

### Transcript Details

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## Expanding Preterm Labor Assessment Evaluations with fFN Testing

### Announcer Introduction

Welcome to ReachMD.

This medical industry feature, titled "Expanding Preterm Labor Assessment Evaluations with fFN Testing" is sponsored by Hologic.

Dr. Caudle:

Even in the age of moderate obstetrics, 2 high-risk disorders continue to plague those of us in this field: preeclampsia and preterm labor, or PTL. And despite the great advancements that have been made over the past several years, there is still plenty more that can be done to address the emotional, medical and financial challenges associated with these 2 conditions.

Coming to you from the ReachMD studios in Fort Washington, Pennsylvania, I'm your host, Dr. Jennifer Caudle, and joining me to discuss the rationale for expanding our evaluations towards a more standardized preterm labor assessment is Dr. Richard Broth, an OB/GYN and maternal-fetal medicine specialist practicing in the DC Metro area. Dr. Broth, welcome to the program.

Dr. Broth:

Thanks so much for having me.

Dr. Caudle:

Well, we're excited that you're here. So, why don't we start with an overview of preterm birth and how it gets on our radar? I mean, how do we currently identify women who are at risk of preterm birth, and what are those specific risk factors?

Dr. Broth:

Well, there are a number of risk factors that we, as clinicians, have to evaluate in patients just to assess whether or not they are at higher risk for preterm delivery. There are demographic factors including ethnicity, most specifically in the African American community; we have what I call the bookend of ages, maternal age less than, say, 18 years old, older than 35 or 40 years old; socioeconomic status plays a significant role in that, which leads potentially to the next one, which is maternal stress, which is impossible to evaluate because there is no model to evaluate stress and how it relates to one person versus another; and then finally, behavioral patterns, things like cigarette smoking, drug use, etc.

Once we get past the demographics, we have clinical factors as well. We have factors like history of prior spontaneous preterm birth, which increases the likelihood of preterm birth occurring in a subsequent pregnancy. We have multiple gestation, which is exacerbated by assisted reproductive techniques, IVF, etc. We also have cervical insufficiency, which is a topic in and of itself, things like vaginal bleeding that can occur during pregnancy. Obesity or low birth or low maternal weight can also be factors, as well as a history of infection. And once you take all of those and put that together, you have a really good clinical historical assessment of the patient. Maternal body habitus, whether it's obesity or low body weight pre-pregnancy can have an effect.

And despite all of those clinical factors that we just discussed, two-thirds of patients with traditional risk factors that we just explained do not go into preterm labor. Fifty percent of patients who have preterm delivery have no clinical risk factors at all, and therefore, we would not even be following them as high-risk patients. So, even for the best of clinicians, this produces a huge challenge for us to be able to identify those patients who are at high risk for preterm delivery.

In fact, the March of Dimes recently came out with their 2018 preterm birth report card showing the US rate of preterm birth at almost 10%, which is 2% higher than their target rate of 8% which they came out with years ago projecting for the year 2020.

Dr. Caudle:

Well, I'm sure that our audience can relate to these challenges that you've shared. But if risk factor assessments alone aren't sufficient for predicting preterm labor, which is really what you just discussed, then what else should we be thinking about or prioritizing?

Dr. Broth:

The most important thing is that immediately when a patient hits the triage area or the emergency room, they need to be quickly evaluated for preterm labor. There are many patients who come in who are in true preterm labor, and if that's the case, they need to be treated immediately. Having patients sit around in triage not being evaluated would be counterproductive. Once we assess the patient's acuity, then we can take a step back. It's the next level of patient that we need to address in a more systematic fashion to see whether or not they truly are in labor.

The important part of this is that what we want to try and do is target those patients that need to be admitted and those that are able to be discharged.

Additionally, we don't want to keep patients in the hospital who don't need to be in the hospital, as they'd rather be home, and it takes up space in the hospital, financial implications of their admission and other assorted problems that go along with them being in the hospital.

