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Postpartum Depression: A Significant Burden and a Novel Approach to Treatment

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Dr. Shulman:
I'd like to welcome everybody to this program on “Postpartum Depression: A Significant Burden and a Novel Approach to Treatment.” My name is Lee Shulman. I'm a Professor of Obstetrics and Gynecology at the Feinberg School of Medicine at Northwestern University in Chicago, Illinois. And I'm joined today by Dr. Kristina Deligiannidis, who's the Director of the Women's Behavioral Health Zucker Hillside Hospital of Northwell Health, Professor of Psychiatry, Molecular Medicine, and Obstetrics and Gynecology at the Donald and Barbara Zucker School of Medicine at Hofstra Northwell, and Professor at the Feinstein Institutes for Medical Research at Northwell Health.

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We'll start today's presentation with an overview of postpartum depression. Postpartum depression is depression that begins for the mother within the first 12 months after a baby has been born. It's one of the more common complications of childbirth, and yet it's one of the more commonly ignored complications of childbirth. In fact, up to 15% of women will experience some form of postpartum depression after their baby is born. Of these women, about two-thirds have no previous history of a diagnosed mental illness. And perhaps that's one of the factors that leads it to being readily not evaluated for. But it's important to know that those women who have had a previous episode of postpartum depression have an increased risk for yet another postpartum depression episode to close to 30%.

Postpartum depression can be a mixture of mood disturbances, it's not just one set group of disturbances. It can go from being sad or blue with a low mood or increasing irritability or tension. It can be presenting with increased anxiety, both in the body as well as in thought. And while it is frequently dismissed as an adjustment to that new child, again, as I stated earlier, it is unfortunately not recognized widely as a treatable illness. So these symptoms can range from mild dysphoria all the way to suicidal ideation and psychotic depression, although the far more severe presentations are far less common.

The other issue is postpartum depression symptoms don't just last for a couple of days: “She’ll get over it at the end of the week,” “She'll feel better when she gets home.” That's not true. In fact, half of women are symptomatic for up to 6 months, and 1/3rd of women continue to be symptomatic for 12 months, especially if they have been untreated.

So let’s talk of the range of the types of postpartum depression. The most common of what has been called postpartum blues or baby blues. And this really affects the vast majority of women who likely have some form of postpartum depression, probably 1/2 to 3/4 of all women after delivery. And this does usually subside within 2 weeks without treatment. That doesn't make it any less of an episode of

postpartum depression. And it obviously behooves us to evaluate women for this, and to make sure that it not only doesn't last longer, but that it is something that doesn't require treatment.

Postpartum depression something more than just the blues or baby blues affects about 1 in 7 new parents. And again, as I stated earlier, a previous episode increases the risk to almost one-third. Postpartum depression as opposed to baby blues, which usually subsides without treatment, is amenable to treatment with either psychotherapy or antidepressants, or some of the new therapeutic options that we'll be hearing about in a moment.

Now, the most extreme version of this is postpartum psychosis. This only affects about 1 in 1,000 women after delivery. Postpartum psychosis requires immediate medical attention as there is increased risk both for mother as well as the baby. And in this very rare, uncommon situation, treatment usually includes hospitalization, psychotherapy, as well as medication in a variety of combinations.

So, why does depression risk increase after a baby is born? Well, there are lots of reasons for it. Again, the dismissive concept of, “Oh, she's just hormonal.” Now hormones do likely play an important role. But there are other aspects postpartum that can lead to an increased risk for depression. Sleep deprivation in new parents is a very common occurrence and is a general trigger for mood regulation problems. There are major changes in an individual's role, especially new parents not just in the role as a parent, but in relationships with a partner. And expectations for what that new role can bring can contribute to depression in any person, including perhaps the partner as well. The usual coping strategies may not be as easy to do, such as daily exercise or getting back into one's routine. Obviously, a new parent has a completely new routine. And again, we still have women who have chemistry, brain chemistry that is triggered by the hormonal changes that occur immediately after delivery of the baby as well as the delivery of the placenta. And in these situations, this can be a factor that is shared by family members and something that we would potentially find out about in discussing family history with our patients.

