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Real-World Treatment of Retinal Disease

Announcer:

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Dr. Sridhar:

Clinical trials are great at demonstrating intravitreal drug therapies' efficacy. But why do our real-world outcomes fall short of clinical trial results when we look at visual outcomes in the real world? I'm Dr. Jay Sridhar, and this is CME on ReachMD.

Dr. Dang:

And I'm Dr. Sabin Dang. Jay, that's a great question. I think that's really important to our patients. When we look at clinical trials, especially our seminal anti-VEGF trials, such as ANCHOR and MARINA, we see that patients are getting visual benefits from the anti-VEGF treatments that exceed what studies show we're getting in the real world.

One of the other things that we note in these studies that are often reported is that the amount of injections that patients are getting in these clinical trials are higher than what we're getting in the real world. So, the outcomes are not the same. Jay, how much do you think this is the number of injections versus maybe other barriers to care that patients are experiencing in the real world?

Dr. Sridhar:

That's a great question, Sabin. I mean, I think that for sure the number of injections has to play a role, and there are a lot of reasons that patients get more frequent injections in trials. One, it's mandated as part of the protocol for the trial. Two, these patients are called and seen at very, very regular intervals. There's no rescheduling in a clinical trial visit to go visit your grandkids, or take a trip, or if you have an illness, you know. So, in the real world there are other limitations, right? Clinical trials, besides being well-controlled, don't always have the most diverse populations historically in the retina space, and so that's something that future trials are trying to address. But that may explain why our outcomes in our real-world populations don't match the clinical trial populations.

There's also the idea of how do we decide if the disease is active? So, a lot of these trials maybe had fixed dosing for a period of time and then had treatment if there was noted to be disease activity, but there were very strict criteria with the reading center to determine if there was disease activity or not. In the real world, most of us aren't making this clinical decision by looking at imaging and there's a lot of provider intervariability in deciding what is the criteria to retreat wet AMD [age-related macular degeneration]. There may be a lot more tolerance for subretinal fluid in the real world for various reasons. And then, also, part of it is just the patient factor like I was referencing earlier. Patients may have many reasons why they don't come in for those regular visits, and so, as a result, the frequency of treatment when you compare the real world to the clinical trial is not adequate, and it really shows that this is an unmet need in our space. And that's why it's so important to have real-world data submitted.

Dr. Dang:

Yeah, I agree with you completely. I think the points you highlighted on, specifically, you know, clinical trials. Those are highly motivated patients, and heck, a lot of them get their transportation covered for, which is something that patients in the real world don't get. These

are patients who are missing work or having to ask loved ones to take off of work to come bring them into their visits, which can impair their ability. And so, these type of barriers to treatment, I think, are really important for us as a field to evaluate, and I'm really excited to see some of the work done in this space.

Jay, I know you're familiar with the IRIS Registry. I mean, this is a huge comprehensive dataset of what is actually happening to millions of patients in the United States, and I think this dataset is a goldmine for us to evaluate and see exactly what type of different demographic groups are responding differently to treatment, but also what is actually happening in the real world.

The other thing, Jay, that I'm excited about is the VOYAGER study. As you know, this is a study that's going to be looking at the port delivery system as well as faricimab in the real world for these patients. So, looking at over 12 months what is happening to these patients in terms of their visual acuity gains, in terms of the number of injections they're getting, how many visits they're getting, what are the criteria that providers are using. As you had mentioned, imaging is so key to us as physicians when we're managing these patients, and this will allow us to kind of get some introspection into the minds of retina specialists and get a sense of, okay, how tolerant is the group into tolerating fluid, versus how aggressively are they treating. You know, the labels for a lot of these products say that there should be a loading dose phase. What percentage of retina specialists are actually providing loading doses for these patients, and how do loading doses versus not loading doses, how does that impact long term care? So, I'm excited to see how all this data starts coming out and informing us on how we can best take care of our patients.

Dr. Sridhar:

That's really exciting, and hopefully gives us some answers to some of the fascinating questions you referenced. And it really underlines why real-world data is so important to define in clinical practice, even in the context of clinical trial data. Unfortunately, Sabin, that's all the time we have for today. I always love talking to you, but we'll talk to you soon. Thanks so much for joining us.

Dr. Dang:

Thank you, Jay. Take care.

Announcer:

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