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Shining a New Light on the Contraceptive Patch

Announcer:
Welcome to CME on ReachMD. This activity, entitled "Shining a New Light on the Contraceptive Patch" was presented during Omnia Education's Women's Health 2021: Beyond the Annual Visit.

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Dr. Faught:
Welcome to Omnia Education's Women's Health 2021 – Beyond the Annual Visit. Thank you for joining us today. I'm Dr. Brooke Faught. In this presentation, we will be taking a closer look at contraceptive choices for women, more specifically the contraceptive patch. So let's get into it.

These are our educational learning objectives. First, I will identify information that will overcome the most common misperceptions that clinicians may hold regarding contraceptive patches and other non-LARC methods. Second, I will explain the advantages and drawbacks of contraceptive patches and other hormonal non-LARC methods. Last, I will identify counseling strategies for engaging patients in a shared decision-making discussion regarding sexual health and contraception.

During this discussion, we will review the evolution and history of the contraceptive patch, and other combined hormonal non-LARC methods. We'll also discuss what is the Pearl Index and why does it continue to creep upwards regarding real-world contraceptive usage.

What are some of the advantages and drawbacks of contraceptive patches and other combined hormonal non-LARC methods? And we'll review some counseling strategies for engaging patients in shared decision-making discussion regarding sexual health and contraception, in order to bring patients full circle into the conversation so that you work as a team to determine the best course of action for contraceptive options.

So now, let's talk about contraception and the evolution and history of contraception.

We have so many contraceptive options nowadays, which is so fantastic because our patients are not all the same. Our patients come in different sizes and backgrounds and needs and goals when it comes to their contraceptive needs. And so when deciding upon what the best course of action is for choosing a contraceptive option, we really have to take into consideration all of those factors. And it requires the involvement of the patient, of course, in determining which option is going to be best.

When we're talking about the evolution of modern contraception, really this all began in the 60s. The birth control pill, for instance, first was developed in the 60s, along with the plastic and copper IUDs, followed by postpartum laparoscopic sterilization and non-scalpel vasectomy in the 70s as well as biphasic and triphasic pills in the 80s. And then in the 90s, Depo-Provera and Preven and Plan B, emergency contraceptive pills. In the 2000s, we started to see a plethora of options come on the market, which has just kind of snowballed to current day with hysteroscopic sterilization, the Mirena IUD, Ortho Evra patch, NuvaRing, Implanon. And in 2010 and moving forward, Nexplanon, Skyla, Kyleena, Liletta. And then, more recently, we've had a huge amount of options that have come on

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the market, including Twirla patch, Annovera ring, Nexelis, and Phexxi. And so, again, we are very lucky in this modern day and age to have these options for our patients to meet the needs of our unique patients and their concerns.

With regard to transdermal hormonal contraception, more specifically, the first patch on the market was Ortho Evra back in 2002, followed by its generic option which was Xulane, which is still on the market, followed by Twirla which came on the market in 2020. And we'll talk a little bit more in detail about these options. So Ortho Evra and Xulane are very similar. Obviously, as I mentioned, Xulane is the generic alternative to Ortho Evra, and Ortho Evra is no longer available on the market. But you'll see here that both Ortho Evra and Xulane have the same type and amount of estrogen and progestin. So you see 35 micrograms of ethinyl estradiol and 150 micrograms of norelgestromin, whereas Twirla, the most recent patch on the market, has 30 micrograms of ethinyl estradiol – so a bit less although the same type of estrogen, and a different type of progestin, levonorgestrel at 120 micrograms. So the current 2 patches available – we have the Twirla patch and Xulane – you see the size and the shape does vary between the patches. And then the usage is pretty similar. So the patch is changed weekly and then left off on that fourth week to allow for menstrual flow. Contraindications include women with a BMI of greater than or equal to 30. So this is important to consider in patients, in understanding their weight and BMI.

Now we're going to move into measuring contraceptive efficacy, and more specifically, the Pearl Index. So if you're not familiar with the Pearl Index, the definition is the number of unintended pregnancies in 100 woman-years of exposure. So if you think about this, obviously we want this number to be low.

For a woman who does not want to get pregnant, we want the number of unintended pregnancies to remain at a low level in a contraceptive product.