So, why is this important? Well, while we don't really have a miracle cure for preterm birth or preterm labor, we do have interventions that can be used to delay the progression of labor and allow us to intervene and maximize the outcome for the neonate. While the neonatologists have been excellent and their ability to help us has grown over the years and really serve as an excellent backup for us, we would like to keep the baby in utero as long as possible. If we're able to slow down the contractions, if we're able to give steroids to be able to accelerate the fetal lung maturation process and be able to gain time for the patient to remain pregnant, that would be ideal.

Dr. Caudle:

So, let's then focus on the methods of evaluation that are available. Can you give us a better sense of what's commonly used compared to tools that are underutilized?

Dr. Broth:

Traditionally, we have used physical components in order to evaluate the process of labor. And while this is an excellent way of evaluating a patient, it is not the end-all be-all, and because of that, we have implemented over the years vaginal ultrasound to take a look not only at what we can get from a digital perspective, which is the consistency of the cervix, the dilation of the cervix, but also the cervical length, and the combination of the digital exam and the transvaginal ultrasound was able to give us increased information.

The length of the cervix by transvaginal ultrasound gives us a lot of information. There is an inverse correlation with the likelihood of delivery and the cervical length. The longer the cervical length, the better the prognosis. The shorter the cervical length, the more likely the patient will deliver preterm. When we talk about a cervical length, usually a long cervix is defined as anything longer than about 2.5 cm, whereas a short cervix is defined as anything shorter than about 1 cm. In between 1 cm and 2.5 cm is the area with which we are uncertain what to do in many cases because some patients will have a shorter cervix and continue their pregnancy for a longer amount of time and some patients may have a longer cervix and deliver earlier, and this is the time where we need additional information.

Because of this, a tool came out called the fetal fibronectin, which is a biochemical assessment rather than a physical assessment. It is a tool that is able to transcend the physical and actually use as a biochemical marker. Fibronectin is a glycoprotein that is present in the posterior vagina. It should be present in the early stages of pregnancy as well as the late stages of pregnancy but should not be there in high quantities between 22 and 34 weeks gestation. The way the test is used is by identifying its negative predictive value: What is the likelihood that the patient will not deliver if there is a negative test result? We send off the test, we get a negative result, and we can reassure the patient with over 99% confidence that they will not deliver within the next 2 weeks.

Dr. Caudle:

So, as we cover these methods of evaluation, how do they ultimately help us address some of the challenges that you mentioned earlier?

Dr. Broth:

Well, I think if we can take the physical evaluation of the digital exam, the transvaginal ultrasound as well as the fibronectin and put them together, data show that that increases the likelihood that we will get the answer better than using any of them independently. While using that information, we can then, discharge patients that should be discharged and keep patients that should be kept. Patients that have a negative fibronectin test, despite having contractions, despite even having a shorter cervical length, despite having clinical risk factors, even a prior preterm birth, those patients can still be discharged home with the confidence that they're not going to deliver within the next 2 weeks.

Additionally, patients under 32 weeks will receive magnesium sulfate for membrane stabilization and neuroprophylaxis. There are patients that potentially will need to be transferred from the periphery, that by having a negative test, they can stay out in the periphery. They don't have to travel 2 hours to a tertiary care facility that can take care of their newborn, causing a disruption not only in their lives but in their family lives for people to travel to visit them and see them, etc.

So, in reality, the ability to use the physical, the historical, as well as the biochemical together can give us a better potential outcome for the patient, both those that need to be admitted as well as those that we are able to discharge home.

Dr. Caudle:

For those of you who are just tuning in, this is Women's Health Update on ReachMD. I'm your host, Dr. Jennifer Caudle, and with me today to discuss the need for standardized preterm labor assessments is Dr. Richard Broth, an OB/GYN and maternal-fetal medicine specialist practicing in the DC Metro Area.

So, I'd like to come back to the concept of standardized preterm labor assessments, which we know is a problem in obstetric care. So, why is this so important from your vantage point, and what's going to really help us get there for this patient population?

Dr. Broth:

We strive to help the patients in the best way possible. And if the data show that doing things in a systematic fashion is the right thing to do, then we have to appreciate that and we have to do it.

