Medical Xpress

Point-of-care diagnostic for detecting preterm birth on horizon

October 22 2019

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A new study provides a first step toward the development of an inexpensive point-of-care diagnostic test to assess the presence of known risk factors for preterm birth in resource-poor areas. The study found

that measuring levels of TIMP-1 and D-lactic acid in vaginal secretions may be a non-invasive, cost-effective way to assess the risk for preterm birth due to a short cervix and microbiome composition. The research is published in *mBio*, an open-access journal of the American Society for Microbiology.

"We have found that there are components in the vagina, proteins and bacteria, that can be used to identify women who are at elevated risk for preterm birth," said Larry Forney, Ph.D., a member of the Institute of Bioinformatics and Evolutionary Studies and Distinguished University Professor in the Department of Biological Sciences, University of Idaho, Moscow, Idaho. "There is a need to have a cost-effective diagnostic that can be used to identify women who are at risk for a preterm birth, so more intensive monitoring and, if needed, the most appropriate therapies can be initiated. The goal is to have a point-of-care diagnostic that people can use in a clinic that doesn't require any advanced technology, expensive instrumentation, or extremely specialized skills." Dr. Forney, along with Steven Witkin, Ph.D., Department of Obstetrics and Gynecology, Weill Cornell Medicine, New York, NY, USA and Antonio Moron, MD, Ph.D., Department of Obstetrics, Federal University of Sao Paulo, Sao Paulo, Brazil, served as principal investigators of the new study.

Complications of preterm birth account for roughly a third of the world's 3.1 million neonatal deaths each year. For years, clinicians have known that a short cervical length and depletion of Lactobacillus species in the vaginal microbiome are significant risk factors for preterm birth. In prosperous countries, most pregnant women undergo a transvaginal ultrasound at 18 to 24 weeks gestation, to determine cervical length, and women with a short cervix are treated with progesterone, a cerclage, or a cervical pessary, to reduce the likelihood of premature delivery. Similarly, women who show signs of bacterial vaginosis, by microscopy of Gram-stained smears or various diagnostics based on gene

amplification, are given antibiotics to restore dominance of lactobacilli and reduce the risk of preterm birth.

In many less prosperous areas of the world, however, the resources to perform a transvaginal ultrasound or characterize the composition of vaginal bacterial communities are unavailable. Often, women in resource-poor countries who are at-risk for preterm birth fall through the cracks. "Women with shortened cervixes can have ascending infections from the vagina into the uterus that can elicit inflammation and trigger contractions and preterm births," explained Dr. Forney. "If you can identify people at risk, there are standard therapies that can be given, but if you don't know who is at risk, then you can't very well have a basis of choosing who should receive the additional therapy."

In the new study, funded by the Bill and Melinda Gates Foundation, researchers from Idaho, Brazil, and New York City set out to identify low-cost, point-of-care measures that might be used to predict bacteria that dominate the vaginal microbiome and indicate the presence of a shortened cervix. The researchers collected and analyzed vaginal fluid samples from 340 mid-trimester pregnant women to determine correlates of a short cervix. Roughly 10% of women in the study had a short cervix. They found that tissue inhibitor of matrix metalloproteinases (TIMP-1), D-lactic acid, p62, age and race all directly affected cervical length. TIMP-1, p62 and belonging to the black race had strong negative effects on cervical length (standardized regression coefficients of -0.162, -0.094, and -0.181, respectively).

"Measuring levels of TIMP-1 and D-Lactic acid in vaginal secretions might be a straightforward way to assess a woman's risk for preterm birth," said Dr. Forney. "Our next step is to do a larger study that includes women in their first trimester so that if the findings are similar, monitoring and possible treatment can begin earlier in gestation."

The researchers said the work wouldn't have been possible without the expertise of several disciplines coming together as a team. "This is a prime example of the kind of research that can be done when you bring people in from different disciplines," said Dr. Forney. "This team of investigators included obstetricians, gynecologists, immunologists, microbial ecologists, and statisticians."

More information: Steven S. Witkin et al. Vaginal Biomarkers That Predict Cervical Length and Dominant Bacteria in the Vaginal Microbiomes of Pregnant Women, *mBio* (2019). DOI: 10.1128/mBio.02242-19

Provided by American Society for Microbiology

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