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Expanding Choices in Combined Hormonal Contraceptives—Seeing Beyond LARCs

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

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Dr. Nelson:
With patient-centered counseling today, we no longer offer contraceptive options to women in order of their efficacy. IUDs and implants are convenient and highly effective, but they are clearly not for every woman, especially those women who don’t want to surrender control over their fertility to a medical care system.

Dr. Portman:
You’re right, Anita. It’s not just going to the tier of effectiveness and directing women only to the absolute most effective and ignoring the others. The way clinicians have been taking about LARCs, long-acting oral contraceptives, you’d think that there aren’t any other effective contraceptive methods available. I’m here to say non-LARC contraceptives are alive and well, and the number of options are growing quickly.

Dr. Nelson:
Today, on Clinical Countdown: Selecting Contraceptives Edition, we will be taking a closer look at the advantages and disadvantages of LARC and non-LARC options. Are you ready, David?

Dr. Portman:
I’m ready.

Dr. Nelson:
All right. Over the last five years, there have been many updates in the contraceptive world. Can you tell us a little about the non-long-acting reversible contraceptive methods that are now available for patients?

Dr. Portman:
The contraceptive patch was designed to address the challenges posed by requiring a daily oral administration of contraception. The patch utilizes a once-weekly dosing schedule. Up until now, the only patch available has been one delivering 60% more estrogen than a 30 mcg pill, along with a high rate of breast tenderness and headache consistent with that, as well as concerns and a unique warning around VTE risk. And this led to a huge drop-off in that once-popular method used by 1 out of every 10 women in the early 2000s. Twirla is a recently approved once-a-week low-dose patch; the first after close to two decades with ethinyl estradiol or EE in combination with a long-established and well-researched progestin, levonorgestrel, delivering the equivalent of a 30 mcg pill. We are very familiar with combined oral contraceptives and progestin-only pills. They’re convenient; however, daily and often burdensome use and missed pills do contribute to contraceptive failure in the real world, as well as side effects, such as breakthrough bleeding. Vaginal rings are also a non-daily method, delivered intravaginally. We had one available until recently, and now there is a newly approved Annovera ring, which

is a reusable monthly ring with a year of use. Barrier methods continue to be part of our armamentarium, condoms, contraceptive sponges, spermicides, diaphragms, cervical caps, and there is a new on-demand pH modifier. While these are clearly less effective than hormonal contraceptives over a long period of time, they may fit nicely into an overall contraceptive plan, either in addition to or between other methods. And, of course, there are fertility awareness apps with the new technologies that patients and women are using with their smartphones.

Dr. Nelson:
That's kind of an exhausting list, and to try to cover all of that in a busy visit is really quite challenging. But I think now that women are more familiar with IUDs and implants as options, we don't have to spend as much time introducing them to our patients. So we can really focus where we've always wanted to be, and that's clearly with her own preferences. For instance, what are her reproductive life plans? When does she want to get pregnant next? What methods does she think will work best for her? What does she like to use? And, importantly, what non-contraceptive benefits is she looking for? Is she even aware that she can get a lot of benefits from hormonal methods? And, importantly, what concerns does she have? How many of those are misperceptions that we need to reassure her about? Does she know about all of her options and their efficacies and side effects? So, we start off with first analyzing what is she eligible to use, using either labeling or recently, of course, the US Medical Eligibility Criteria, or what we call USMEC. Another great place to start is does she want to have cyclic bleeding, or does she want to have no bleeding? Does she want visual confirmation that her method is working for her? We have many ways of approaching this, but we want to make sure that they are all patient centered.

So, Dr. Portman, let's dive deeper into the non-LARC options. Please discuss the advantages of selecting a non-LARC method.

Dr. Portman:
Well, the non-LARC method that's been around the longest is combined hormone contraceptive of the oral variety. In fact, the pill is synonymous with contraception; however, we've come a long way since the discovery and advent of the pill, and we have other methods to discuss. But starting from the beginning, oral contraceptive is an effective daily method. It's discreet, its ease of use is very welcome by many, and the routine of doing something daily often fits in with many women's lifestyles, especially if they're taking other medications as part of that routine. However, when asked, over 50% of women surveyed will say that a daily pill is burdensome and often difficult to remember. So there are advantages to non-daily methods, such as weekly methods as the patch. It's less reliant on that daily routine. Remembering something once a week versus every day is less prone to user error in the real world, especially for those with unpredictable schedules; if they're working night shift or if they're going across time zones, they don't have to remember what that 24-hour interval is to be consistent with their pill taking. And with pills, often patients will miss one or even two pills each month, and we know that this leads to significant failure in the real world. So we don't have the effectiveness that we often see in clinical trials where you have nurses and physicians daily accounting for drug taking, as well as staff support encouraging that compliance. So non-daily methods in the real world may offer some real flexibility for patients, whether it's a patch or a ring. Regarding LARC, it's often –even though the most effective, it's a big decision for a patient to make about a five-year time horizon. Often we don't even know what we're going to be doing from the next day to the next, so asking a patient to commit to five years of contraception and losing that autonomy can be a significant challenge to many women.

