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The Vaginal pH Modulator: A Revolutionary Approach to Contraception

Announcer:
Welcome to CME on ReachMD. This activity, entitled "The Vaginal pH Modulator: A Revolutionary Approach to Contraception" is provided by Omnia Education.

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Ms. Cason:
At this point in the history of sexual and reproductive healthcare in the United States, we are undergoing what would be best described as a revolution. When I was first in practice, we had very few methods to offer people, and the methods that we did have to offer, we were pretty directive in the way that we would talk about those methods with the patients.

I think we are coming very far from the place where we used to be, where we would just say to somebody, "What method are you interested in?" and we just signed the prescription. I think we're really trying to individualize the conversation so that we understand people's preferences, their values, what's important to them in their birth control. And one of those things that tops the list is how it impacts their sexuality and their sexual life.

Dr. Eisenberg:
You know, finding contraceptive options that allow women to feel in control of their sexual health and reproductive well-being is really important. And one of the things that I think is really exciting about this time is the fact that we are emphasizing, you know, sexual satisfaction and having improved sexual experiences. And one of the things that I know is helpful for my patients is having more choices at hand, and having more nonhormonal choices for women is one of the real important advances in the recent years.

And you know, these newer options have novel mechanisms of action that I think are important for patients to understand, for providers to understand, and when they can use them as a dual method for both pregnancy prevention as well as STD risk reduction.

Dr. Portman:
This is CME on ReachMD, and I'm Dr. David Portman. I'm joined by my distinguished colleagues, Patty Cason, a nurse practitioner who is well known for her work in contraception, and Dr. David Eisenberg, Associate Professor of Obstetrics and Gynecology at Washington University in St. Louis and a specialist in family planning and contraception.

As you've heard, it's been a very active year in contraceptive development with multiple new options introduced. Let's get into it and hear a little bit more about the vaginal pH modulator.

Dr. Eisenberg:
It's an excellent advance to be able to take advantage of the body's own mechanisms to maintain the vaginal pH during intercourse, because when a patient is engaging in heterosexual vaginal intercourse, you know, the pH of the vagina is what protects the patient from the potential for infection. But also, those natural bacteria, the microbiome that make up the vaginal environment, are important in keeping the health of the vagina outside of vaginal intercourse in terms of ensuring there's an adequate production of lactic acid from the lactobacillus that are present in the vagina.

Those natural defenses are neutralized in the presence of semen in a process that has been understood for decades, where the semen carries with it not just sperm, but many different buffering proteins for those sperm to be able to capacitate and then start the process of swimming up the reproductive tract towards the fallopian tube.

You know, any drug that could be put in the vagina to maintain that pH could incapacitate those sperm. But the key things that are different about the first ever vaginal pH modulator, Phexxi, is the fact that it not only maintains that vaginal pH, but it sticks around long enough to incapacitate those sperm without being sticky.

What I mean by that is it was originally approved as a personal lubricant for vaginal intercourse and it was a known product. These 3 active ingredients, lactic acid, citric acid, and potassium bitartrate, have been in combination in use as a personal lubricant for a long time. And when the company that took over the patent brought up the idea of potentially studying this as a contraceptive, they did a really good job of trying to identify how it worked in terms of its mechanism of action. And those bioadhesive properties that keep it in the vagina long enough, the viscosity of it that keeps it from just kind of flowing out, are the key things that make it possible to prevent pregnancy, by having that natural pH maintained below 4.5. That natural pH of the vagina where sperm can't do their job, they need a pH higher, like 7.2 to 8.0. And that doesn't happen in the presence of this vaginal pH modulator, now branded Phexxi.

And when it comes to talking to patients about this, I think it's important for them to understand that they don't have to have this all the time. They only need it when they're having vaginal intercourse. And it comes in a prefilled applicator that looks a lot like a tampon applicator. If they've ever used a vaginal antibiotic for a vaginitis-type infection or a vaginal estrogen treatment, it's a very similar applicator to that. These prefilled applicators come 12 in a box if you're prescribing it to a patient. And they can have that, you know, for a long period of time in their medicine cabinet or in their bedroom and for as often as they need it, kind of like having condoms in the bedside drawer.

But like condoms, they need to make sure that that vaginal pH modulator is placed in the vagina prior to vaginal penetration with their heterosexual partner. And they need to make sure that it's been within an hour. If it's been longer than an hour of foreplay, or hey, things didn't work out, they have to redose.

And lastly, just like if they're using male condoms, they would have to use a new male condom with every act of vaginal intercourse. They really need to understand the need to redose that vaginal pH modulator before a new act of sexual activity.

Those are the key things that I think are important to understand about how it works and the ways in which I make sure to counsel patients about that.

Dr. Portman:
I'm so glad that you mentioned the sexual satisfaction importance in contraceptive research. As a contraceptive researcher, as well as someone who's been involved in sexual function and dysfunction research, I'm amazed at how many contraceptive trials really don't look at sexual satisfaction outcomes. One would think that that's a logical endpoint to look at, given what's under study. But they simply focus often on just pregnancy rates.

So the fact that the vaginal pH modulator actually looked at and asked about sexual satisfaction in their phase 3 study, I think, is a real important advancement. They noted that, you know, most subjects report improvement in their ability to maintain lubrication during intercourse and other measures of sexual satisfaction. So I think this is an incredibly important aspect to both discuss as the trial results, but also in our counseling of patients.

Ms. Cason:
I loved David's explanation of the mechanism of action as essentially keeping the vagina the way that it is.

