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ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Second-Generation Biomarkers for Treatment Outcomes

Dr. Ehlers:
As retina specialists, fluid is our number one biomarker in treatment decision-making, but what other biomarkers should we be considering as a measure of treatment response in our patients with diabetic macular edema?This is CME on ReachMD. I'm Justis Ehlers, and here with me is Jennifer Lim.

Dr. Lim:
Thanks so much, Justis. It's really great to be here today, and you're absolutely right. There are many more things we should look at aside from just fluid control, and one of these is macular leakage. We know that macular leakage early on at baseline is associated with worse visual acuity outcomes, and we know that change in macular leakage, as seen on fluorescein angiography, is associated with better outcomes.

In fact, as we see here, when we use a second-generation agent, such as faricimab, we can get a marked decrease in the amount of fluid macular leakage that's present.

Compared to day one, at Week 16 we see a marked reduction in the area of macular leakage to 0.4 mm2 compared to 38.5 mm2 at baseline. And in fact, in a post hoc analysis looking at angiographic data, we see that faricimab was able to result in greater reductions in the area of macular leakage as compared to aflibercept 2 mg.

Another biomarker that we can look at is hard exudates. And of course, hard exudates can be a surrogate for the amount of leakage that's present. Again, we see, when we use a second-generation agent, more marked lowering in the proportion of patients who have hard exudates with faricimab compared to aflibercept, and this was true at week 96 as compared to baseline. It was also true early on in the head-to-head phase when we compared faricimab to aflibercept when they had equal numbers of treatments of respective drugs. Another biomarker we can look at is hyperreflective foci. And hyperreflective foci is indicative of more disease severity. However, with this biomarker, it's unclear whether decreases in hyperreflective foci are related to treatment outcomes.

Dr. Ehlers:
It's really interesting, Jenny. As we look at all that, one of the challenges as retina specialists is trying to figure out what modalities we should be using to look at these various biomarkers. Additional things that we know play a role in the progression of diabetic retinopathy and potentially diabetic macular edema, includes underlying ischemia and nonperfusion that we can identify on fluorescein. But additionally, there are other structural biomarkers as well that we know have been linked to visual acuity outcomes. This includes things like disorganization of the retinal inner layers, as well as ellipsoid zone integrity, a marker for photoreceptor damage.

So, when you look at this from a clinical side, should we be integrating how we use these biomarkers in our treatment decisions, for example, when we choose to use a second-generation treatment? How do you use it from a clinical side?

Dr. Lim:
From a clinical standpoint, I think, if I see a lot of leakage on an angiogram, if I see a lot of hard exudates, if I see a significant amount of hyperreflective foci, I'll go ahead and reach for second-generation agent. In terms of DRIL and nonprofusion, I don't have as good a feel for those with the outcomes, and it's really hard to say if you see DRIL more so in one patient than another, how that will affect which drug I'm going to reach for.

In general, if the patient has good insurance, I'm going to reach for the drug that results in the best drying ability, usually a second-generation anti-VEGF agent.

Dr. Ehlers:
Yeah, that's great. I completely agree, and ischemia and DRIL have been one of those things that have been challenging for us over the years, to figure out what the best way is to measure. Things like fluid, hyperreflective foci, leakage that are more dynamic, certainly I think are something that we can lean on to look for change in our patients.

This has really been a great discussion. Unfortunately, that's all the time that we have. Thank you to our audience, and thank you, Jenny, for joining us today.

Dr. Lim:
Thanks so much, Justis. Pleasure to be here today.