Our goal is to optimize the patient care, maximizing their outcomes with the least amount of morbidity, and it's been shown numerous times—ACOG specifically has addressed this issue—that standardized protocols for the management of many medical things, but specifically the management of preterm labor, decreases intervention, increases and maximizes patient care as well as decreasing the cost of care, which we all know is creeping in in the background in many, many hospital environment situations, etc., where they're looking at how to decrease those costs to be able to provide better care to the patients.

Our goal should be to strive to treat as many patients who are truly high-risk while avoiding unnecessary interventions for those who are not as high risk. There are patients that should be and can be treated at home, because most patients who come to triage with contractions and with signs and symptoms of preterm labor are ultimately going to deliver full-term. Our goal is to assess those patients and treat those patients who have the highest risk of delivery because that is where we need to focus our concentration. By using fibronectin in our regimen, instead of just using the historical factors, instead of just using the physical factors, we should be able to decrease the amount of patients that we have to admit and we have to treat and hone in on those patients that really need our intervention.

Dr. Caudle:

Well, excellent. And so, along those lines then, do you personally have a specific algorithm that you use?

Dr. Broth:

Yes. Thanks for asking that. I think different institutions have different algorithms. What we do here is evaluate, with a history, with a physical exam, if we can with a transvaginal ultrasound depending on its availability, as well as with a fibronectin.

Before doing any exam in my office or the obstetricians in their office in a patient who is complaining of anything that may resemble preterm labor, I suggest that we do a fibronectin before we do the transvaginal ultrasound or the digital exam. So, the patient comes in complaining of lower abdominal pain or pressure. The first thing I do is a fibronectin test; then I do a vaginal ultrasound followed by a digital exam. If the vaginal ultrasound and the digital exam reveal a long cervix that does not appear to be consistent with preterm labor, I throw the fibronectin test in the garbage and I do not send it. If the cervix is short or the patient's symptoms are significant enough that I want to know the answer to the test, I will send off the fibronectin or I will send the patient to the hospital with the fibronectin with them, and they will give it to them and send it through the hospital because the turnaround time is much quicker and we'll get the answers much quicker.

The advantage of the fibronectin test with regard to doing it in this fashion is that the test itself does not cost any money to obtain. It only costs once it hits the laboratory, which means that if a patient comes in and has a long cervix and the digital exam shows that the cervix is closed, you can take that fibronectin sample and throw it in the garbage without costing the patient a dime. It only costs the patient a few minutes of their time.

Dr. Caudle:

And finally, Dr. Broth, are there any other takeaways that you'd like to leave our audience with as we wrap up today's program?

Dr. Broth:

I hope that we were able to explain clear enough that utilizing fibronectin as part of our toolbox in evaluation of preterm labor is

beneficial. I hope that people understand that integrating the physical examination of the cervix, both digitally and with a transvaginal ultrasound, as well as the biochemical marker fibronectin increases the ability to stratify patients by higher and lower risk and be able to focus more on the patients that have higher risk and to be able to discharge patients with lower risk.

Unfortunately, we are not medically advanced enough to be able to have the magic bullet to stop preterm labor, and that's likely because there are many causes of preterm labor and we are unable to define, let alone treat, all of them. However, the goal in 2019 is to try and at least maximize what we can do for the benefit of the patient and the unborn fetus, trying to keep the patient pregnant as long as possible and to be able to intervene with magnesium sulfate, with steroids, in order to benefit the fetus and help the neonatologists.

One exciting thing that is on the horizon is the ability to quantitate the fibronectin value. Currently, we just have positive or negative results. and as we discussed, the negative result is reassuring, and the positive result gives us a moment of pause. However, in Europe, they have started utilizing the fibronectin in a quantitative fashion with excellent results, and the potential for us to be able to utilize that here in the United States soon is very exciting.

This may better help us stratify patients into higher or lower risk categories, but I do stress that this is yet to be FDA approved.

Dr. Caudle:

Well, this has been a great look into ways for us to improve our preterm labor assessments and, in turn, take better care of our at-risk patients. I'd like to thank my guest, Dr. Richard Broth, for joining me today. It was wonderful having you on the program, Dr. Broth. Thank you.

Dr. Broth:

Thank you.

**Announcer Close**

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