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Journal Club: Tapinarof Cream in Pediatric Patients

Dr. Peter Lio:
Hello, everyone, and welcome to the Atopic Dermatitis Journal Club. I'm Dr. Peter Lio. I'm a clinical assistant professor of dermatology and pediatrics at Northwestern University, Feinberg School of Medicine, in Chicago.

And today, I am delighted to be joined by Dr. Mona Shahriari, assistant clinical professor of dermatology at Yale University. Mona, welcome.

Dr. Mona Shahriari:
Thank you so much for having me, Peter.

Dr. Peter Lio:
I am so glad you're here. And today we're going to be talking about a very interesting paper, fairly recently published just a couple of months ago, and this is a study that is by Igarashi, et al, and it's called, “A Phase II Randomized Double-Blind Vehicle-Controlled Trial of Tapinarof Cream in Japanese Pediatric Patients with Atopic Dermatitis.”

And this is a paper looking at one of our newest agents for atopic dermatitis, a non-steroidal, topical, aryl hydrocarbon receptor modulator, that now is approved in the US down to age 2 for atopic dermatitis, kind of exciting, and really helping kind of round out our armamentarium of treatments.

The first question I want to ask you is kind of framing everything. Why are non-steroidal topicals so important in this age, where we have all these incredible systemic therapies? And I guess, do you think they're important, still?

Dr. Mona Shahriari:
Well, I really do. I know both of us, we see a lot of pediatric patients, and whether you're treating adults or pediatrics, topicals are still a cornerstone when it comes to managing our patients, whether we're talking about atopic dermatitis, or even psoriasis, so in general, inflammatory skin disease. And I think, particularly in this age group, because a lot of parents can be risk averse, and they may be hesitant to start a systemic, even though in some scenarios, it may be appropriate, it's nice to have alternative options to our topical corticosteroids that our patients that are younger can use, which can also be effective.

Because I think my beef with the topical corticosteroid has always been, especially in the younger crowd, that we have to be cautious. If you're treating an infant, for example, they have a high body surface area to volume ratio, and you may have risks of systemic absorption. Or sometimes, kids, they want to be independent, like when you're five or six years old. You want to be the one applying your cream.

But if I'm sending them home with this complex regimen that involves topical corticosteroids, and calcineurin inhibitors, "Use this one twice a day for the first two days and then, transition to that one," no child's going to be able to take that on themselves. So I think some of these newer agents are going to have the ability to empower our younger ones.

Dr. Peter Lio:
I really like that. That kind of brings us to our next question is, when you're thinking about these kids, the 2- to 11-year-old range, what are some things that you're looking for, for an optimal non-steroidal?

So one is just being not a steroid, because we have some of the issues with prolonged corticosteroid use, and absorption, as you've said. Are there other things that you might be interested in, in terms of an ideal agent?

Dr. Mona Shahriari:
I think there's a couple of things that come to mind, but for starters, something that is simple to use. So once daily dosing is always going to trump twice daily dosing. I want something that's going to be safe, especially in that younger population, with a limited to no systemic absorption.

Tolerability is going to be big, because a kid does not want to put something on their skin that's going to burn. And I think these three highlights would really make me pick that agent, for example, over my steroidal agents.

Dr. Peter Lio:
I really like that, and I totally agree. In this study, what they found, the common adverse events in patients who were using Tapinarof, they had some gastroenteritis, some application site irritation, and some nasopharyngitis.

But I will say that the incidence of discontinuation due to adverse events was pretty low in the Tapinarof group. It was essentially one patient for each strength that discontinued.

So I think that's pretty reassuring, in the fact that it really does have that once daily application, fairly well tolerated. These are things I think that will make it a really useful addition for us.

Dr. Mona Shahriari:
Exactly. And I actually feel like our Asian population, in general, sometimes, they have a very heterogeneous presentation of their AD. It may be classic AD that we're used to, but you also have the psoriasiform varieties that can be a little bit more common. So I found that particularly interesting that this medication was effective in this population, whose AD may not necessarily be the classic type.

I do wish the article had commented a little bit more on the variety of the clinical presentation, but it was a Phase Two, so I know they were limited. So maybe in the Phase Three, they could explore that further, because as we know in the US, Tapinarof is FDA-approved for both psoriasis and AD.

So I'm wondering, in this particular population, who may have a Th17 and a Th2 predominant form of their AD, maybe this is going to be a better agent than our topical corticosteroids.

Dr. Peter Lio:
I really like that. And speaking of the efficacy, so this study had some pretty impressive numbers. I'm curious your take on it.

So they found that the proportion of patients who achieved EASI 75, so 75% or better improvement in the eczema area and severity score at Week 8, was over 70% for the Tapinarof groups. In fact, it was 77% for the 0.5%, and 70.7% for the 1% group, compared to 15% in the vehicle.

Now, I know we cannot compare across different studies, there are different parameters, but that is a pretty big delta, and I'm just curious, your take on that.

Dr. Mona Shahriari:
I think that's very reassuring for the space, because these are numbers that we tend to see with systemic medications. We are not used to seeing such impressive numbers with topicals. This might have to do with the fact that it's easier to comply with the once a day.

So I would love to see, in the real world, if maybe this is going to translate even more. Because let's face it, you asked me to put my moisturizer on twice a day, I can't remember. So how do I expect my patients to use a cream that's medicated twice a day, for the foreseeable future?

But I also think what was interesting was in the trial, these patients could have had up to 30% BSA. So we're getting these impressive results with BSAs that we don't historically use topicals in. So then again, this could be another alternative to our systemics in patients in which systemics may not be appropriate.

Dr. Peter Lio:
I think that is so spot on, and I'm so excited to have these different options. Because for me, at least, and I'm curious for your take on it, the way I tend to build an action plan for my eczema patients is, I'll have sort of a rescue plan if when they're bad, they can typically use their topical steroid, and do that for a period of time, maybe a week, maybe two weeks, if they need to, ideally even less.

And then, they can switch to these non-steroidals, and we can use that to then maintain, and spot treat anything before it gets bad. Do you foresee yourself using it in this way, or do you have other designs on it?

Dr. Mona Shahriari:

I think that approach would be a really great option to start with, especially since the speed of efficacy in some of our patients is going to be important. And this study, though it didn't really comment on that speed component, specifically. I do think that from what we know in the US trials of this medication, AD, it does take a little bit longer to kick in than, historically, our topical corticosteroids.

But I can also see it for people who, maybe they don't need that speed, they just want one agent to use, having this be the monotherapy that we give them. At least in our US studies, we saw a remittive effect with Tapinarof where, once the patient's cleared, and they stop the drug, they did stay clear for an average of one to two months, which I think is going to be very promising for patients who, I can tell, "Maybe if things get better, and you stop your medicine, you might not need the cream again, for quite some time."

Dr. Peter Lio:
Oh, my goodness. I love that. The idea of a relative remission, or ability to actually discontinue for a while. So state of the art, we have, initially, our topical calcineurin inhibitors, way back in 2000 and 2001. Then we got Crisaborole in 2016, and then, more recently, we've had a flurry. We have our Ruxolitinib, we have our Roflumilast, and now, we even have our Tapinarof.

We have, finally, I think, a pretty formidable set of tools here. And I'm so excited for us, because we get new things to try, and for our patients, who hopefully are going to find new ways to relief.

Thank you so much for joining us today. It's always such a pleasure to have you, and I look forward to seeing you soon.

Dr. Mona Shahriari:
Thank you so much for having me.