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AMOR-IPAT: A New Idea to Reduce the Rate of Cesarean Section

PREVENTIVE INDUCTION OF LABOR IN AN EFFORT TO REDUCE CESAREAN SECTION RATE

You are listening to ReachMD, The Channel for Medical Professionals. Welcome to Advances In Women's Health. Your host is Dr. Lisa Mazzullo, Assistant Professor of Obstetrics and Gynecology at Northwestern University Medical School, The Feinberg School of Medicine.

Cesarean section is the most common operative procedure that women undergo in the United States today. From 1990 to 1999, the National Cesarean Section rate was approximately 22%, but in the last decade a steady increase in cesarean rates have been noted as high as 30% in some areas of the country. Are there ways to reduce the incidents of cesarean delivery while ensuring the safety of maternal and neonatal health?

Welcome to Advances in Women's Health on ReachMD XM 157, The Channel for Medical Professionals.

Today we are being joined by Dr. James Nicholson, the Assistant Professor of Family Practice and Community Medicine at the University of Pennsylvania in Philadelphia. He is also a co-author of a number of studies looking at reducing the incidents of operative delivery by prevented induction of labor known as AMOR-IPAT or the active management of risk in pregnancy at term.

DR. LISA MAZZULLO:

Welcome Dr. Nicholson.

DR. JAMES NICHOLSON:

Thank you very much, thanks for having me.

DR. LISA MAZZULLO:

My pleasure. So, why do you think the C-section rate has risen so much in the last 10 years.

DR. JAMES NICHOLSON:

Well, there are a variety of factors. It's really a multifactorial issue. I think one has to do with a changing population so there is more and more women who are delaying childbirth into their later years, there is a higher rate of obesity in our population, but I think also driving it has to do with medicolegal issues and physicians being concerned about poor outcome so they are less likely to tolerate troubles during labor and then, of course, with more section in the higher primary section rate comes a higher secondary section rate with fewer and fewer physicians being willing to do VBAC or vaginal birth after cesarean delivery, so it's kind of a snowball effect where we are having a higher primary cesarean delivery rate and a higher secondary cesarean delivery also.

DR. LISA MAZZULLO:

You know, I totally agree you know a few years ago in the New England Journal when the article came out talking about uterine rupture rates being double, what we thought they were in VBAC, everyone took a complete step backwards, though our personal rates have not been anything like what had been reported. You know, what's interesting with all that in mind is, do you think the higher section rate really has reduced medicolegal situations or improved maternal and fetal morbidity and mortality.

DR. JAMES NICHOLSON:

Well, I think there is a broader question, which has it improved maternal or fetal as well as maternal outcomes and I think probably the answer to that is it has not, for example, one of the most concerning thing I see is that the actual US maternal mortality rate is actually rising so while it was 7 women per 100,000 death rate back in 1998, now it's risen up through to 13 and now up to 15 out of 100,000 and I would love to change that answer if I could, the bottom line is the maternal mortality rate in our country, although it's still quite low, has increased fairly significantly over the past 5 years. Along with that is I think our term birth in NICU or Neonatal Intensive Care Unit admission rate probably has gone up, although that's a statistic that's very hard to pull out of the preterm NICU admission rate, but lastly the medical liability situation I don't think has improved a whole lot even though we are doing more cesareans, so we are using this procedure more and more, but I am not sure that we are seeing better outcomes as a result, I think probably we are seeing worst outcomes.

DR. LISA MAZZULLO:

But I think, I totally agree, certainly not the first cesarean section, but the second is where you really start to have an increasing maternal risk from that. Well, you know traditional protocols in the OB-GYN community have always encouraged induction of labor when it is an absolute medical necessity because we felt that induction of labor would increase the cesarean risk for a patient.

DR. JAMES NICHOLSON:

Correct.

DR. LISA MAZZULLO:

And it seems like the tenets of your plan are the opposite of that.

DR. JAMES NICHOLSON:

That's right.

DR. LISA MAZZULLO:

Can you explain a little bit why?