The impacts of postpartum depression I think are rather obvious. Obviously start with mom. Start with mood and social interactions as well as physical and mental health. With the baby, we can find delayed cognitive and psychological development if mother is having severe depression, they tend to be a fussier and vocalize less, you have delayed motor skills, as well as the need for increased healthcare resource use. And as far as impact on marriage and partnerships, postpartum depression has been shown to, potentially, up to doubling the risk of divorce or dissolution of the relationship.

Again, the signs and symptoms that obstetrical providers and women's healthcare providers are really called to evaluate and recognize are not necessarily specific to postpartum depression. Mood changes, inability to concentrate, sleep and appetite disturbances, you can read them on this chart. But these are issues that myself as an obstetrician/gynecologist, evaluate in both pregnant and nonpregnant women all the time. And obviously, when it occurs after a baby has been born, hopefully, that would be the trigger in the clinician that this may be related to postpartum depression, and initiate a more thorough evaluation and the potential for intervention with either psychotherapy or chemotherapeutic options.

So what can be done? Number one, first and foremost, which has been called for by almost every organization that is involved with the care of pregnancy and the care of children is to screen all women for postpartum depression during the antepartum visits. And again, why do we screen all women? Because number one, a woman may be unable to recognize that she is actually depressed or has issues that can be described as depression. She may believe that her symptoms are normal. Maybe she discussed this with a family member who said, “Yeah, just buck up, this is what it is, you know, you're – you're going to have a baby. This, you know, we all went through this.” There’s a fear that if she says something, she’ll be considered a bad mother or a bad person instead of this almost ridiculous concept that every woman, when pregnant, has to be in a state of bliss, smiling, happy, waiting for this blessed event to occur. This is not a reality of taking care of pregnant women. And again, she may fear that her baby will be taken from her if she admits in any way to having some sort of symptom set or maybe even considered to be depressed. So there's going to be, not necessarily a volunteering of this information, and that's why we as clinicians need to be able to screen patients for postpartum depression.

First approach, there are screening options, but a very simple option are 3 simple questions: Have you felt overwhelmed in the last 7 days about anything? Do you have any thoughts of harming yourself or your child? And are you having difficulty adjusting to your new role as a mother or as a pregnant woman? And if the answer is yes to any of these questions, then at that point, the system needs to get together and get this individual to a nurse or a clinician or healthcare provider who can provide a more formalized screening option and intervention for this. This is not something that, “Oh, call me in a week and tell me if it's gotten any better or any worse,” this needs to be addressed if there's a yes answer to any of these 3 very simple, direct questions, immediately acted upon.

I mentioned there are screening tools, the one we use at Northwestern is the Edinburgh Postnatal Depression Scale, but there are others here. They work well to identify and to quantify the level of depression in a patient. And it's something that it needs to be familiar with clinicians, whether or not they're going to provide these formal screening tools, getting them to people who can provide those

screening tools to their patients.

Now, the interventions, I'm going to leave to Kristina in a moment. But again, just looking at this overview. The treatment for postpartum depression is usually dependent on the type and severity of symptoms, and includes psychotherapy, cognitive behavioral therapy, support group participation. There are new medications, antidepressant, and we'll talk about 2 of the newer medications that have been specifically approved for treating postpartum depression. And it's important to know that breastfeeding is not necessarily a contraindication to pharmacotherapy, as well as in severe cases, still electroconvulsive therapy, but clearly not as a first, second, or even third-line option.

So in summary it's important to recognize that postpartum depression is relatively common, can have long-term consequences for mother, baby, as well as family, can be easily missed, in particular, if it's not being looked for, should be screened for in all women, can be treated successfully and not necessarily with drugs, but with a variety of interventions, as you'll hear in a moment, and is best addressed in a multidisciplinary care approach.

So with that, I'd like to turn this over to my colleague, Dr. Kristina Deligiannidis, who's going to talk about the therapeutic intervention for postpartum depression. Kristina?

Dr. Deligiannidis:
Thank you so much, Dr. Shulman. So I'm going to focus on a little bit about the new approach to treating postpartum depression. And I'm going to start out with just kind of setting the stage for why these new therapeutics may be beneficial for women with postpartum depression. So a little bit about the underlying pathophysiology of PPD, postpartum depression, and also how that's tied into how these new medications might work.