So if you look at research moving forward, we see that over the years, the Pearl Index, or that number of unintended pregnancies, seems to be increasing. And the question is, is it really that contraceptive options are not quite as efficacious? Or are there other options, or are there other explanations? And we think that, more than likely, there's other explanations. Specifically, we're testing more frequently, so more frequent pregnancy testing with more sensitive tests. We have much more effective testing options available and more availability. So women are capable of purchasing pregnancy tests at their local store. There's availability at their local walk-in centers, at their gyn. And also less adherent study populations, so we're looking into a more broad patient population in the study populations. And so we're not just looking at the patients that are going to adhere very, very strictly to the contraceptive approach; we're looking at real-world patients that may forget to take their pill or forget to apply their patch or whatnot, as a typical woman. And then, also, there's a creeping BMI in the United States, and so that seems to be impacting hormonal contraceptive efficacy, including the transdermal approach, which we'll talk about here.

So specifically with BMI, as you can see here, we're simply looking at the time period between 1994 up until 2014. You can see here the percentage of US women classified as obese in 1994 was only 25%, moving up to 36% in 2010 and then 40% in 2014. So this is a radical difference over the years, and this is a very strong potential for that creeping Pearl Index and reduced contraceptive efficacy when we're talking about hormonal contraceptive agents.

In 2019, the Food and Drug Administration released a draft guidance to help guide pharmaceutical companies on establishing effectiveness and safety for hormonal drug products intended to prevent pregnancy. So essentially, their goal was to improve efficacy, improve safety, and just improve the quality of research in this realm. So the most recent patch clinical trial that was done for, specifically, Twirla, implemented the following criteria that was per the FDA guidance. So for instance, no enrollment restrictions occurred on weight or BMI, so women of all weights, all BMIs were included. There's actually a very large population of women that were classified as obese, especially compared to past research. It included women over the age of 35 years old to assess safety in that population. The research also anticipated regular sexual activity, at least once per month, and when that did not occur, the data was excluded from the final outcome. Individuals completed an eDiary and captured backup contraception and sexual activity. There was regular pregnancy testing at home as well as in the clinic, and so all of the factors, or all of the components of this draft guidance were included in the most recent research for this patch, which is really encouraging and really exciting as we continue to watch our patient population become more diverse and their needs begin to change over the years.

Some of the pros and cons of combined hormonal contraceptives – and we're going to talk more specifically about non-LARC options – let's get into the advantages, so the advantages of oral contraceptives, specifically. They're easy to use, they're easy to dose, and they're discreet. You can hide them in your purse and your pocket. There's many options available on the market. Some people look at this as a disadvantage because it's difficult to pick one when there's hundreds of options available. There's a variety of estrogens and progestins within these various oral contraceptives. The cost varies widely, but there are lots of generics available, and so for patients on a budget, this oftentimes is a great approach. We have lots of long-term safety and efficacy data for oral contraceptives. And the newest combined oral contraceptive contains a new form of estrogen. The newest progesterone-only pill has more serologic stability and less potential side effects according to their side effect profile. So we have newer agents in this realm as well.

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Some of the disadvantages of oral contraceptive agents are daily dosing – some women have a difficult time remembering to take a pill every single day, and this can impact serologic levels, so we see fluctuating pharmacokinetics, where there's peaks and valleys of the serologic levels, and this can lead to decreased potential efficacy. Also changing side effects – like breast tenderness, nausea, migraines and headaches – we tend to see when individuals are not taking oral contraceptives consistently. And then with combined oral contraceptives, we can also see an impact on sex hormone binding globulin. So what this is, is a protein that's derived from the liver, and in and of itself, is not overly concerning. However, it does bind to testosterone molecules and can render them useless, essentially reducing bio-available testosterone. So in sex medicine, we tend to see women that report loss of sex drive, sometimes vaginal dryness, diminished arousal, lubrication, that sort of thing. So that's something that I see quite a bit in patients that are on combined oral contraceptive agents. For women on progesterone-only pills there's an increased potential for breakthrough bleeding, compared to the combined options, and potential decreased efficacy compared to the combined options.

Some of the advantages of vaginal rings include avoidance of daily dosing, so you don't have to remember to take a pill every single day or utilize a product every single day. The individual can manage the ring on their own at home. They don't have to come in for a procedure to have it placed. The newest ring on the market contains a progestin that's derived from progesterone, and the most recent ring on the market does last a full year, so one prescription will last a full year.

Some of the disadvantages of vaginal rings include the requirement for vaginal insertion and removal, and I know some of my patients are uncomfortable with inserting something vaginally. They don't even use tampons. They don't admit to masturbation. And so this may not be the best approach for those patients. It's also not the most discreet approach for patients that partake in penetrative partner play – or I should specify sex play – because the ring is obviously present inside the vaginal canal. So for a patient that wants to maintain discretion with their contraception, the ring, obviously, being inside the vaginal canal during sexual activity may not be the best option for the patient, again, that is trying to maintain discretion. And the ring may also potentially increase the potential for vaginal discharge, infection, and/or irritation.

