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Role of Fetal Fibronectin (fFN) in the Risk-Assessment for Preterm Birth (PTB)

Announcer:

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Here's Dr. Cynthia Gyamfi-Bannerman.

Dr. Gyamfi-Bannerman:

Hello, my name is Cynthia Gyamfi-Bannerman and I'm a maternal-fetal medicine specialist at Columbia

University in New York City. Today we'll be discussing the roll of fetal fibronectin and the risk assessment of preterm birth.

You can see that preterm birth has increased, actually for the first time in eight years. The United States notoriously has done worse than other developing nations, with earning a grade of "C" and you can see the different states represented here.

So, what are the consequences of preterm birth? There are several, in fact. One is the health impact. More than one-third of deaths during the first year of life are attributed to preterm birth-related causes. There is lifelong complications related to that, including developmental delay, cerebral palsy, and chronic lung and visual problems. The economic impact is also very large. The annual cost of preterm birth, on average, is about $52,000 per premature infant that averages $26 billion in the United States each year. The cost includes not only healthcare cost, but education and lost productivity.

Preterm birth rate in Singleton's is really mainly encompassed by late preterm birth. About 75% of preterm birth is late preterm birth, and then your early premies are less than 32 weeks up to about 33 weeks.

Survival after preterm birth is also directly reflective of the gestational age when these infants are born. At 22 weeks you can see that the survival is quite low but it really increases and by 32 weeks it approaches 100%. Versus mortality which is highest at 22 and 23 weeks, and then really goes down and approaches 0 after about 34-36 weeks.

Acute morbidity by gestational age is also really increased at the earlier gestational age windows. Certainly those respiratory distress, as we know the lungs are the last organ system to develop, that is seen with increasing amounts from 22 weeks to really all the way to the late preterm infants as well at 34 and 36 weeks. But sepsis, intraven tricular hemorrhage, and necrotizing enterocolitis are also elevated among infants that are born preterm.

So one of the goals of Healthy People 2020 was to reduce preterm birth. Some of the sub-objectives here were to reduce the total rate of preterm birth, as well as late preterm birth, 34 to 36 weeks; live births at 32 to 33 weeks; and also the very early preterm births.

So we're here today to discuss fetal fibronectin and how this may have a role in decreasing preterm birth. the utility for it is for women who are symptomatically contracting. What we know is that fetal fibronectin is present normally until about 20-22 weeks and then it goes down. It can help us differentiate if there's a breakdown of the barrier that perhaps is leading to fetal fibronectin release.

The utility of fetal fibronectin is really in its negative predictive value. So it's reassuring in that, if it's negative, a patient who is symptomatic will have less than a 1% chance of delivering both within seven or 14 days.

Let's start with our first clinical scenario. So, Amy is a 26-year-old, Gravita2 Para1001, and she's at 27 and 3/7 weeks, so she's emotive. She has no significant medical history, and she comes to triage with back pain and contractions that are every 15 minutes. She is known not to have a previa, so you're comfortable doing an exam, and she's placed on continuous electronic fetal monitoring.

So what would you do next in this scenario?

So here's what you would end up doing, which is very appropriate. You can use a sterile speculum and take swabs for fetal fibronectin, group B strep, gonorrhea and chlamydia. You did your vaginal exam and she was 1 cm dilated, 60% effaced and at -2 station. Then you performed your sterile vaginal ultrasound and you find her cervical length of 3.1 cm.

So kind of based off of your clinical assessment, and using some of the algorithms which we'll talk about in a bit, she's considered low-risk based off her cervical length measurements and absence really of any other symptoms of preterm labor.

You can be reassured that she probably will not benefit from antenatal corticosteroids because she's unlikely to deliver. You can actually discard your fetal fibronectin swab because her cervical length of greater than 3cm is considered reassuring.

So what if her cervical length was 2.3 cm?

So here's one thing that you can do. You've preformed your fetal fibronectin swab and now you can send it out for testing to see what that result shows. If the results are negative, then you can discharge Amy home, reassuring her that she has a less than 1% chance that she'll deliver in the next 1-2 weeks. Of course, she has to monitor her symptoms because there can be some false negatives.

If it's positive, however, you may want to consider giving antenatal corticosteroids. You may not have to tocolyze her if she remains very softly symptomatic and maybe even admit her for 24 hours and reassess as you're giving her the second dose of steroids. Or she might be able to be discharged and return the next morning, depending on her symptoms, to receive that second dose of steroids.

But what if her cervical length is now 1.4 cm?

Really in this scenario you can consider more strongly administration of steroids, plus or minus tocolysis, depending on the clinical picture, admission, and then steroids at the next point. Your fFN swab can be discarded because a cervical length of less than 2 is concerning for preterm birth.

Moreover, if she were greater than 3 cm or 80% effaced, this is absolutely someone you would submit to labor and delivery, potentially for tocolysis and to receive antenatal corticosteroids.

So there are algorithms that are available to you in managing patients like this when they present to your triage or labor and delivery unit. The Mayo Clinic algorithm is one that we've found particularly helpful and it's downloadable on our website.

ACOG and SMFM have given guidance related to fetal fibronectin testing, and there's also a lot of published expert opinion.

You should keep in mind a few considerations. You shouldn't contaminate the swab with lubricants and you shouldn't use it if there's been sexual intercourse within the past 24 hours. Similarly, if there's blood present it's not something you should use within 24 hours. If someone is 3 cm dilated or more, so those patients don't actually need a fetal fibronectin test, they should be monitored more closely. Certainly not necessary to use in the setting of ruptured membranes, and also avoid absolutely with previa or abruption.