Dr. Portman:
For those just tuning in, you're listening to CME on ReachMD. I'm Dr. David Portman, and I'm here with 2 renowned thought leaders on contraception, Patty Cason and David Eisenberg. We're just about to tackle broader issues of efficacy, the creeping Pearl Index, and counseling diverse patient populations.

Dr. Eisenberg:
You know, one of the things I was interested in as a person who was involved in the phase 3 trial was the fact that we did, in a prospective way, not only take into account whether people had satisfying sexual experiences during the trial, but whether they had sex. And we were really testing the effectiveness of this contraceptive, not just, you know, whether someone got pregnant, which a lot of studies in the past weren't keeping track of those sexual acts during the contraceptive trials.

And so, you know, David, I would like to ask you for your expertise as someone who's really delved into the understanding of what we described as the Pearl Index, a measure of contraceptive effectiveness, and how has this impacted our understanding and our

development of contraceptives over the decades?

Dr. Portman:
Yeah, that's a really important point, to look at the differences in contraceptive study design. As you mentioned, it's very important to know that the treatment population is at risk for pregnancy, which means that they need to be engaging in sexual intercourse. Often, trials only ask patients if they were sexually active. And it could have been that they were the previous months but weren't in a relationship and, therefore, may not have even had intercourse in the cycles under investigation.

So as you mentioned, in the pH modulator studies patients were required to have a certain amount of intercourse that was documented so you know that those were at-risk cycles.

The other challenges in modern contraceptive design are that they're much more rigorous now and much more real-world in that they're enrolling patients that are not like the older trials that were conducted largely in slender, affluent populations, many based in Europe where there's a high degree of persistence on therapies, a very strong desire to avoid pregnancy. So when you lift some of those restrictions, such as weight restrictions, which we now are enrolling patients of a variety of BMIs, a variety of race and ethnicities, we are seeing much more real-world pregnancy rates in trials.

So the Pearl Index, which is a useful measure in hormone contraceptive studies of a year in duration or more, has really been creeping up so that the Pearl Indices that were less than 1 pregnancy per 100 patients per year are now upwards in the 3 to 5 pregnancies per 100 patients per year. So this is not because these contraceptives are becoming less effective. In fact, many of the earlier contraceptives that were studied and had low Pearls have had much higher Pearls in modern trials, even though it's the exact same medication.

So I think we're getting a much better handle on what patients experiences are in the real world based on these trial designs.

So take, for instance, the effectiveness of the vaginal pH modulator. A little over 13% pregnancy rates over the 7 cycles. If you look at those sexually active acts, that translates into a pregnancy rate of only 0.4% for each act of intercourse, which for many patients, an on-demand method that fit in with her lifestyle would be deemed quite effective, even though it would be in a category 3 in the tiered definitions of contraception, with the first category being the injectable and the long-acting reversible contraception, tier 2 being oral contraception, and tier 3, those barrier methods. That might be effective enough, given the other benefits and spontaneity that it allows.

The Pearl Index is essentially a math equation, and the bigger the denominator, the smaller the Pearl. And these older trials that included many, many more cycles clearly would have an impact and make a drug appear far more effective than perhaps it would if you eliminated those cycles as we're doing now.

What can we do to optimize patient adherence with counseling strategies? Patty, can you give our audience a brief overview of the strategies that you use with your diverse patient population when discussing contraceptive options?

Ms. Cason:
You have some knowledge of the person. You've asked questions about sexual history, you understand that they are actually having sex with someone with whom a pregnancy could occur. And you've also hopefully asked, “How important is it to you to prevent pregnancy? Do you have a sense of what's important to you about your birth control?” Other options for that first question are things like, “Do you have a sense of what you're looking for in your contraceptive method?” or “Can you tell me some things that are important to you about your birth control?” or “Can you tell me something that's important to you about your birth control?”

And then you keep asking that question in a variety of ways until you have a fairly clear sense of the things that matter to that individual.

Dr. Eisenberg:
It's important that you point that out because one of the most effective ways to help someone prevent pregnancy is to help them find a contraceptive method that they are satisfied with and they want to continue using and that they'll be adherent to the kind of instructions for use.

Dr. Portman:
I think that's critical because we often assume that if a patient has stayed on a particular method, that they're completely satisfied with every aspect of it.

A good example is oral contraception, which we know is the most popular reversible method. But many patients have an increase in SHBG [sex hormone-binding globulin] and therefore less free testosterone. And it can have a challenge with their sexual function, both desire as well as in hormonally induced vestibulodynia.

So it would be very important, as we're talking about the benefits of a vaginal pH modulator, that perhaps those additional lubricating

benefits and benefits on satisfaction could enter into that conversation.

Well, this has certainly been a fascinating discussion. But before we wrap up, can each of you share one take-home message with our audience? David, let's start with you.

Dr. Eisenberg:
It's our job as clinicians to help them on that, you know, journey through their sexual and reproductive lifespan, to be successful in planning their family and how they want their family to look.

Ms. Cason:
I think it's really important to focus on the person's preferences and their values.

Dr. Portman:
I want to thank our audience for listening in and thank you, Patty Cason and Dr. David Eisenberg, for joining me and for sharing all of your valuable insights. It was great speaking with you today.

Dr. Eisenberg:
Thanks a lot.

Ms. Cason:
Thank you. And I'm really looking forward to a future program where we'll be delving more deeply into counseling strategies.

Announcer:
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