Dr. Nelson:
I think the points you make there are very important. We all recognize that with correct and consistent use, most methods will provide excellent pregnancy protection. So our question becomes: How successful will this woman be if she uses this method? Would she really enjoy the convenience of a LARC? Is she concerned about daily, so maybe some middle ground in between? Is she concerned about losing control over her fertility, so she'd prefer a patient-controlled? And, there again, as you say, the intermediate – the short-acting but more convenient patches or rings would be very attractive to her.

Dr. Portman:
Yeah, when we talk about efficacy and effectiveness, this can be a little bit tricky, and as I've eluded to earlier, the efficacy in clinical trials may not really be reflective of what the effectiveness in the real world is. So, for instance, a Pearl Index of 1 to 1.5 in a clinic simply may not be achievable and may be disingenuous to tell patients that that's what they should expect from combined hormone contraception, where real-world population surveys have effectiveness closer to 93%. But if you tell somebody that they have a 93% to 95% effective method, you have their attention, and that is an option. So the unrealistic perfect use in trials may not be appropriate when looking at how real women contracept. Given most unintended pregnancies are from improper use, having a woman pick the one method that best fits her lifestyle should work best for her when she uses it as directed.

Dr. Nelson:
Well, I think you're absolutely right. When we counsel women, we should use typical-use failure rates that come from population studies. I kind of hold out that perfect-use calculation they make from clinical trials as sort of a lure, right. If you use it correctly and consistently, maybe. But there are many considerations that play a part in selecting a contraceptive method. Dr. Portman, could you please discuss

the non-contraceptive benefits of non-LARC methods, specifically the patch?

Dr. Portman:
Well, you know, there's established non-contraceptive benefits of combined hormone contraception from the decades of the research we have with pills, such as reduction in dysmenorrhea, menorrhagia, ovarian and endometrial cancer reduction – a very important, significant risk to some women – as well as the treatment of endocrine disorders, such as polycystic ovary syndrome. It's unclear if these benefits translate to the non-pill CHC method such as patches and rings. We simply don't have that evidence, but there could be some similarities. The patches and rings are not dependent on daily oral absorption. They offer steady blood levels, avoiding peaks and troughs, which may translate into better side effect profiles for some, along with that autonomy that we discussed, which is so important in shared decision-making, which may have been taken out of the equation with LARC methods.

Dr. Nelson:
I think you make a very important point there, that we want to make sure that the patient feels that she has the trust, that she has control over her own fertility. And somewhere in between, offering her convenience, can be very important to her lifestyle and to her success. Absolutely.

Now, David, we're moving into our lightning round. This section should be quick and pithy. You're up first. Please discuss the creeping Pearl Index. Ready? And go.

Dr. Portman:
Well, I wrote a paper on this, so this is going to be tough. Over the years, clinical trial efficacy has been based on the Pearl Index. That's the number of pregnancies per 100 woman-years of use, and that's been increasing from under 1 to now being closer to 3 and as high as 5 currently. And this occurs even with pills that have very low Pearls that are studied 30 years ago and now used as a control in more modern studies yielding an 8-fold higher Pearl. Now, clearly, that pill is not less effective. We're including broader and more diverse populations with higher BMI, checking pregnancy tests, and excluding more cycles. This has all driven the Pearl Index higher and why we need to focus also on effectiveness in the real world in real patients.

Dr. Nelson:
I think this is so important because people are concerned that lower dose means lower effectiveness, but it's really the world that's changed, not the efficacy of the pill. So how do we bring all of this information to our patients is very important, I think, because we want to, first, have them know as much as possible before they come into the visit. Having good websites they can turn to is always very important. Having information in our offices there. But I think really knowing the woman, her priorities, and what her wishes are can really be a fulcrum that can make it so much easier for us to counsel our patients and help them make appropriate decisions that will make them successful contraceptors.

Dr. Portman:
So what might the future hold for contraceptive methods? Well, we've all been waiting for an effective reversible male contraceptive, and unfortunately we'll be waiting longer with nothing for that on the near horizon. A nonhormonal ring may soon see approval, and progestin-only rings and patches are in development, and a recently approved pH modifier contraceptive is looking at STI protection, as well. So, stay tuned. The future is bright in providing more options and flexibility for our patients.

Dr. Nelson:
Yeah, but at the end of the day, we're still working with people, and we want to be patient-centered, right? Well, this has certainly been a fascinating and educational conversation. But before we wrap up, Dr. Portman, can you share with our audience your one take-home message?

Dr. Portman:
With more inclusive clinical trials being conducted recently, we can offer our patients, who are as diverse as their diverse needs, data and prescribing information, particularly around BMI, that is now more generalizable to them. With several new, very effective options, we can, with good evidence-based medicine, share with them in their decision-making and tailor contraception to their specific situation.

Dr. Nelson:
As we've pointed out, we have new methods – many new methods, for our patients to consider for their contraceptive choices. We want women to find the one method they think that they will be most successful using. This may well be a new chapter for non-LARC contraceptive options.

Unfortunately, that's all the time we have today, so I want to thank our audience for listening in, and to thank you, Dr. Portman, for joining me and for sharing all of your valuable insights. It was great speaking with you today.

Dr. Portman:
It was great speaking with you today, as well.

Announcer:
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