The new transdermal contraceptive patch: Does it offer protection with less VTE risk?

It has been 20 years since a new transdermal patch has been approved for contraceptive use. What should you know about this new option for patients?

Q&A with Barbara Levy, MD, By Allegra Sparta, Content Manager

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The first transdermal contraceptive patch was approved by the US Food and Drug Administration (FDA) in 2001.[1] A 2018 survey revealed that 5% of women in the United States between the ages of 15 and 49 years reported the use of a short-acting hormonal contraceptive method (ie, vaginal ring, transdermal patch, injectable) within the past month, with just 0.3% reporting the use of a transdermal patch.[2] Transdermal contraceptive patches are an effective form of birth control that may be a convenient option for patients who do not want to take a daily oral contraceptive pill but want similar efficacy and tolerability. Typical failure rates of patches are similar to that of combined oral contraceptives (COCs).[1,3]

While transdermal hormone delivery results in less peaks and troughs of estrogen compared with COCs, the total estrogen exposure is higher than with COCs; therefore, the risk for venous thromboembolism (VTE) with previously available patches is about twice as high.[1] Twirla (Agile), an ethinyl estradiol (EE)/levonorgestrel (LNG) patch, delivers a low and consistent daily dose of hormones over 3 patches replaced once weekly, with no patch on the fourth week.[3] Twirla contains 120 µg/day LNG and 30 µg/day EE. Ortho Evra, FDA approved in 2001 as mentioned, contains 150 µg/day norelgestromin and 35 µg/day EE.[1] A reduction of the EE dose in COCs has been associated with lower risk for VTE.[4]

The addition of Twirla to the market offers another contraceptive option for patients who opt for a weekly, self-administered method.

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How much lower is the VTE risk?

OBG MANAGEMENT: Can you define what is the reduction in VTE risk for the EE dose in Twirla versus Ortho Evra (a norelgestromin/EE patch) and similar contraceptive patches already available?

Barbara Levy, MD: The reality is we can't designate a reduction of risk, except; in general, when the dose of ethinyl estradiol is lower, we think that the VTE risk is lower. There has not been a head-to-head comparison in a large enough population to be able to say that the risk is reduced by a certain factor. We just look at the overall exposure to estrogen and say, "In general, for VTE risk, a lower dose is a better thing for women."

That being said, look at birth control pills, like COCs. We don't have actual

numbers to say that a 30-µg pill is this much less risky than a 35-µg pill. We just put it into a hierarchy, and that's what we can do with the patch. We can say that, in general, lower is better for VTE risk, but no one can provide absolute numbers.

Efficacy

OBG MANAGEMENT: What is Twirla's efficacy in preventing pregnancy, and how does this compare to previous patches and other types of hormonal birth control?

Dr. Levy: You have to look at the pivotal trials and look at what the efficacy was in a trial setting. In the real-world setting, the effectiveness is never quite as good as it is in a clinical trial. I think the bottom line for all of us is that combined oral contraception, meaning estrogen with progestin, is equivalently effective across the different options that are available for women. Efficacy really isn't the factor to use to distinguish which one I'm going to pick. It is about the patient's convenience and many other factors. But in terms of its clinical effectiveness in preventing pregnancy, from a very practical standpoint, I think we consider them all the same.

Considering route of administration

OBG MANAGEMENT: Are there benefits associated with transdermal birth control versus other contraceptive options, and are women interested in transdermal contraception?

Dr. Levy: I think there's always a benefit in having lots of choices. And for some women, being able to put a patch on once a week is much more convenient, easier to remember, and delivers a very consistent dose of hormone absorbed through the skin, which is different than taking a pill in the morning when your levels go up quickly then diminish over the day. The hormones are higher at a certain time, and then they drop off, so there might be some advantages for people who are very sensitive to swings in hormonal levels. There's also a convenience factor, where for some people they will choose that. Other people might really dislike having a relatively large patch on their skin somewhere, or they may have skin sensitivity to the adhesive. Overall, I always think that having more options is better and individual girls/women will choose what works best for them.

Counseling tips

OBG MANAGEMENT: What are the instructions for patients to effectively use Twirla, and how should they be counseled regarding the expectations for their menstrual cycle?

Dr. Levy: Like other patches that are available on the market, these are a once-a-week patch. The patch should be placed on clean, dry skin. No lotions, perfumes, or anything on the skin because you really want them to stick for the whole week, and it's not going to stick if there's anything oily on the skin. The first patch is placed on day 1 of a menstrual cycle, the first day of bleeding, and then changed weekly for 3 weeks. Then there's a 7-day patch-free time in which one would expect to have a period.

In general, breakthrough bleeding was not a significant problem with the patch, but some women will have some irregular spotting and bleeding with any sort of hormonal treatment; some women may have no periods at all. In other words, the estrogen dose and progestin may be of a balance that allows the patient not to have periods. But, in general, most of the women in the trial had regular light menstrual flow during the week when their patch was not on.[5]

Pricing

OBG MANAGEMENT: Are you aware of the current payment options for Twirla? Is it covered by any insurance plans right now?

Dr. Levy: That's a tricky question. Insurance plans through Obamacare, the Affordable Care Act, are required to cover every form of contraception. That means they must cover a patch. It doesn't mean that they have to cover *this* patch. And because there are generics available of the other patch formulation, it is likely that this would be a higher tier, meaning

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that there may be a higher copay for someone who wanted to use Twirla versus one of the generic patches.

I can't say that that's universally the case, but my experience with most of the health insurance plans is that they tend to put barriers in the way for any of us to prescribe, and for women to use, brand-name products. So Twirla is new on the market; it's a brand-name product. It may work much better for some people; and in those cases, the health care provider might have to send a letter to the insurance company saying why this one is medically necessary for a patient. There probably will be some hoops to go through for coverage without a copay. I think coverage will be there, but there may be a substantial copay because of the tier level.

OBG MANAGEMENT: Do you think that there would be a challenge for someone trying to get a prescription for a patient saying that there is a need because it is a lower dose of estrogen?

Dr. Levy: I don't think that the payer is going to buy that argument unless the requirement is to use a patch. If the patient, for example, has some sort of gastrointestinal disease where they don't absorb things well, so pills don't work well, we might get to the place where they have to have a patch. If the patient has a lot of breast tenderness or has symptoms on the generic patch that delivers a higher level of estrogen, then we would have to document those symptoms to say, "She's not tolerating this one and, therefore, we need to go to that one." So, I think as prescribers we would have to justify not only the lower dose but also the form.

As a clinician, I would always like to put somebody on the lower dose. We do think lower is better, but we have to be sensitive to the costs of all of these things too. I'm very sensitive to my patients' out-of-pocket costs because, in the end, if the costs are a lot of money or she can only afford one month at a time, then she may miss a window where she may not have the money to buy next month's supply when it's due, and get pregnant. We have to balance all of those things as we're thinking through the best option for an individual.

We have more to learn

OBG MANAGEMENT: Is there anything else you would like to add?

Dr. Levy: I think it's always exciting when we have new products available, and there's a lot more we'll learn as Twirla comes into commercial use and millions instead of thousands of people are using it. Overall, I think it's fantastic that there's ongoing research and that there are new products out there. And kudos to the company for doing the research and for getting approval, and I'm looking forward to learning more about it. ●

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