So here, you know, in this figure it really kind of gives a summary of where the field is. It's a very rich research field that we're all very active in. And while the precise mechanism of perinatal depression or postpartum depression is unknown, there are numerous pathophysiologic theories of postpartum depression that had been proposed. And this outlines some of those, so endocrine, epigenetic, synaptic transmission, neural circuit, inflammatory mechanisms, neurosteroid, which I'm going to talk more about, and also stress mechanisms. The evidence to date really supports a synthesizer integrated mechanism of disease hypothesis. So it's an integrated process of both psychological and biological risk factors that are coming together in a patient's environment that brings on the symptoms of depression, which can occur either in pregnancy when the hormones are high, or after delivery as the hormones drop.

And one of the leading hypotheses is that women susceptible to developing depression during pregnancy or after delivery, is that they have a higher sensitivity to stress during times of hormone change or hormone variability. And that sensitivity corresponds to a communication in the brain between neuroactive steroids, which we'll talk a little bit more about, and the GABA A receptor in the stress circuit in the brain.

So this next slide, you know, again, is like another picture to just give an overview that these neuroactive steroids, which are the basis of these novel therapeutics that have been FDA approved for postpartum depression are naturally made in the body. So they're pregnenolone metabolites. They're made in the brain. They're made also in the periphery by the adrenal glands, the placenta, and other sources. And they modulate both GABA and glutamate in the brain. So for inhibition and excitation balance in the brain, and they do this, the ones that we'll see today are mainly working as positive allosteric modulators of the GABA A receptor. And we have decades of data really showing that these neuroactive steroids have really important roles in the modulation of acute and chronic stress conditions. And so, they're really important. We think of depression as a stress disorder.

We see on this next slide that during times of hormone change, we also see neuroplasticity or changes in this important GABA system in the brain, in areas of stress regulation. And so here's a figure of an inhibitory synapse in the brain. And you see in the blue, this GABA neuron, and then across from that at the post synapse, where you see the orange receptors, which are GABA receptors, synaptic GABA receptors. And then to the right, you see these blue receptors, which are extrasynaptic. And neuroactive steroids are a little bit different than other GABA-binding substances or GABA receptor-binding substances, like benzodiazepines or barbiturates, because they only bind very specific types of these receptors in the brain. They have to be neurosteroid sensitive. It has a very unique profile.

But the main takeaway here is that there are two types of neurotransmission, a phasic response from the synaptic receptors, and a tonic response from these extrasynaptic receptors. We know that based on hormone levels, when they're high in pregnancy, and then the drop, that those changes in those steroids actually change the number and the density of these neurosteroid sensitive receptors. And they actually influence the excitation inhibition balance in the brain. It's part of this maternal transition that happens in the brain circuit. And so it's thought that either when the hormone levels are high, the brain is not able to adapt its communication between the neurosteroid and the GABA receptor, or for some women, they have their onset right after delivery, and it's the withdrawal of the hormones, or again, these receptors are trying to reset.

Now, when things don't reset appropriately, either during pregnancy when the hormones are coming up or coming back, you'll see on the next slide, then we see network dysfunction, which we diagnose symptomatically in our patients as postpartum or perinatal depression. And so we know through brain imaging studies that postpartum depression is associated with changes in different networks in the brain, the default mode network, the salience network, and others. And we've shown that actually the blood levels of allopregnanolone, one of the key neuroactive steroids, is strongly correlated with these changes in the brain.

And so I give you that background because it's important to understand the pathophysiology in order for us to develop novel therapeutics, and then to understand better how they might work for patients. And so this table here just is a nice summary of both what has been implicated in the pathophysiology of perinatal depression. But then also there are preclinical data studies showing the potential mechanisms, actually mediating antidepressant effects. And you'll see that many of those are matching up and then there's further research that needs to be done as well.