Some of the advantages of the transdermal contraceptive options are that it's a weekly change versus daily dosing again, so for patients that have a difficult time remembering to take a daily pill, this is a great option. And it's also self-managed, so patients can remove and apply the patch on their own, without having to come into the office for a procedure. It's a continuous absorption, again, so avoidance of those peaks and troughs of serum hormone levels, more steady pharmacokinetics. With this, there is reduced potential for some of the side effects that we see, including breast tenderness, nausea and headache, that are associated with some of the daily products.

Some additional advantages of transdermal contraception include the fact that the most recent patch on the market has a lower estrogen exposure. So again, I mentioned that the most recent patch has 30 micrograms of ethinyl estradiol, compared to the older option which had 35 micrograms of ethinyl estradiol. And the steady-state concentration for this patch was 14% lower than the 35 microgram ethinyl estradiol oral contraceptive pill.

The most recent patch on the market has safety, efficacy, and tolerability data in a very inclusive and diverse population. When you look at the data on this product, they included not just a diverse patient population, including BMI, but also from ethnicity and other background factors. So this was consistent with the FDA draft guidance for hormonal contraceptive studies. The patients in the studies for this particular product are more representative of what we see in our clinics.

Some of the disadvantages of transdermal contraception for patients that are more sensitive: potential for localized skin irritations. I always ask my patients if they're sensitive to Band-Aids or medical tape. It's not ideal for patients with frequent water exposure, so if you have any Olympians that are swimmers, this might not be the right option for them. Also, the cost of name-brand products – if you have a patient that may need a generic option, you know, there is a generic patch option, but if you're looking at one of the brand-name options, it may be a bit pricier. And then, reduced efficacy and increased risk of venous thromboembolic events with increasing BMI. So as I mentioned, the patch is contraindicated in women with a BMI of greater than or equal to 30. And we do know that there's also reduced efficacy when BMI increases above 25, so between 25 and 30. So use caution and use your clinical judgment in patients with a BMI of over 25.

And then, unlike the patch, there is limited data on the vaginal ring in obese women. So we do have data to say that, to know that an increase in BMI reduces efficacy with the patch and also increases potential for VTEs. However, we assume the same with the ring, but we have very, very limited data on that.

Some additional disadvantages – it does not protect against STIs. Again, external visibility, so this is not discreet. It certainly can be hidden with clothing. So it's not inside the vagina during sexual activity, but it's definitely visible, especially in a bathing suit or during showering. And at this point, all the patches only come in one flesh tone color, so for women with darker skin tones, this may not be the best option.

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Regarding patient counseling, how do we begin the conversation about transdermal contraception? When discussing this with our patients, some of the contraceptive goals that not just you have for your patient, but also what are their contraceptive goals? So for instance, how long do they want to prevent pregnancy? Do they ever want to consider pregnancy? How would they feel if they were to find out that they were pregnant? I ask that to my patients often. You know and I always have to preface. I always say, "Just so you know, you're not pregnant, but you know, how would you feel if you found out you were pregnant?" And if they say, "Yeah, it wouldn't be that big of a deal," I may not be as concerned about a less effective option. But if they say, "This is really important for me to not get pregnant," then we're going to really take into consideration efficacy. Also sexual transmitted infection prevention. You know, if you have a patient that may have multiple partners or high-risk partners, you have to consider that, and using barrier protection, with or without hormonal contraception. And then menstrual regulation – some patients may have a condition such as PCOS or heavy, painful periods, and they may need regulation of their cycle in addition to contraception.

Additionally, the need to know about partners – not just current partners, but past partners. Even if you have a patient that may currently be in a same-sex relationship that may identify as lesbian, they may, in the future, have a male partner, so it's still important to have a conversation about contraception and the options available. And then, as I mentioned, future family planning. So you know, even though you're working on preventing pregnancy at this point, at what point do you plan to pursue pregnancy, or do you have a plan for that? And some patients will say, you know, "I really don't have any interest in ever becoming pregnant," and that's fine. So you might want to look at a more long-term option in those patients. And then what is their experience with contraception? Maybe they've had a bad experience or even experience in the sense of conversations they've had with friends and family. That can be really powerful. I have lots of patients that come in with a preconceived notion that oftentimes is erroneous regarding a contraceptive approach, and so we have to debunk those theories first before we dive into some of the safety and efficacy data that is truthful.

