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Clinical Evidence for Durable Treatment of DME

Announcer:

Welcome to CME on ReachMD. This episode is part of our MinuteCE curriculum.

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Dr. Weng:

What is the latest clinical evidence around durable treatment modalities for DME [diabetic macular edema]?

This is CME on ReachMD, and I'm Dr. Christina Weng.

Dr. Borkar:

I'm Dr. Durga Borkar. Great question.

I think one of the most exciting developments in this space was the approval of faricimab early last year for the treatment of both neovascular AMD [age-related macular degeneration] and DME. This is particularly novel, because this is a new dual mechanism of action, with inhibition of both the VEGF and Ang2 pathways. YOSEMITE and RHINE were the two phase 3 RCTs looking at the efficacy, safety, and durability of faricimab for DME, and these studies showed that treatment with faricimab was noninferior to aflibercept 2-mg treatment. And they showed demonstrated BCVA [best corrected visual acuity] gains and reductions in CST [central subfield thickness]. The durability results are particularly impressive, with 80% of study eyes achieving a treatment interval of 12 weeks or more at week 96.

I think there were some interesting post hoc analyses related to these trials as well. At ASRS [American Society of Retina Specialists], a study was presented showing a greater reduction in macular leakage compared to aflibercept after 16 weeks of treatment. And there was another post hoc analysis presented at ASRS that showed that treatment with faricimab was associated with lower rates of ERM [epiretinal membrane] formation at 2 years, compared to treatment with aflibercept. In both cases, it's hypothesized that the Ang2 inhibition is likely related to these findings.

I think we're also really trying to amplify treatments that we already have to make them more durable. For example, the PHOTON phase 2/3 study evaluated aflibercept 8 mg and showed that treatment with aflibercept 8 mg, both at Q12 and Q16 weeks, resulted in noninferior BCVA compared to Q8-week treatment with aflibercept 2 mg at week 96. And the patients received 6 fewer injections in that time period.

What about the new data around the new steroid implant?

Dr. Weng:

Yeah, great question. Well, the latest data comes from a phase 4, prospective, 3-year, nonrandomized, open-label study called PALADIN, which evaluated the fluocinolone 0.19-mg implant in treatment-experienced patients with persistent or recurrent DME. This therapeutic provides continuous therapy for up to 36 months with microdosing, and in this study investigators aimed to quantify the number of treatments required by eyes before versus after the implant was placed. Not only were there significant improvements in the mean retinal thickness and visual acuity, but investigators found that the implant reduced the total number of therapies administered by 46% and, very impressively, that 25% of eyes remained supplemental treatment-free through 36 months. Additionally, you can see in

the bar graph to the right that eyes that were switched to fluocinolone acetonide earlier in the treatment course had better visual outcomes. From a safety standpoint, remember that these patients had already passed a steroid challenge per the label. While most eyes were pseudophakic at baseline, 62% of phakic eyes underwent cataract surgery. Mean IOP [intraocular pressure] remained stable throughout the trial, with 28% of eyes completing the study experiencing an IOP increase of greater than 10 mmHg. Slightly over a fifth were started on IOP-lowering medications, and IOP-lowering surgery was performed in 3% of patients. Only about half of those were actually due to steroid-induced IOP increase, while the other half was due to neovascular glaucoma.

Of course, in addition to fluocinolone, we have other steroid options like the dexamethasone implant, triamcinolone acetonide, and don't forget about focal laser, which still can be helpful in certain cases.

Never before have we had so many effective options for the treatment of DME, I'm sure you'll agree, Durga, and the key will be really deciding how to select the best one for a given patient. And fortunately, I predict we'll learn a lot more from clinical trials along with ongoing real-world studies.

Dr. Borkar:

That's exactly right. Stick around to learn more about real-world data around durable treatments for DME as well as neovascular AMD.

Dr. Weng:

See you next time.

Announcer:

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