid amplification test (NAAT) that yields results within an hour – was compared with a conventional antepartum bacterial culture, the rapid test was superior in identifying which of the 559 laboring women in the study had group B streptococcus (GBS) colonization (sensitivity, 91% vs. 69%). The rapid test also had a significantly better negative predictive value, and its specificity and positive predictive value were similarly high.

"In our population, intrapartum NAAT appeared to have superior test characteristics to antepartum culture for predicting intrapartum GBS culture status," said Dr. Munish Gupta, an associate director of the neonatal intensive care unit at the Beth Israel Deaconess Medical Center in Boston.

"NAAT may be able to help identify women who are positive for GBS by intrapartum culture but negative by antepartum culture, a group of women that would be at particularly high risk for GBS transmission to their newborns by current standard management," he commented.

In fact, about 60% of cases of neonatal early-onset GBS disease occur in infants born to mothers who screened negative by conventional means during their pregnancy, according to Dr. Gupta. "In addition, it has been well documented that results of antepartum GBS screening cultures do not always accurately predict

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Major Finding: The rapid intrapartum GBS test, compared with antepartum culture, had a significantly better sensitivity (91% vs. 69%) and negative predictive value (97% vs. 91%). The specificity and positive predictive value were similarly high.

Data Source: A prospective study of 559 women in labor who had documented antepartum culture results and had not received intrapartum antibiotics.

Disclosures: Dr. Gupta did not report any relevant financial disclosures. Cepheid loaned the investigators the system used for rapid testing.

intrapartum GBS status."

The investigators prospectively studied pregnant women who were admitted to the labor and delivery department, had documented results of an antepartum GBS culture performed at 35-37 weeks' gestation, and had not received intrapartum antibiotics.

Two intrapartum rectovaginal samples were obtained according to Centers for Disease Control and Prevention guidelines.

One sample was sent for GBS culture by the hospital laboratory, and the result of this intrapartum culture served as the reference standard for the study, Dr. Gupta explained.

The other sample was used for rapid testing with the Xpert GBS test, performed in the department 24/7 on a system loaned to the investigators by the manufacturer, Cepheid.

"Of note, the intrapartum culture and NAAT results were not used for clinical management," he pointed out.

Study results were based on 559 women who were 32 years old, on average. About 61% were white, 14% were Asian or Pacific Islander, 13% were black, 10% were Hispanic, and the rest were of other races or ethnicities.

The women had a mean gestational age of 39.4 weeks, and 99% had singleton pregnancies. Nearly three-fourths delivered vaginally.

Overall, 24% of the women had a positive result on the intrapartum GBS culture, according to Dr. Gupta.

The rapid test, compared with antepartum culture, had a significantly better sensitivity (91% vs. 69%) and negative predictive value (97% vs. 91%), and a similarly high specificity (98% vs. 96%) and positive predictive value (92% vs. 84%).

The results of antepartum and intrapartum culture were discordant in 10% of women overall. But the rate of discordance varied by race/ethnicity ($P = .006$), ranging from 4% in Asian women to 18% and 19% in their black and Hispanic counterparts, respectively.

Among women with a negative antepartum culture, 9% had a positive intrapartum culture, Dr. Gupta reported. Most of this subset did not receive intrapartum antibiotics (98%) and had infants who did not receive a sepsis evaluation (78%). Fully 81% of the subset had a positive rapid test result.

Previous studies of NAAT testing have raised concerns about the frequency of indeterminate test results in clinical practice, he noted. The results of the rapid test were indeterminate on first testing in 13% of the women studied, but they were indeterminate on repeated testing in merely 2%. The sample preparation time for the rapid test was 5 minutes, and the median processing time was 48 minutes, with 99.6% of samples processed in 50 minutes or less.

"Future work is needed to continue to explore the role of intrapartum GBS NAAT in clinical practice," Dr. Gupta asserted. "It may be that the NAAT will prove to be a useful adjunct in certain populations in which the antepartum culture may not be a sufficient determinant of intrapartum GBS risk, such as [women who] are GBS negative on antepartum culture, black and Hispanic women, and preterm deliveries."

The study did not have adequate power to assess the potential impact of the rapid test on neonatal outcomes, but they should be a focus in future studies, he recommended.

When asked by an attendee if he would argue with new guidelines that recommend prophylaxis in women with risk factors even if they have a negative NAAT test result, Dr. Gupta emphatically said he would not argue with them.

"I don't think any of us ... involved in this study would look at the NAAT as a replacement for antepartum screening. Antepartum screening clearly has been incredibly effective and very important for reducing the burden of GBS disease, so I think the idea would be that NAAT might be a supplement in certain populations who are currently being missed by the antepartum culture," he commented. "So I agree with current treatment for either antepartum culture–positive moms or moms with other risk factors. This [test] doesn't really seem to replace that." ■