And so as Dr. Shulman noted, there are a couple of different types of modalities in the way we approach a perinatal depression. And so for mild/moderate, and again, this is unipolar perinatal depression or clinical depression with functional impairment, the recommendation is psychotherapy, usually as monotherapy. And in certain patients who have a more significant psychiatric history also, you know, with pharmacotherapy, which we'll discuss. But I listed the most highly evidence-based psychotherapies here on this slide. So interpersonal therapy and cognitive behavioral therapy have the largest evidence base of randomized clinical controlled trials.

Antidepressants, as you can see on this next slide, are indicated for more moderate/severe unipolar postpartum depression. So the wonderful thing about the American College of OB/GYN, or the ACOG [American College of Obstetricians and Gynecologists] guidelines of the Patient Safety Bundle, is that the recommendations of using these validated screeners, we actually use them to track treatment as well. So if you see and you're using the Edinburgh Postnatal Depression Scale, you see someone come in with a 24 or a 26 and you start a standard-of-care antidepressant or any other type of therapy, you can recheck it and see if the treatment is effective. And so we use that for sort of like an indicator to see how treatment is progressing. But for many years, we've used standard-of-care antidepressants. These are the serotonergic antidepressants that are used for major depressive disorder outside of the postpartum period. And there is some evidence, when used for moderate/severe depression, that they can be effective. And I have you know, some of those Cochrane Database data here.

Now regarding lactation in postpartum patients you know, we often use a relative infant dose as a key indicator for one aspect of safety of medications in breastfeeding. And I love this resource at the National Library of Medicine, LactMed. So we often have our providers use that federal resource because it's an up-to-date resource on everything under the sun that's been studied in lactation. And usually, RIDs [relative infant doses] less than 10% are considered acceptable by the FDA and other authorities. And the relative infant dose for antidepressants is standard-of-care SSRIs and SNRIs, they're typically less than 10%.

Now I'll just transition into the newer options, which are not serotonergic antidepressants, they're neuroactive steroids. And so what we're talking about are these naturally made neurosteroids made in the brain, the ovaries, the adrenal glands. Brexanolone was the first FDA approved antidepressant for postpartum depression and the first ever in its class. And this was an IV administered, it's identical to the naturally made allopregnanolone. As I said, a 60-hour infusion and we titrate up and we titrate down. And the relative infant dose for that medication in lactating patients is about 1.3%. So it's quite low. But many women will choose to pump and dump milk and to give milk that they've already pumped prior to the infusion, since it is a short treatment period. Now their scheduling is Schedule IV, and I'll talk to you about the safety around this medication as well.

But just briefly a summary of the randomized clinical trials with brexanolone just to show you really that the treatment is so different than anything else we do in depression care. We enrolled women with moderate to severe depression, and they were randomized to placebo or 2 different doses of the IV brexanolone, just for 60 hours. And then that was the primary endpoint of those trials. And then we followed up at day 7, and day 30. And you can see the rapid reduction. So on the y axis, you see the change from baseline in their total depression score. So you saw that the depression went down quickly, as early as 24 hours, but our primary endpoint was hour 60. And then you don't see any return of depressive symptoms all the way out to day 30, even though it was just the 60-hour infusion.

Now there is a boxed warning for excessive sedation and sudden loss of consciousness that did occur and 5% of brexanolone-treated patients compared to none in placebo. The more common side effects are sedation, somnolence, dizziness, vertigo, things you would think about with a medication that is a positive allosteric modulator of GABA. All patients with LOC [loss of consciousness] or altered consciousness did recover without any intervention. But brexanolone can only be prescribed to certain facilities due to this Risk Evaluation Mitigation Strategy, or REMS. And so that has brought some challenges in access for women with more significant postpartum depression, more severe depression. But encouragingly recent data report that the rate of loss of consciousness might be much lower in clinical practice compared to what we saw in those trials. So that is good news.

What is also good news is that just in early August, zuranolone was the second antidepressant FDA approved for postpartum depression. Now, it's important to understand the differences. Zuranolone is really similar to allopregnanolone, what our brain and our ovaries make; however, there's just a single ring difference at the end that changes the structure slightly that allows this to be given as an oral medication. And so this is a 14-day at-home oral administration that was FDA approved. And we did a lactation study, the relative infant dose was 0.314 at the 30-mg dosing. So again, very low and lower than most standard-of-care antidepressants.

