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Expanding Choices in Combined Hormonal Contraceptives: The Creeping Pearl Index

Announcer:
Welcome to CME on ReachMD. This activity, entitled “Expanding Choices in Combined Hormonal Contraceptives: The Creeping Pearl Index” is provided by Omnia Education and is supported by an independent educational grant from Agile Pharmaceutical.

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Dr. Shulman:
Contraceptive method effectiveness is critically important in minimizing the risk for unintended pregnancy. Methods that depend on consistent and correct use by patients have a wide range of effectiveness between typical and perfect users. How does the creeping Pearl Index play a role in selecting contraceptive methods?

This is CME on ReachMD, and I am Dr. Lee Shulman.

Dr. Kimble:
And I am Dr. Thomas Kimble.

Dr. Shulman:
So let’s dive right in. To start, can you please give us some background information on the newer contraceptive patches?

Dr. Kimble:
Sure. The contraceptive patch was designed to address the challenges posed by the requirement of a daily administration of an oral contraceptive. That’s not easy for a lot of people. For example, women who have jobs, women who are in school, women who are taking care of a family or have other interests they’re pursuing, it’s not always easy to take a pill every day, especially at the same time every day, as we counsel our patients. The contraceptive patch follows a once-a-week dosing schedule. That’s much easier for many people.

Twirla is a once-a-week, low-dose patch that contains ethinyl estradiol as the estrogen component, and it is combined with a progestin called levonorgestrel. Levonorgestrel is a very long-term established, very well-researched, and often-used progestin that we’re very familiar with. The second new transdermal contraceptive patch which is under development contains 0.55 mg of ethinyl estradiol and 2.1 mg of gestodene. This also uses a once-a-week dosing regimen.

Dr. Shulman:
Clearly, the transdermal patches, which are a combination of an estrogen and a progestin, feature, as you said, the convenience of non-daily dosing with basically the side effect profile of a combination pill, and that clearly led to the success of transdermal combination patches over a decade ago. So, let’s follow up a little bit on contraceptive patches. How do these non-LARC methods compare to other options?

Dr. Kimble:
The fortunate thing about contraception, there are a variety of options that women and couples have to choose from. As you mentioned,

when the first patch was introduced a little over 10 years ago, at one point it was the most prescribed form of temporary birth control, so the popularity is up there. Now, there are a lot of other options. We have our long-acting reversible forms of contraception. That includes things like the contraceptive implant and intrauterine devices. Those are great products but not for everybody. Then you have what I call your intermediate forms of birth control, so that includes things like injectable forms of contraceptive, which last anywhere from 1 month up to 3, potentially maybe more months, and also intravaginal rings, which typically have a once-a-month dosing, although there will be another ring that is changed once a month but you can use the same ring. Then we have your temporary forms. That includes things like the birth control pill, which is a daily administration. Pills are great for some people, but they're not for everybody. I typically think of that person who is busy. They are busy with their career; they are busy with their school; they are busy with their family or other interest. Sometimes it's hard to remember to take a pill every day. Then there comes an option like the patch, transdermal birth control. The benefit of that is it is a temporary form of birth control that still gives the woman the power to control her contraception. That's very popular with a lot of our patients. But it's only once a week. It's not daily. And once a week is a lot easier for patients.

Dr. Shulman:
I think you very well stated the importance of the patch as well as other non-LARC methods, and that is they provide a particular side effect profile that many women want, but those methods that are able to provide that side effect profile as well as contraceptive effectiveness without the need for a daily dose clearly facilitates proper and correct use, and we all know that proper and correct use is what's needed for optimal contraceptive effectiveness as well as the best side effect profile.

For those just tuning in, you're listening to CME on ReachMD. I'm Dr. Lee Shulman, and here with me today is Dr. Thomas Kimble. We're about to discuss the role of the creeping Pearl Index on newer non-LARC options like the contraceptive patch.