DR. JAMES NICHOLSON:

Sure. So, it's a pretty classic case of confounding by indication in that if inductions are safe for only those cases where there are major problems, for example, significant postdatism or high blood pressure or a fetus that looks unusually large. If those are the cases where induction of labor is being used and usually in this day and age, most people only do inductions when there is an ACOG indication, if you compare those cases to cases where labor develops more naturally and somewhat earlier in the term period, then the induction cases will always have worst outcomes than the spontaneous labor cases, but the question that I've raised is it the induction itself or is it the reason that

the induction was necessary that caused the worst outcomes in the induced group and I can, you know, point out a 100 different studies where they've shown that induction is linked with higher cesarean delivery rates, but again all those studies have involved women with increased risk for cesarean delivery before the induction even started. So what I do which is different is to use preventive induction in what I call the optimal time of delivery before problems develop and in that setting, it seems that induction or higher use of induction is actually linked with lower C-section rates and better other outcomes in childbirth.

DR. LISA MAZZULLO:

So Dr. Nicholson, how do you decide what the risk profile is for a patient when you are looking at your AMOR-IPAT study?

DR. JAMES NICHOLSON:

Well, basically it comes straight after the problem list that most physicians keep on their patients so the risk factors that women have for cesarean delivery and other problems usually is in the chart in a specific place, but the risk scoring sheet is based on the two most common reasons for primary cesarean delivery which is (1) cephalopelvic disproportion or baby that's too large to fit through the pelvis and (2) uteroplacental insufficiency where the placenta doesn't support the baby during labor and there is fetal intolerance and then a C-section, so the 2 risk categories are used in my scoring sheet to determine the optimal time of delivery. So, for example, for uteroplacental factors things like chronic hypertension, sickle cell trait, cigarette abuse, advanced maternal age and anemia, all of those risk factors have an odds ratio for their impact on cesarean delivery risk and I convert those odds ratios into a number of days using a conversion formula that I developed about 6 years ago and then you can take any lady from your practice and add up her number of days based on her risk profile in the uteroplacental category, you get a number of days and you subtract that number of days from 41 weeks 0 days gestation and you get what is the upper limit of the optimal time of delivery for the placental group so might be 38 weeks and 6 days, for example.

DR. LISA MAZZULLO:

So if you were going to look at a patient in your practice, can you just give us an example of one patient and how that works out?

DR. JAMES NICHOLSON:

Sure. So, let's say we have a patient who comes in for her first visit. She is 5 feet 1 inches tall, she already weighs 200 pounds and with the previous baby she had a vacuum delivery for a baby that was somewhat large, let's say 8 pounds, that gives her 2 days for her elevated BMI; it gives her 6 days for her short stature; and it gives her 9 days for her previous vacuum delivery which gives a total of 17 days and if you subtract that from 41 days, that would give you 38 weeks and 4 days for her upper limit of the optimal time of the delivery and in this multiparous woman, I would want her delivering by 38 and 4.

DR. LISA MAZZULLO:

So, that makes more sense, it makes it very easy to say.

DR. JAMES NICHOLSON:

Sure, if the same lady had, for example, cigarette abuse and sickle cell trait, that would give her 2 days plus 3 days, which is 5 days, so her uteroplacental optimal time would be 40 weeks and 2 days, but we would pick the lower of the two groups so the 38 weeks and 4 days time, so you always pick the lower of the two groups because you want to get the baby out before one of those two risk group is going to be negatively impacting the delivery.

DR. LISA MAZZULLO:

Okay so if patients have multiple risk factors, you take the one that gives you the earliest delivery date.

DR. JAMES NICHOLSON:

Correct, in the two groups.

DR. LISA MAZZULLO:

If you're just tuning in, you're listening to ReachMD, The Channel for Medical Professionals. I am Dr. Lisa Mazzullo and we are speaking to Dr. James Nicholson and we are talking about some advantages of elective preventive labor induction for patients to reduce the cesarean section risk.

