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New Strategies for Individualizing Treatment in DME

Announcer:
Welcome to CME on ReachMD. This activity, titled “New Strategies for Individualizing Treatment in DME ” is provided by Prova Education. Prior to beginning the activity, please be sure to review the faculty and commercial support disclosure statements as well as the learning objectives.

Dr. Gonzalez:
We want to give our patients with diabetic macular edema the best care possible. The good news is we now have several treatment options available with the emergence of second-generation agents and the recent approval of the port delivery system. So how do we decide which treatment is best for each patient?

This is CME on ReachMD, and I'm Dr. Luis Gonzalez.

Dr. Brown:
I'm Dr. Jeremiah Brown.

So I think that this is a very timely and important question. We know that patients with a high baseline central subfield thickness have a poorer visual outcome, but there's a lot of factors that go into treating our patient population, particularly those that are from a lower socioeconomic status and minority populations. Sometimes those patients aren't always able to take time off from work. They may not have a ride to the clinic. And these factors are going to affect outcomes.

Dr. Gonzalez:
This is so true. The real challenge in treating DME or patient with diabetes is that every patient is different. They face unique obstacles when it comes to starting, sticking with, and staying committed to treatment. And more importantly, I always stress that we can throw everything we've got at the eye, but if metabolic control is off track, we're only providing temporary effects. Despite these challenges, our ultimate goal is to dry the retina as much as possible and as soon as possible.

How do our anti-VEGF therapy that we have available now correlate with your practice, Dr. Brown?

Dr. Brown:
Sure. One thing that I think is worth just stating right off at the top is realizing how variable this population is in terms of how they will respond. If you look at, in YOSEMITE and RHINE, one arm of that study had a variable treatment interval based on how the patient was doing. And if you look at the results on this first slide, you can see that 78% of the patients were able to go 12 to 16 weeks by the end of the study. The graph on the right, that kind of gives you more clarity into that issue. So starting from the left to the right, it's showing a particular patient's journey through this study. And you could say in the beginning, everybody was in the green, where they were getting every 4 weeks. And the patients who did well at 4 weeks could then graduate onto going every 8 weeks, such as that gold color. And then when they hit that point, if they were still doing well, they could go out to every 12 weeks in the purple, and then every 16 weeks in

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the pink. And you can see how it kind of stacks up that, yeah, there's a large number of patients who were able to make it out to every 16 weeks, which is tremendous. But take a look at the variety. You have some patients even at the end, were still needing injections every 4 weeks. So our goal is to try to optimize the treatment for that patient, a more personalized treatment. And the medications that we have do offer us some ability to do that.

One study that I think is helpful in this population is a study that was looking at how do patients respond after their first injections with bevacizumab. And it was shown that African American patients were less likely to have vision improvement with bevacizumab. You can see on this graph here that after one dose, if you see the Black versus White patient, Hispanic versus White, and then after 3 doses that the African American patients tended to not have as good a visual improvement after doses of bevacizumab. Unfortunately, many times we are forced to use bevacizumab as our first option.

Another trial that helped us get a little more insight into this question was the ELEVATUM trial. The ELEVATUM trial, the goal was to try to increase the number of African American, Hispanic, and Pacific Islander and Native American patients in our database. And so in this study, the goal was to have about 45% African American, 45% Hispanic, and 10% of the Pacific Islander population. At baseline, we saw some very interesting things, talking more about the diversity of the patients that we face with diabetic macular edema. So at baseline, you can see that the Hispanic patients tend to have slightly poorer vision at baseline, 59 letters versus 62 letters in the African American group, and their central subfield thickness was thicker, 490 microns compared to 467 microns in the African American group. And this was similar to what was seen in YOSEMITE and RHINE, where it was 60 letters in the Hispanic Latino group, and 63 letters in the African American. So it gives us a good idea about the validity, that the data has the validity and repeatable.

But what's amazing, if we go to the actual study results, is the Hispanic Latino population knocked it out of the park. I mean, in 1 year, the average letters gained was 14.1 letters, at the end of 1 year. You can see the African American group gained 11.3 letters, and that compares to the YOSEMITE/RHINE overall population of 11.2 letters. If you look at how did their retinas respond, you can see that purple line going down and steadily improving in terms of improving central subfield thickness, improving macular edema, all throughout that whole first year, with a total of 230 microns of improvement in the Hispanic group, 193 microns of improvement in the African American group, and 203 if you look back at the old YOSEMITE and RHINE data. So this just gives us an idea of the diversity of the patients that we're going to be facing.

Now, if we look at the actual Diabetic Retinopathy Severity Score, it was interesting. The patients that were in the African American group tended to be more in the mild to moderate group in terms of diabetic retinopathy, whereas the Hispanic group tended to have a little more severe retinopathy at baseline. However, by week 20, 40% in the Hispanic Latino group had gained 2 steps on that scale, and at week 56 that was upheld with, again, 41% at 56 weeks.

So I think this data gives us a good glimpse into the diversity and the challenge that we will face in our clinic every day.