So just a couple of slides, and I'll finish up on the results that led to that FDA approval. Again, the study design was similar, but the treatment period was 14 days at home with nighttime dosing. So women with severe postpartum depression were randomized to placebo in this study. The first study was at 30 mg. And then they were evaluated the next morning at day 15. And then we followed up to see how they were doing 30 days later, when they weren't on that medication any longer. And you'll see a really similar curve. So we see again sort of a rapid reduction of depressive symptoms. And then our day 15 time point is here, then we followed them out, you know, 30 days after without treatment, and they maintained the benefit that they had.

We replicated that with a 50-mg dose. And that's actually the starting dose and the recommended dose, so there's actually no titration of the medication. The FDA in their labeling recommends that the dose is 50 mg for 14 days. And if there are patients that have some side effects, you can lower it down to 40 mg. There are some exceptions for patients with types of renal impairment, those patients can be dosed at 30 mg, and there are details in the labeling. But it was this data from the 50-mg trial, the SKYLARK, that they analyzed and took into their consideration, and they decided that the 50-mg dose would be the dose. And so very similar design. And then as you see in this slide, again, a really similar curve, really similar drop in depressive symptoms. And I think the takeaway from this slide is that we had statistically significant differences after 2 doses. So day 3.

So you think of it as a clinician, you know, if you do prescribe an antidepressant serotonergic, you have a certain follow-up of your patients of checking in for potential side effects. And then they take time to work, so you have them come back in or you have a nurse reach out to see how things are going and check out side effects. Here, this is all done in 14 days. And so you really want to change the way that you're doing your check-ins with the patient, to check for tolerability, everything is going to be a much shorter course, as we think about how are we going to use this with patients in our practice?

We do need to be aware that again, the most common side effects are going to be somnolence, dizziness, sedation, and headache. And there is a boxed warning for impaired ability to drive or engage in hazardous activities due to central nervous system depressant effects. So this is a GABA PAM [positive allosteric modulator]. And so you know, we usually dose around 8 PM with a fatty food usually - or if it's a late dinner, and then 12 hours later, so we advise patients not to drive or operate machinery for these 12 hours after taking the medication.

And then, what's really great about these medications that are coming through and getting FDA approval is that now there are more neurosteroids under development for postpartum depression. So this has just opened the field for treatment of patients with postpartum depression. I've listed 4 here ganaxolone BRII-296, NORA520, and LYT-300. Most are approaching phase 2 trials, or have just completed phase 1 development. Ganaxolone had done many trials with a PO and IV formulation but for whatever reason, they halted their PPD development, and they did go towards an FDA approval for a type of seizure disorder. They found greater benefit for patients with that neuropsychiatric illness. But we do have these 3 other areas of active investigation.

So I think for me as a perinatal psychiatrist and neuroscientist this is incredibly exciting for our patients. It's been something that's been neglected for way too long, and just really exciting to have new options for patients to make their decisions around.

Dr. Shulman:
Kristina, thank you so much for that wonderful presentation. I do have a question, primarily because I'm not a psychiatric healthcare provider, and I've witnessed patients that I've taken care of or other clinicians have taken care of, and there has been a very different approach to not only evaluation, but treatment. So how do you select a specific treatment for a patient with postpartum depression?

Dr. Deligiannidis:
Thank you. It's an important question, because I think in this area of medicine, there's no specific algorithm that states what everyone should start with. So some of the key things I think about are obviously the past medical history. So what is the medical history, the current medical conditions, any current medication that the woman's taking? Where is she in the postpartum period? Did she just deliver? Is she 6 months out? Is she lactating and breastfeeding? If she's lactating, how far out she is, and what's the medical condition of her infant that she's breastfeeding? All of these things are, you know, really important places to start.

And then past psychiatric history, so is this a patient who has had multiple episodes of depression or anxiety? Is it somebody with chronic anxiety in addition to this episode of postpartum depression? Because they might need something that's a little bit longer-term treatment than maybe some of these more acute treatments that are now FDA approved for postpartum depression.