So, Dr. Nicholson we were talking about the risk factors you look at and in the study that you had originally done, it looks like you've combined both first time parents as well as second or third time parents in the same risk factor criteria, is that true?

DR. JAMES NICHOLSON:

Yes.

DR. LISA MAZZULLO:

Okay, you know, typically in the obstetrical community, we feel the risk of induction in a patient who has had a baby already vaginally is much less than inducing someone who is a nulligravid patient, so how do you attribute both of those people being in the same study?

DR. JAMES NICHOLSON:

Well, it had to do with the fact that the way the study was developed, which was when I came to University of Pennsylvania we were allowed to do a study of women in the practice that I was working in and basically in order to get a study that was large enough to develop results on, we included both first birth moms and moms that had babies before. Within the study, there clearly was a difference in cesarean rate reduction in the first birth moms and the multiparous moms, but both were significant reductions. So, for example, the first birth moms they just had a much lower section rate, I don't have that information right here in front of me.

DR. LISA MAZZULLO:

My other question was that in looking at this, it wasn't clear when I was reviewing the study, if the patient had a Bishop score of less than 5, did you find that that affected your outcome for successful vaginal delivery.

DR. JAMES NICHOLSON:

Yes, and traditionally an un-ripened cervix has been a major impediment to induction of labor, however, about 25 years ago, we started to develop a variety of methods to ripen the cervix prior to induction of labor. The main group has been prostaglandin medications, prostaglandin E1 and prostaglandin E2, but there have also been mechanical methods like Foley bulb insertion and laminaria and other things that ripen the cervix, these medications specifically the prostaglandins have been essential in the research I am doing in that many women in the first birth category need to have their cervix ripened prior to induction and I would not have been able to do what I have done without the use of these medications so it's an essential piece, but having that piece available in my mind isn't being utilized as much as we could to help moms get into labor a little earlier and safer.

DR. LISA MAZZULLO:

Thanks to Dr. Nicholson who has been with us as our guest and we've been discussing in preventive induction of labor in an effort to reduce cesarean section rate.

I am Dr. Lisa Mazzullo. You've been listening to Advances in Women's Health on ReachMD, The Channel for Medical Professionals.

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DOCTOR:

So, Rachel.

RACHEL:

Hmm. hmm.

DOCTOR:

Now that you are past menopause and we have determined you have osteoporosis, I would like to start you on prescription only Evista, raloxifene-hydrochloride tablets.

RACHEL:

Why Evista?

DOCTOR:

Because it's the only medicine that reduces the risk of osteoporotic fractures and invasive breast cancer in women like you. It's important to note that Evista does not treat breast cancer, prevent its return, or reduce the risk of all forms of breast cancer.

RACHEL:

Am I really at risk for invasive breast cancer?

DOCTOR:

Based on my risk assessment, you may be. Some risk factors for breast cancer include advancing age, family history, and personal history.

RACHEL:

So even though no one in my family has ever had breast cancer, I am still at risk for other reasons including my advancing age?

DOCTOR:

Exactly, and I think the benefits outweigh the potential risks for you. It's the one medicine that treats osteoporosis and reduces the risk of invasive breast cancer in postmenopausal women with osteoporosis. Individual results may vary, of course, but that's exciting news.

RACHEL:

Exciting? I would have to take your word on that doctor.

DOCTOR:

Evista increases the risk of blood clots. It should not be used by women who have or have had blood clots in the legs, lungs, or eyes. Evista may increase the risk of dying from stroke in women at high risk for heart disease or stroke; talk to your doctor about all your medical conditions. Seek care immediately if you have leg pain or warmth, swelling of the legs, hands, or feet, chest pain, shortness of breath, or a sudden vision change. Do not use Evista if you are pregnant, nursing, or may become pregnant as it may cause fetal harm. Women with liver or kidney disease should use Evista with caution. Evista should not be taken with estrogens. Side effects may include hot flashes, leg cramps, and swelling. For more information about Evista, contact your Lilly sales representative. Visit www.evista.com. See our ad in good housekeeping or call 1-888-44-EVISTA.