Dr. Gonzalez:
These are great points and very interesting observation, and it really highlights how every patient starts from a different place at their first visit. As you mentioned, the diversity of the patients we encounter in our clinics, the worse their vision or CST, the greater the potential for improvement. But there are many other variables that we have to consider.

And that said, I can't stress enough how important it is to customize the treatment plan for each individual. And getting all this information and evidence we have from ELEVATUM and from YOSEMITE and RHINE, to incorporate that into our clinical practice.

For those just tuning in, you're listening to CME on ReachMD. I'm Dr. Luis Gonzalez, and here with me today is Dr. Jeremiah Brown. We're discussing new data that will help better customize treatment and optimize vision outcomes in your patients with diabetic macular edema.

What can you tell us about the patients who responded to treatment in the ELEVATUM trial?

Dr. Brown:
I think this case touches on many of those points that we've discussed. This is a 46-year-old African American woman who presented with type 2 diabetes mellitus and severe diabetic macular edema. You can see, on her fluorescein angiogram, diffuse leakage in the temporal macula with clusters of microaneurysms. On her OCT, she has foveal-involved cystic edema. There's a small amount of

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subretinal fluid. Visual acuity is 20/50, and her central subfield thickness is 446. So this is the type of patient we see in clinic every day, and we would love to be able to get them back to normal as quickly as possible.

Well, she was started on treatment with faricimab. After one injection, visual acuity improved to 20/40, she had 165 microns of improvement on her OCT from her first injection. You can see those central cysts improving. After 4 injections, at week 16 you can see the dramatic improvement in a normalization of her retinal contour. There's still some hyperreflective foci, reflecting exudates there, but much improved. Visual acuity is still 20/40 so we don't give up there. Let's see what she's like at week 20. After her fifth faricimab injection, visual acuity 20/25. She's improved overall another 22 microns, and you can see how much better her fluorescein angiogram looks and the reduction in all that vascular leakage.

Dr. Gonzalez:
That's an impressive, impressive response to treatment in an amazing case. But I think you have a little bit more information on this case to share?

Dr. Brown:
Yes. Well, what I just wanted to add is some people will say, Well, what did the ELEVATUM study really do for us? What did it add? And one of the things I think is important is it showed that it was possible to enroll a study with underrepresented patient populations and do it in a timely manner. This study enrolled faster than was expected. By a year, it was completely enrolled. It also shows that you can have good retention in this patient population, which some of the patients, up to 20%, had a hemoglobin A1c of 12%. And 87% of the population completed the study. So I think those were some very important points from a clinical research standpoint.

The other thing I think that this showed that you can take home with us, is it's interesting that Hispanic patients tend to present with worse vision and more advanced retinopathy; however, they responded the best to faricimab. And this study really highlighted that finding.

Dr. Gonzalez:
So thank you so much for sharing that amazing case and those insights on what ELEVATUM has reported to our scientific community. One of the interesting facts about ELEVATUM, it's a phase 4, open-label trial without a comparative arm. However, we have strong evidence supporting the non-inferiority of faricimab when compared to other agents, especially aflibercept. We have from pharmacokinetics and pharmacodynamic studies, how faricimab is able to suppress Ang-2 in patients with DME quickly and for a longer time than other agents. When we take a look at the data that we got from YOSEMITE and RHINE studies, these studies are very interesting because they demonstrate equal efficacy, right, between aflibercept and faricimab. But faricimab achieved dryness more quickly with less injections. And as we were talking, this is extremely important in our population, when obstacles to come to clinic and being are of most relevance.

Dr. Brown:
I agree with you. I think this is so important, this slide.

And looking how much longer it took with aflibercept to reach that 50%, nearly 48 weeks longer of continued treatment to get to the 50% having absence of intraretinal fluid, that's dramatic.

Dr. Gonzalez:
Yeah, for me, this slide summarizes the best of YOSEMITE and RHINE, especially, we're talking about patients that are at a working age. They have to go to work; they have to take time off to come to the clinic. So allowing them to have less visits is extremely, extremely important.

And if we add on to the data that came from Protocol T, we know from the 1-year outcomes that aflibercept was quicker in achieving dryness than ranibizumab or bevacizumab. But if we take a look at the 5-year outcomes, all of these 3 agents are almost equal in achieving improvement in vision, right, or having a positive effect in improving OCTs and biomarkers.

Overall, I would say the evidence confirms that these agents are all valuable tools in the fight against DME in patients that need this type of treatment.

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Dr. Brown:
I agree.

So my key takeaway from this, I would say, is consistent treatment can lead to good results, even in more difficult-to-treat retinas. And it's nice that we have more options available to us to treat and maybe customize our treatment based on the individual that we have in front of us. I think this is just so encouraging to see this data, and I discuss these topics with my patients every day.

Dr. Gonzalez:
Well, this has been a fantastic conversation. I would say listen to your patient, understand the challenges they face in sticking to the treatment plan, having open discussions about potential barriers to success, and keep fighting.

That's all the time we have today. Thank you to our audience for tuning in, and thank you, Dr. Jeremiah Brown, for joining me and sharing all of your insights.

Dr. Brown:
Thank you very much. It was great speaking with you today.

Announcer:
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