Transcript Details

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Integration of Photobiomodulation Therapy into the Age-Related Macular Degeneration Treatment Landscape

Announcer:
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Dr. Boyer:
Hi. This is CE on ReachMD, and I'm David Boyer. I'm pleased to be joined by my colleague, Marion Munk. Thanks for being here. Today, we're going to discuss how to integrate photobiomodulation therapy in the treatment landscape of age-related macular degeneration.

There are a number of endpoints, Marion, that we saw in the LIGHTSITE III trial; a number of changes in iRORA and cRORA. But again, this study was not powered to see that. A lot of people looked at the post-hoc analysis and said that it was a treatment. Can you discuss that? You've been involved in a number of clinical trials.

Dr. Munk:
Yeah, that's a very good point. And this is also why, sometimes, physicians and ophthalmologists and retina specialist get a little bit confused by the data, because the primary endpoint here was always functional visual acuity, and it was no morphological endpoint. So, the morphological endpoints, they were all secondary endpoints. It was very interesting to see that there was significantly less onset of geographic atrophy or cRORA, and also the progression from iRORA to cRORA in the PBM-treated group compared to the sham-treated group, was significantly lower.

However, it has to be stressed out that these were secondary and post-hoc analyses, because the primary endpoint of the study was always visual acuity and visual function.

When you compare the PBM trials with the other GA trials, which led to the approval for different intravitreal injections for or against geographic atrophy, what is the take, at least for you, David?

Dr. Boyer:
Well, I think that I look at these as exploratory endpoints. I think that you've had a lot of experience in Europe, much more than we've had in the United States. You're able to treat more patients. I think that the data that will be coming out from Europe are going to be extremely important because you have longer follow-up, and I know you, personally, have used this PBM modality with excellent results in other patients.

As you pointed out, the visual acuity is key in this study, but there are other endpoints that we should look at in the future. And again, as you pointed out, iRORA going to cRORA, the change in the size of the lesion, all can be monitored, and I think the company will go forward in the future and look at those.

Dr. Munk:
Yeah, that's a very good point. So, what we saw also, in the trials is, for example, there was a drusen volume increase, for example, but a drusen volume increase was significantly less compared to the sham-treated group. And like I said, there were also patients who developed geographic atrophy, or who developed neovascularization. But in terms of geographic atrophy, for example, the numbers of patients were significantly lower.

But, as you pointed out also, it was not the primary endpoint, so it will be very interesting to see whether, also for these morphological endpoints, PBM can be a very efficient and effective therapy.

When it comes to the perfect patients, nowadays, at least in the US according to label, what patient profile should be looked at?

Dr. Boyer:
Well, I thinkthe ideal patient is a patient with 20/40 or less vision, large semisoft drusen, and perhaps even a small extrafoveal iRORA, or even a small cRORA. If you treat patients that are better than 20/40, you may get a response, but you may not get the 5 letters and the patients can get disappointed, even though we may see anatomic benefits. So, I think the ideal patient is 20/40 or worse vision. Certainly, 20/20 patients may benefit greatly compared to the natural history, but it's much harder to find that they're going to be happy.

Dr. Munk:
Yeah. I have a couple of patients who have, for example, geographic atrophy like, again said in Europe, so our label is much broader. And I have a lot of patients who are treated with PBM for or against geographic atrophy, or in order to improve visual acuity when they have geographic atrophy. And I have a lot of patients who have, like, 20/20 vision in one eye, and geographic atrophy extrafoveal, and in the other eye, center-involving geographic atrophy, and are also treated with PBM. And often, in these patients, I can see a visual acuity improvement from 20/20 to maybe 20/16, and also the patients are realizing a visual acuity benefit. Of course, their concern is primarily to kind of sustain their visual function as long as possible, and also to improve the visual acuity in the eye who has center-involving geographic atrophy.

But while we are talking about patients and patient's perspective, I may share a case here with you which we can discuss. The patient is female, 88 years old, and so far, had 5 PBM cycles in both eyes over the last 2.5 years. And based on the numbers of PBM circles and the time she has been treated, you can already see that, very often, the patients do not stick to these 4 monthly treatment interval, which is recommended. Just because it's, of course, time consuming to come to clinic and, of course, it's sometimes hard to find, like, 3 to 4 weeks where you can really come to the office 9 times. So, very often you will find patients who maybe had 5 to 6 circles over maybe 2 to 5 years, and usually their treatment interval ranges from 4 months to 6 months.

What you can also appreciate, when we look at the OCT on top, this is at baseline and on the right-hand side, after 2.5 years, that here, at least in this slide, the patient mainly has SDDs and subretinal hyperreflective material right in the center. And over the 2.5 years, you see no development of cRORA or iRORA, and you can also appreciate that the numbers of SDDs have not increased over time.

Also, what is important, the visual acuity of remains stable. So, this was a patient who did not show significant improvement in visual acuity, however, her visual acuity remains stable on 0.8 over the whole course of 2.5 years. And when we look at the drusen volume, you can see here. So on the left-hand side, this was at baseline, and then after 2.5 here. You can also appreciate that the drusen volume remained stable, so there was not significant decrease and also no significant increase. Both parameters would be markers for progression to either advanced dry AMD or progression in terms of intermediate AMD.

Sometimes, of course, it's very hard to follow the improvements or the sustainability of the treatment over time on the OCT, for example. But we can see that there is an effect. When we, for example, have a look here, the patient, again, and we look and evaluate the outer retina, we see, actually, that over time, the thickness of the myoid zone as well as the thickness of the ellipsoid zone. Also, the RPE and also the choriocapillaris and choroid remain completely stable over time. And usually, what we expect from a degenerative disease, we would expect a decline or thickness decrease, due to SDDs, for example, or due to the onset of geographic atrophy, which actually

doesn't happen in this case.

Any take-away from this case, David, from your side?

Dr. Boyer:
Oh, Mary, I'm very happy that you shared that case. This would be a patient that would not have noticed a visual improvement, but anatomically, probably, you saved her from—or him—from going on to developing a problem. And we certainly look forward to hearing the results of the trials going on in Europe, as they do have a large registry. I want to thank everybody for your time.

Announcer:
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