There's also looking at the severity, as I believe you noted, you know, that's a key differentiator. And so for more mild symptoms with less functional impairment you know, it's always a conversation with patients of what their treatment preferences are. But we often can start or do start with psychotherapy. But it's really the patient's choice. And so you know, we can make the recommendations, but some patients will still opt to take a medication. Maybe they have had psychotherapy in the past, it wasn't something they derived benefit from, or they're looking for something different or something they want in combination.

So it's really a lot about their medical history, their past psychiatric history. Obviously, if there's a patient with history of recurrent episodes of depression and chronic anxiety, I'm leaning towards the use of something that I can use more chronically. And so combined psychotherapy, and likely a standard-of-care antidepressant.

For a patient who has more moderate/severe with significant functional impairment, I want to get that woman better as fast as possible. And so that's where I think these rapid-acting neurosteroid antidepressants are really critical. They're going to get patients back up on their feet, functioning, doing all the things that they want to do for themselves and with their baby. And hopefully, we're able to reduce the impact of the illness on, you know, that maternal baby bond and interaction. So quite a few things to consider. It's not just one medication for every patient or one approach.

Dr. Shulman:
Well, your answer, I think, bespeaks something very interesting, is that it doesn't seem that it fits into a simple algorithmic process that the patient's past history or lack thereof, plays a role. Her presentation plays a role. Timing plays a role. And I think that, in a sense indicates the importance of, first of all, being able to screen people for it. And then secondly having a team available that is going to be able to do that proper assessment and recognize the various interventions according to the severity and the temporal nature of the presentation.

Dr. Deligiannidis:
As you mentioned about having a team in place, I'm in the perinatal psychiatry side of things, and so when patients come to me, they've already been screened, they've had an evaluation at some point where they need to see a subspecialist. What type of multidisciplinary team is needed to really optimize the treatment of postpartum depression? Because we know that there are so many gaps and areas where women can fall through the cracks during this process of screening and diagnosis and treatment.

Dr. Shulman:
Well I think the first and most important part of that team is the obstetrical provider. Because if the obstetrical provider is not screening her or his patients then that is just a recipe for disaster. And yes, you're maybe missing the most common baby blues or "Don't worry, dear" but you're also going to be missing those severe cases that could lead to a variety of morbidities and even mortality.

So first and foremost, whether it's a nurse, midwife, an obstetrician, whoever is taking care of this patient during her pregnancy, this has to be as intrinsic a component of her obstetrical care as screening for fetal aneuploidy as screening for gestational diabetes. It is not an also, added to – it is an intrinsic part of routine obstetrical care.

Now, getting to the multidisciplinary team, I've been asked this question before. And sometimes people will hear this and say, "Oh, I work in a community-based hospital, I don't have that team," or "I'm not at Northwell or at Northwestern, or somewhere we have the wherewithal." I would dare say that perhaps outside of an academic center, you're probably somewhat easier to develop that team. Because one of the problems with academic medical centers is that we tend to live in siloed practices. We are involved in obstetrics and gynecology and, yes, we reach out to other specialties. But this clearly, while it is intrinsic to obstetrical care, it clearly involves psychiatric and psychological care. So we first and foremost have to get buy-in from all obstetrical providers, whoever they are. Once that happens I think nurses who are trained in mental health assessment are an important first step. Psychologists, other mental health providers who can provide a thorough screening of a patient who has come up with a positive result or for whom somebody is concerned about their mental well-being. And at that point, bringing in people like social workers who can work the system to make sure that specialty care and subspecialty care is readily available to them. And then finally, psychiatric and psychological professionals who have not just an interest in this, who have experience in this. I can take this patient down the various treatment paths that are needed with understanding that not only does one size not fit all, one size is likely not going to be appropriate for more than a couple of patients, that there are going to be so many other factors involved that make a simplistic algorithmic process probably not a valuable approach in this regard.

Dr. Deligiannidis:
Thank you so much. It's such an important viewpoint and something, you're right, that regardless of where one is practicing medicine, you know, it might look a little different in each practice and each location, but the key pieces need to be there for optimal care.

Dr. Shulman:

Absolutely. I'd like to thank everybody for joining us here today. Dr. Deligiannidis, thank you so much. This was a wonderful overview of an incredibly important topic for women who are pregnant and for new parents and even not so new parents. It was a real pleasure to work with you here today.

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