So here is another scenario that will help us understand the utility of fetal fibronectin in clinical practice. Cheryl is a 31-year-old, Gravita-1 Para-0 and she's at 30 and 1/7 weeks, presenting to her community hospital complaining of contractions. She also has an unremarkable medical history and her pregnancy course has been unremarkable. She doesn't complain of leaking fluid. Her vital signs are normal. And everything is well with her.

You insert your sterile speculum and you get your samples, including your fetal fibronectin test.
So what do you do if she's less than 3 cm dilated and her contractions are a little bit more close, and you don't have a transvaginal cervical length?

In a scenario, particularly where you don't have the aid of a transvaginal ultrasound, or a provider who can preform the test appropriately, you can send out your fetal fibronectin test. If the result is negative, then you'll feel more comfortable discharging Cheryl to home. If it's positive, then you can preform further clinical assessments and decide on use of corticosteroid, tocolysis, admission, etc.

There's other algorithms similar to the one used by Ochsner, which this scenario is based off of, that should us how to use fetal fibronectin in the absence of cervical length.

So, what are the learning points that are demonstrated by these cases? When transvaginal ultrasound is available, you can incorporate fetal fibronectin testing into your clinical decision making. So, not necessary if greater than 3 cm, the risk of preterm birth is high. It's pretty valuable in the midportion when the cervical length is between 1.5 and 3. If it's negative, you can discharge the patient home, with precautions, and if it's positive, you may want to admit them to manage for preterm birth risk. Now if it's less than 1 cm then the risk of preterm birth is fairly high and the patient should be managed accordingly.

If transvaginal ultrasound is not available, you can use the Ochsner algorithm, which shows that fetal fibronectin alone is also helpful in managing the patient.

So, what about the economics of using fetal fibronectin?

So here's one study by Giles and colleagues. They found that 90% of patients who came from their outside referring hospitals with threatened preterm labor and who had a negative fetal fibronectin were not transferred, as opposed to when they had previously not used fetal fibronectin. So this had a cost savings of over $30,000 in that unit.

Similarly, Joffe and colleagues evaluated the impact of fetal fibronectin testing in their unit. They found a significant number of reduction in the number of admissions, number of prescriptions for tocolysis, length of stay, and with an estimated cost savings of almost $500,000 in their yearlong study period. So sending a patient home based off of negative fetal fibronectin results was cost saving in these two scenarios.

Rose and colleagues conducted a 12-month retrospective observational study to look at the effect of a standardized, evidence-based protocol for preterm labor evaluation on outcomes and resource utilization. So they reviewed about 200 patients who had gone to their triage units for protocol with a combination of fetal fibronectin and cervical length measurements.
They found that the hospital admission rate was actually reduced to 56% compared to the previous year where they didn't have that algorithm in place. This resulted in a yearly cost savings of about $39,000 – almost $40,000.

And, finally, van Baaren and colleagues found that fetal fibronectin testing in their unit in Europe saved between 2.4 and 2.7 million Euros per year compared to treating all symptomatic patients, so that was almost 4,000 Euros savings per patient.

There's been a recent systemic review and meta-analysis of randomized clinical trials of women who underwent fetal fibronectin testing, and the meta-analysis shows that there was no difference in the incidence of preterm birth rates, no difference in the number that delivered within 7 days, no difference in the rate of maternal hospitalization, or the length of stay, administration of steroid, no difference in neonatal outcomes, and that management based off the fetal fibronectin test actually required higher hospitalization charges.

I think it's important to put this into context. There are folks who will send fetal fibronectin but then not necessarily manage the patient based off the results. The meta-analysis may have been underpowered and they included studies were designed differently. So there was kind of inconsistent application of the fFN testing. And, like I mentioned, lack of adherence to standard protocols and it's really important that fetal fibronectin testing is not intended for women who are asymptomatic, so that was a potential flaw as well.

Recently, there was a paper published in JAMA So it was a prospective cohort of almost 10,000 nulliparous women, who received serial transvaginal cervical lengths and quantitative measurement of fetal fibronectin 474 of those 9,000 had a preterm birth. They found that a short cervix occurred in about 8% at 16 to 22 weeks and a little bit of a higher portion at 22 and 30 weeks. The fetal fibronectin cut off of about 50 ng/mL identified only 7.3% and 8.1% of women who delivered at 22 and 30 weeks respectively.

So what does this study tell us? I think the important information here is that we didn't have details on whether or not the women were symptomatic. So certainly the use of this modality for women who are not symptomatic, and who are not contracting is, I think verified in this study not to be helpful.

It is certainly an incredibly valuable tool to help identify women who are low risk for spontaneous preterm birth and women who present with symptoms of preterm labor.

The lack of strict adherence to diagnostic and treatment protocols, as well as the expansion of use of fetal fibronectin beyond its core assessment strength, is probably not a great idea. There is evidence-based literature to show that this has really confounded our understanding of fetal fibronectin because we're not necessarily applying the results of the test appropriately. And, it's likely diminished the value of fFN testing as a diagnostic tool in clinical settings, but I think importantly, the take-home piece here is that it's helpful in women who are symptomatic, there are algorithms out there to help guide management and it's a tool that we currently use in our institution.

Thank you for listening, my name is Dr. Cynthia Gyamfi-Bannerman and I'm a maternal fetal medicine specialist at Columbia University in New York City.

Announcer:
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