Transcript Details
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DRCR.net Anti-VEGF Comparative Effectiveness Trial for Diabetic Macular Edema: Additional Post-Hoc Analyses

Opening Wrap:

For ReachMD, this is Audio Abstracts. The following is brought to you by the Diabetic Retinopathy Clinical Research Network, sponsored by the National Eye Institute of the National Institutes of Health, and provided by Prova Education.

Dr. Bressler:

I am Dr. Neil Bressler, Past Chair of the DRCR Network and serving as the Chair of the Network's Education Committee.

Diabetic retinopathy, including diabetic macular edema, or DME, is a leading cause of vision impairment and blindness in the United States and throughout the world. According to the Centers for Disease Control and Prevention, both type 1 and type 2 diabetes affect about 26 million people in the United States. Among these 26 million, more than 5.3 million Americans age 18 and older are estimated to have diabetic retinopathy, and vision loss from diabetic retinopathy is the leading cause of new blindness among people between 20 and 74 in the United States and many other places in the world.

The Diabetic Retinopathy Clinical Research Network (DRCR. net) is a collaborative network dedicated to facilitating multicenter clinical research of diabetic retinopathy, diabetic macular edema and associated conditions. Since September 2002, the DRCR. net, currently including over 115 participating sites with over 400 physicians throughout the United States, has supported the identification, design, and implementation of multicenter clinical research initiatives focused on diabetes-induced retinal disorders. Principal emphasis has been placed on clinical trials, but epidemiologic outcomes and other clinically relevant research have been supported as well.

Of particular recent interest to the eye health community has been a protocol by the DRCR. net entitled: A Comparative Effectiveness Study of Intravitreal Aflibercept, Bevacizumab and Ranibizumab for Diabetic Macular Edema. Among the alphabetical list of protocols, this study is listed as Protocol T. This clinical trial has prompted many discussions at conferences, as well as in both peer-reviewed and non-peer reviewed journals. These discussions have resulted in exploring additional clinically relevant post-hoc analyses. This podcast will present these exploratory findings based on a recently published article entitled "Anti-VEGF Comparative Effectiveness Trial for Diabetic Macular Edema: Additional Post-Hoc Analyses".

As background, Protocol T was a 2-year randomized clinical trial of 660 participants that compared three anti-VEGF treatments, including intravitreous aflibercept (2.0-mg), repackaged or compounded bevacizumab (1.25-mg) and ranibizumab (0.3-mg dose), administered up to monthly based on a structured retreatment regimen in eyes with these center-involved DME causing vision impairment. For persistent DME that no longer was improving after 6 monthly injections, focal/grid laser could be added to the residual DME if there were areas to treat. This involved about 40% to 65% of eyes over two years, usually with one or two sessions of laser, depending on the anti-VEGF agent that was used. The primary efficacy outcome was change in visual acuity from baseline to one year adjusted for baseline visual acuity.

Results from Protocol T at 1 and 2 years demonstrated similar visual acuity improvement with all three agents, on average, for eyes that had visual acuity 20/32 to 20/40 at randomization. For baseline visual acuity 20/50 or worse, aflibercept produced, on average, greater visual acuity improvement than the other two agents at 1 year. Visual acuity improvement ***at*** the 2-year time point with aflibercept remained superior to bevacizumab, but was not shown to be superior to ranibizumab at that time point. However, in an exploratory, post-hoc analysis, looking at the average letter change in visual acuity ***over*** two years – based on a statistical method called the area under the curve – the visual acuity gain, on average, was greater with aflibercept than bevacizumab or ranibizumab. When visual acuity was 20/50 or worse, bevacizumab reduced central subfield thickness less than the other agents at one year; but at two years these

differences had diminished.

Based on these results, a question that many eye health clinicians have put forth in their discussions surrounding Protocol T focuses on whether efficacy is impacted by deferring injections after the initial 6 months of treatment. Injections were deferred if visual acuity and central subfield thickness were stable following 2 consecutive injections, that is, central subfield thickness was changing less than 10% or a visual acuity change of less than 5 letters of visual acuity. In other words, neither a ***normal*** central subfield thickness on OCT nor a visual acuity of 20/20 is required to defer injections after 6 monthly injections have been given. Implementing this strategy was associated with a decreased injection frequency between year 1 and year 2. In a prior DRCR.net protocol evaluating ranibizumab compared with focal/grid laser for DME, called Protocol I, continued decreases in the median number of injections were noted from years three to five.

In conclusion, for eyes with DME and worse initial visual acuity, aflibercept leads to greater visual acuity gains, on average, compared with bevacizumab at two years, but the difference was no longer statistically significant when comparing aflibercept with ranibizumab at two years. However, over the course of 2 years, the average visual acuity improvement was greater for aflibercept compared with either bevacizumab or ranibizumab. For eyes with better visual acuity at baseline, approximately 20/32 to 20/40), there was little difference on average in visual acuity outcomes among the three agents at 1 or 2 years, although bevacizumab thins the retina less than the other 2 agents. These outcomes should be balanced with safety, accessibility due to expenses or local regulatory issues, and cost-effectiveness of these treatments. For more information, go to drcr.net.

Closing Wrap:

This has been Audio Abstracts on ReachMD. The preceding was brought to you by the Diabetic Retinopathy Clinical Research Network, sponsored by the National Eye Institute of the National Institutes of Health, and provided by Prova Education.

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