In addition, just trying to make sure that patients are comfortable with the option that you're discussing. So again, if a patient is just really timid, really uncomfortable with inserting something inside their vagina – they don't use tampons, they don't admit to masturbation, that sort of thing – maybe a ring isn't the best option. Or I have a patient that really just has a really difficult time swallowing pills, and so oral contraception just is not a good approach for her. And then patients that are hypersensitive – maybe a patch isn't the best approach for that patient. Regarding cost, what type of insurance do they have? What type of cost limitation are we dealing with? And so I'll ask patients, what is reasonable for a monthly cost for your contraception? And then hormonal versus nonhormonal. Some patients, you know, you go through the whole entire conversation about options, and then they admit to you, "I don't want anything with hormones," or again, they might have some preconceived notion that may not be entirely truthful about the use of hormones, and so you have to have a conversation about what that looks like, where they got this information, what this means to them, and explaining the pros and cons of hormonal versus nonhormonal options. And then just understanding more about your patient, and their individual and personal lifestyle. So do they travel? What are their physical activities? What type of partners do they have? Do they need to be more discreet? I have patients that are conservationists, so they are really concerned about disposable paper and packaging and that sort of thing. And so just really understanding what their full goals are for contraception in order to meet their needs and also to enhance their potential compliance with their regimen.

I put this up here. I'm not going to read through the FDA class label warning for hormonal contraceptives, but I think it's important for us as healthcare providers to read this and really understand what our patients see. Here in the United States, combined hormonal contraceptives, we have a class label warning, so basically all of the contraceptive options that we prescribe for our patients that include combined hormonal contraceptives are going to have a variation of this same warning as you see here. For the patch specifically, or for transdermal contraception, the most important thing is that this particular product is contraindicated in women who are over 35 years of age and smoke, and also women with a BMI of greater than or equal to 30 due to decreased efficacy, but also the potential increased risk of venous thromboembolic events. You want to make sure, again, that you really are well versed in this, because patients read these warnings and really get concerned sometimes, really get freaked out. And so it's important to bring this out and normalize the warning and explain where this comes from so patients don't go home and think that you're giving them something that's going to cause them serious harm. Explain the data behind this, the risks, the pros, the cons – just like you would with any medication. And that way, it will prevent that 4 p.m. Friday afternoon phone call where they say, "I don't know why you gave this to me. This product has this horrible warning. I want something else," and they don't understand that everything else has the exact same warning. But it's class label warnings compared to individualized warning.

When identifying the proper patient for the contraceptive patch, first of all, you want to make sure that women are of reproductive potential that desire contraception. If they are a smoker, you want to make sure that they are under the age of 35. You also want to ensure that their BMI is under 30, and ideally, under 25. You want to ensure that they do not have cardiovascular or venous thromboembolic risk factors, that they are capable of applying and managing patch changes on their own, and they do not have frequent or prolonged water exposure. So again, patients that are swimmers or submerged underwater for long periods of time, like scuba

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divers, may not be the right approach for them.

Some of the talking points when you're prescribing a transdermal contraceptive agent – you want to talk about where to place the patch. First of all, you can apply it to the abdomen, the arm, or the buttock, and it's really just based on patient preference, what their ideal is. And again, it relates to discretion. You know, do they want to make sure that this is not seen, or are they more concerned about the friction with their clothing or their activities? And so I tell patients if they want to know, that the best adhesion in the clinical trials was on the abdomen, but the best absorption was on the buttock. However, all three areas are perfectly acceptable, so whatever works for them is perfectly fine, and they can certainly rotate with each patch placement. Ideally, they want to apply the patch to clean, dry skin the same way they would if they were applying a Band-Aid or other medical tape.

Additionally, after any type of water exposure, the patch should be checked to make sure that it is still adhered. In the clinical trials with the newest patch, it had a 95% patch adherence at one year. So that was really impressive. And if there is full detachment, that old patch should be replaced with a new patch as quickly as possible. The patch should be changed weekly, with a patch-free week on the fourth week, and that's when we would expect menstrual flow. And then continuous usage is considered off-label; however, many healthcare providers use a lot of these products off-label and in a continuous fashion. But again, that is off-label. It was not researched as a continuous usage.

Some of my final thoughts on hormonal contraception include the fact that we have so many contraceptive options to meet the needs of our diverse patients. And some of the research that we're starting to see in this realm is inclusive of those diverse patients, following that FDA draft guidance.

Thank you for joining me for this presentation on contraceptive choices for women with a closer look at contraceptive patches. Goodbye.

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