As you've mentioned, we've seen the introduction of several new contraceptive methods, like the patch. These options have pregnancy rates that are higher than older contraceptives because they are based on clinical trials that used updated FDA guidance on factors like patient populations and the inclusion or exclusion of certain data. The late James Trussell coined this the "creeping Pearl Index." How does the creeping Pearl Index come into play with the non-LARC options, or specifically the patch?

Dr. Kimble:
Yes, the Creeping Pearl Index is coined by Dr. Trussell and Dr. Portman. That was a really interesting paper. We refer to it often, those of us who are in the contraception product development arena. Historically—and it's very unfortunate—in product development, in the clinical trials of contraceptive products, to bring them to market, there was a very, very narrow approach to enrolling types of patients. Many of us remember this. You had to be an ideal participant in order to be included in a clinical trial. The reasoning behind that was good; however, the implication that it had was it created clinical trials that did not include a diverse population of people. Therefore, they didn't represent our population. It didn't represent the types of patients that we're here to take care of.

So a few years ago, the FDA issued a fairly strong statement to pharma and academia to include a more diverse population. By diversity I mean geographic diversity, ethnic diversity, diversity in ages, and also diversity in weight and BMIs. People who had higher BMIs were often excluded from clinical trials. We all know that a large percentage of our population includes women who have higher BMIs, and unfortunately, they just weren't represented in these studies, so the medications may or may not have been applicable to them.

Now we are including a more diverse population, and in many clinical trials, for example, in the product development of Twirla, the large phase 3 study, we included women with higher BMIs, including BMIs up to 30 or more, so we are seeing more diversity. Because of that, you do see an increase in the Pearl Index. We know that as BMIs go up, the efficacy of hormonal contraception often goes down. There is an inverse relationship there. However, these products are oftentimes still effective in this group, but if you look at large data studies, you may see a little bit of a decrease in the efficacy and therefore an increase in the Pearl Index.

Dr. Shulman:
You know, it's interesting that for the first 20 or so years of my career being involved with contraceptive trials, many of us railed against the studies that were being done, that they clearly, in our opinion, didn't fit the populations that we were serving, and yet these were the studies that were being mandated by the FDA. Now that we are about to—and have already started to—enter the world of studies that are providing a more accurate assessment in a more typical diverse community that we serve, we start seeing all of these issues. And I think it's an interesting thing that not only will we need to address and deal with, but I think it ultimately provides us with a more accurate assessment of how a contraceptive works.

Well, this has certainly been a fascinating and educational conversation, but before we wrap up, Dr. Kimble, can you share with our audience your one take-home message?

Dr. Kimble:

Sure. It is great that we have a plethora of new options that are becoming available, including transdermal contraception. However, it is a little confusing when we look at the data, look at Pearl Indexes, and there may be some concern why you see that creeping Pearl Index. Again, we think—and this is based on studies, and I really think Dr. Trussell's paper was an excellent paper; we refer to it often—but I really do think that it is because of a good thing that is going on where we have a more diverse population of people in clinical trials from which Pearl indices are being calculated.

Dr. Shulman:
You know, for me, the take-home message is this. If we took those older methods that were evaluated in the way they were evaluated 20, 30, even 40 years ago, and we took those methods and evaluated them today in the method that these newer methods are being evaluated, we would not have the low, very low Pearl indices if we evaluated these methods with a diverse population in the approach that's being used now. So my take-home message is this. It's not an appropriate comparison between a method that was approved with a phase 3 trial 50 years ago to a new method today, and we as clinicians need to be accepting of the new approach to clearing contraceptive methods, providing a more accurate assessment for a diverse population that we are likely going to be serving in our offices and in our clinics.

So with that, unfortunately, we really have no further time. I want to thank our audience for listening in and thank you, Dr. Kimble, for joining me and for sharing all of your valuable insights. It was great speaking with you today.

Dr. Kimble:
Dr. Shulman and the audience, thank you. I was really excited to be involved.

Announcer:
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