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

Retinas at Risk: Real-World Cases in High Disease Activity and Adherence Challenges

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Dr. Regillo:
I'm Carl Regillo. Here with me today is Dr. Lejla Vajzovic.

Dr. Vajzovic:
Hi, Carl. It's so great to be here.

Dr. Regillo:
Great to have you, Lejla. We discussed some of the challenges and unmet needs that we face as clinicians in our last episode. So let's take a look at what this actually looks like in clinic. I'm going start with a case. This is a 77-year-old woman, new-onset wet AMD in her left eye. She had visual symptoms with distortion and some blur for about 3 weeks. Her right eye was known to have dry AMD. It has good vision, 20/25, and no symptoms. So what we see in the images, it's a fluorescein angiogram indicative of somewhat of an older case. I don't do much angiography these days, but it does show leaking occult choroidal neovascularization in the central macular region. And, of course, the corresponding OCT below shows central subretinal fluid and the presence of CNV and a little thickening, 20/60 visual acuity in that affected left eye. So what do we do? Of course, after establishing the diagnosis of new-onset wet AMD, we started aflibercept injections, 2 mg, and we're seeing an immediate good response.

After the first injection, 4 weeks. After just 1 injection, the visual acuity is improving, the subretinal fluid is getting better. And now on the bottom, 20/30 vision. This is 4 weeks after the second monthly aflibercept injection. Virtually all the fluid's gone. There's some incidental vitreomacular adhesion, probably again incidental and unrelated. We're seeing excellent improvement. And in a typical fashion, I started to do treat and extend, had the macular dry. So I injected and said, "Come back in 6 weeks." Visual acuity is still 20/30. Six weeks after the third aflibercept injection, you can see the OCT looks excellent, dry, no subretinal fluid. And then when I attempted 8 weeks with a 2-week extension, we can see recurrence of subretinal fluid almost as much as we started with, 20/50 vision, so the vision has started to decline. The patient was definitely symptomatic. So, of course, in the typical fashion, I went back to 6 weeks for the treatment interval, and the visual acuity improved back to 20/30 six weeks after the injection. So, Lejla, is this a common type of case? What do we do now?

Dr. Vajzovic:
Now, Carl, this is a really very common case all of us see in our clinics. A patient who has a newly diagnosed, very responsive CNVM or wet age-related macular degeneration responsive to anti-VEGF, yet, unfortunately, we're unable to extend her past the monthly every-6-week interval with a standard aflibercept 2-mg dose. So, you know, one will wonder, you know, what are the next choices? It would be great to have longer duration therapies for this patient. So, clearly, you've tried several times now to extend her past 6 weeks, and I foresee this patient, you know, having to recur or come back to us routinely for recurrent injections. And so I would love to have, you

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know, exactly discussions of longer duration therapies for her at this opt— at this state.

Dr. Regillo:
Yeah, you're absolutely right. This is not a tolerable amount of fluid. We talked about that 50-µm threshold time and time again. It would probably erode the visual acuity if we had that degree of recurrence. In other words, if I kept trying to extend from 6 to 8 weeks with the same medicine, 2-mg aflibercept, it's not going be a good long-term vision outcome. So options are thinking about switching. You know, we do have so-called second-generation options. That means high-dose or 8-mg aflibercept. That would probably get us a few weeks, when we can talk to real-world data on what it does in the switch setting. And then there's also faricimab. Both of these drugs in their clinical trials suggested longer duration. So keep in mind also there's that third option, right? The FDA-approved port delivery system, as sustained delivery, 6 months, very good disease control in the clinical trials in over 90% of patients.

That is an option, but it is a trip to the OR with a device. So if you had to choose the next step for this patient, what would you choose?

Dr. Vajzovic:
Yeah. Yeah, I would offer all of those options and really depend on her comfort level and, you know, response, in general, to potentially the second generation or port delivery system, for certain. But I think what you pointed out really nicely is this patient has very high biologic disease activity. There's recurrence of fluid that, unfortunately, if not treated, will lead to permanent eye damage and long-term visual risk of it's not recovering. And we all miss visits. We all miss visits because life happens, you know, life events, medical, other medical illnesses, whatnot. So I think the importance of having longer durations, which you referred to that, would be really the time point here.

Dr. Regillo:
Yeah, and in the future, just around the corner, potentially gene therapy is the ultimate sustained delivery long-term disease suppression, potential here. So I know we'll be talking more about that in future episodes. How about your case?

Dr. Vajzovic:
Yeah, definitely. So I have a similarly a 65-year-old female who presented with a peripapillary choroidal neovascular membrane secondary to newly diagnosed wet AMD in this eye. And notice the visual acuity is 20/60, and you'll notice that there's quite a bit of subretinal fluid and exudation extending from that choroidal neovascular membrane to the fovea and really affecting her vision. Now, unfortunately, this patient is monocular patient, so this is her better seeing eye with now diagnosis of this condition, and she very much has aversion to needles. So I was fortunate to get her approved right away to second-generation anti-VEGF agents, in this case, aflibercept 8-mg dose, and treated her with 1 injection and excellent response where you see drying out effect and really resolution of subretinal fluid. And then as we continue to treat with third and fourth dose, really significant drying and even improvement of that exudation took place over time. You know, because this patient has aversion, she was like, "I'm seeing better. I'm—you know, my vision is 20/25. Why don't we, you know, watch it this time?"

And clearly, with a peripapillary CNV, I'm also felt a little more comfortable watching. So I'm following this patient now, routinely on monthly initially, and now every 3 months interval, I'm ensuring that she stays stable. I believe this is a great example of patient, and we have all of these patients have— We have many of these patients who absolutely have aversion to injections who definitely need treatment, and it would be nice to have longer duration.

While this patient responded beautifully to a second-generation anti-VEGF, it would be nice potentially to have long-term suppression. What do you think, Carl?

Dr. Regillo:
Oh, absolutely. You know, long-term or long great durability of disease suppression is not only decreased treatment burden, it's the potential for better long-term vision outcomes, as we talked about earlier. You know, the tricky thing about this case, it's unusual. It's first of all, it's typical in that it responded very well and dried up nicely to an anti-VEGF, and, great that you're able to start with high-dose aflibercept right out of the gate. And so you got a good response, and now you're getting a durable response. After a few injections, you went 3 months, and it's still dry and stable. The question now becomes, you know, peripapillary CNV sometimes can stay quiescent on its own. Certainly, if this was in the macula, the center of the macula, like most CNV, I would definitely continue treatment, perhaps every 3 months, maybe every 4 months with this medicine, depending on, I'll do the typical treat and extend. But I would be very hesitant to not treat or go off treatment or make it PRN because studies show that ultimately, or eventually, there will be disease recurrence. And if the fellow eye doesn't see well or something like that, you just don't want to risk that. In this particular case, again, peripapillary is not the majority.

It's a very small minority of our CNV wet AMD presentations. You might be able to get away with just observation, as long as it's very close with a very low threshold to restart treatment at the first signs of any exudation. Again, especially if the fellow eye doesn't see well,

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you don't want to take those chances.

So this one's a little different. It's a little tricky. It's not typical of most of our wet AMD. It's typical in the good response. I'm going say it's somewhat typical in the fairly good durability of HD aflibercept, but the peripapillary location makes it potentially behave a little different and may or may not recur as most wet AMD typically does.

Dr. Vajzovic:
No, well said, Carl.

Dr. Regillo:
Well, with that, join us for our next episode as we talk about emerging treatments, including gene therapy, that can provide greater durability. Thanks for joining us.

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