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The Durability Dilemma

Dr. Rahimy:
How durable are second-generation agents in the real world? And what is preventing us from achieving the same durability seen in clinical trials? I'm Ehsan Rahimy, and joining me today is Roger Goldberg. Welcome, Roger.

Dr. Goldberg:
Thanks for having me, Ehsan.

Dr. Rahimy:
Roger, trials show that 12- to 16-week dosing intervals achieve these great outcomes that we're seeing published in various studies, but real-world data show that treatment can't quite be extended as far, maybe potentially only an additional 1 to 2 weeks in our established treatment-experienced patients. Why do you think that is?

Dr. Goldberg:
I think it's probably a little multifactorial. First of all, it's sometimes a different patient population that gets enrolled into a clinical trial than we're seeing in our real world. So they tend to be treatment-naïve patients, certainly in the wet AMD space. And the majority of patients in the diabetic trials were treatment naïve. They can't have any other concurrent pathology, including scarring or atrophy or epiretinal membranes at baseline. So they tend to be a really clean population that's not always reflective of the rest of the patients that we see, kind of in the real world.

And then, of course, the clinical trial design, those trials were designed to really test the limits of durability. And you have to be very careful doing head-to-head comparisons, but they all tolerate some fluid, some change of vision that perhaps in the real world we don't tolerate in our day-to-day life. And they have to do that because they want to standardize how every physician is treating the patients across what can sometimes be 100 different clinical trial sites and many, 100 investigators, who are examining those patients. So you can't allow it to be loosey-goosey of like, well, I think it looks a little worse. Or, the patient's dry eye was worse, so their vision dropped. They really need it to be standardized across a global clinical trial program.

So I think it's multifactorial. What's your sense of why we're not seeing the same durability benefits in the real world?

Dr. Rahimy:
I'd echo what you said. I thought you brought up some fantastic points, especially for the neovascular AMD population. As we know, with most of these trials, they're enrolling treatment-naïve patients, whereas when these new drugs come to market, we're typically exposing our treatment-experienced patients, and oftentimes they're the ones that are getting the most injections and have the most active disease process. So one of the things I'm constantly scrutinizing is that inclusion/exclusion criteria. I like to, when I'm reading about a new study or new drug or new trial, I want to see, can I extrapolate this patient study population to what I'm actually taking care of in the real world?

And on the second end are these disease activity assessment periods or dosing-regimen modifications that we see in these studies. They each have their own parameters. We see a lot of scrutiny from them at many of the meetings. But at the end of the day, we all decide to retreat patients or to extend patients different in the real world than we do in clinical trials, as you nicely elucidated.

Roger, if second-generation agents are so good at drying the retina, should our goal be to dry the retina as much as possible before we start extending? Or do you think we should be able to tolerate a little bit of fluid to achieve greater durability if we are to trust in these agents?

Dr. Goldberg:
I agree. It's a great question. I agree that I think myself, like most people, tend to try to achieve a dry retina as best as possible. And I think kind of it's almost a double-edged sword with these next-generation agents, because we expect better performance, both in terms of its drying ability as well as the durability. So I usually start on the drying. So if it's somebody who has fluid, I try to treat them basically monthly or as frequently as possible to maintain a dry retina. And then start to extend the interval using some of the factors that we talked about in an earlier session, around maybe a little bit of subretinal fluid at the edge of a PED, might be okay to tolerate.

Dr. Rahimy:
I agree wholeheartedly. I think I've been trying to challenge myself to extend in larger intervals and to longer intervals. I'm a little bit more lenient, I think, with my diabetic population to attempt this. I think most of us feel a little bit more anxiety around our neovascular AMD patients. We really want to make sure that they're optimally dry before we consider extensions for them.

Well, Roger, this has been a great bite-sized discussion. Thank you for our audience for tuning in. And again, thank you, Roger, for joining me today.

Dr. Goldberg:
Thank you.