New Test Eyed for Ruling Out Preterm Delivery

VITALS

Major Finding: The negative predictive values for preterm delivery were similarly high for *ph* IGFBP-1 and fetal fibronectin; the positive predictive values were poor for both.

Data Source: A prospective cohort study among 349 women with symptoms of preterm labor.

Disclosures: Dr. Cooper reported that she had no relevant financial disclosures.

BY SUSAN LONDON

FROM THE ANNUAL MEETING OF THE SOCIETY OF OBSTETRICIANS AND GYNAECOLOGISTS OF CANADA

VANCOUVER, B.C. – The phosphorylated insulinlike growth factor binding protein–1 test may edge out the fetal fibronectin test when it comes to predicting preterm delivery, a study has shown.

In the prospective cohort study among 349 women with symptoms of preterm labor, the two tests had similarly good negative predictive values, 0.86 and 0.88, researchers reported at the meeting. Both had poor sensitivity and positive predictive values.

However, the phosphorylated insulinlike growth factor binding protein–1 (*ph* IGFBP-1) test (marketed outside the United States as the Actim Partus test) costs about one-fourth as much as the fetal fibronectin test. Also, the former is a simple dipstick test that can be run at the bedside, and it differs in not being affected by recent intercourse or vaginal examinations.

The Actim Partus test is not currently available in the United States. "The timeline for its clearance and availability in the United States is … not yet known," according to a spokes-

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woman for Medix Biochemica, Kauniainen, Finland.

"The Actim Partus compares favorably to fetal fibronectin for the ability to rule out preterm labor," said lead investigator Dr. Stephanie Cooper, program director of maternal-fetal medicine at the University of Calgary (Alta.). "Given the benefit of reduced cost, efficiency, and ability to use it in a broad clinical scenario, institutions should consider using the newer test, the Partus test, until better tools are available."

Her institution has not yet switched to the new test. "But what I will say is these results definitely make me do fetal fibronectin less," she commented. "I don't think Partus is a good test, I don't think fibronectin is a good test. … I'm hoping that there's going to be a better test."

Fetal fibronectin is generally regarded as the gold standard for predicting preterm delivery, according to Dr. Cooper.

However, "it is not a perfect test. In fact, maybe it's more like the bronze standard," she commented. Its limitations include a poor positive predictive value; false-positivity in women who have recently had a vaginal exam or intercourse; cost; and, usually, the need for a laboratory for analysis.

"*Ph* IGFBP-1 is released by the cervix following disruption of the choriodecidual barrier, which we believe occurs with the onset of labor," she explained. It has shown promise for overcoming some of the limitations of the fetal fibronectin test.

The researchers enrolled in the study 349 women who had symptoms of labor preterm (between 24 and 34 weeks' gestation) and no contraindications to vaginal examination.

Women were ineligible if they had ruptured membranes, had antepartum hemorrhage, were in active labor (defined as having a cervix diameter of greater than 3 cm), or had suspected chorioamnionitis.

All of the women received routine care. A swab for fetal fibronectin testing was obtained according to usual protocol; per institutional procedure at the time, the swab was kept for 2 hours and analyzed only if symptoms of labor were still equivocal.

A cervical swab was obtained for *ph* IGFBP-1 measurement with the Actim Partus test. Patients who were ineligible for a fetal fibronectin test because of a recent vaginal examination or intercourse still had this test. All of these swabs were analyzed by a study registered nurse who was blinded to the patient's clinical course.

The women were 29 years old, on average. The mean gestational age was 29.8 weeks. Forty-three percent were nulliparous, and 16% had previously experienced a preterm birth. Three-fourths had a cervical dilation on admission of 0-1 cm.

Swabs were processed for *ph* IGFBP-1 in all 349 women, but for fetal fibronectin in only 288 of them. In other words, 17% of the women did not have the latter test run either because they were ineligible because of recent vaginal examination or intercourse or because labor was no longer equivocal after the 2-hour wait.

Overall, 26% of the *ph* IGFBP-1 test results were positive (had a value of at least 10 mcg/L), and 8% of the fetal fibronectin test results were positive (had a value of at least 50 ng/mL).

Only 16% of the women were delivered preterm (before 37 weeks' gestation). "This just goes to show that the majority of patients who present with preterm labor actually will not deliver preterm," Dr. Cooper commented.

The *ph* IGFBP-1 test and the fetal fibronectin test had similarly good negative predictive values for preterm delivery (0.86 and 0.88).

The positive predictive value was poor for both, although somewhat more so for *ph* IGFBP-1 (0.22 and 0.54).

The *ph* IGFBP-1 test and the fetal fibronectin test also both had poor sensitivity (39% and 33%), while specificity was marginally poorer for the former test (74% and 95%).

The investigators also assessed the performance of the two tests combined. "There were times when they agreed and times when they didn't agree, but it didn't seem to be that combining them together improved your predictability," she said.

Recent data suggest that predictability may improve when a biochemical marker is combined with cervical length on ultrasound, noted Dr. Cooper.

"The problem is, we are looking for a rapid bedside test for people in rural areas who don't have resources," she commented. "So if we start putting cervical length into the mix, then it takes away the primary objective of how do we help people who are living in rural areas that are rural enough to have to make decisions about clinical transfer." ■