# A LOOK AT REAL-WORLD DME TREATMENT OUTCOMES

Comparison with clinical trial data in the treatment of diabetic macular edema

**BY THE EDITORS OF *NEW RETINA MD***



In a recent episode of the *Retina Today* Journal Club, Jonathan L. Prenner, MD, and guest moderator Charles Wykoff, MD, PhD, were joined by Thomas A. Ciulla, MD, MBA, for a look at real-world treatment outcomes in diabetic macular edema (DME) patients.

In research he described in the Journal Club video, Dr. Ciulla and colleagues mined an electronic database containing information on more than 800,000 patients. He focused on visual acuity results in DME patients with a minimum of three monthly anti-VEGF injections in the first 4 months.

Three cohorts of patients were analyzed in order to model loss to follow-up: those who had been followed for 6 months only, those followed for 12 months only, and those followed for 24 months.

The researchers found that patients gained about 6 letters of visual acuity at 1 year, not the average 11-letter gain seen in large randomized clinical trials. There was no difference in visual acuity outcomes among the three cohorts, and there was also no difference in performance or efficacy between the anti-VEGF agents used—bevacizumab (Avastin, Genentech), ranibizumab (Lucentis, Genentech), or aflibercept (Eylea, Regeneron). Patients who started with better visual acuity tended to experience greater vision loss, likely related to ceiling effect.

Dr. Ciulla said the results confirmed a conclusion he had suspected: Real-world DME patients do worse compared with those in clinical trials in terms of treatment outcomes. There was an approximate 5-letter or 1-line difference between real-world and clinical trial results.

Dr. Wykoff asked whether reduced injection frequency might have had an effect on patient outcomes. Dr. Ciulla said the real-world DME patients received injections with almost the same frequency as patients in clinical trials: eight injections on average, compared with 10 on average for trial participants.

"If we're getting close in terms of the number of injections, why do you think we're not hitting the target endpoints that we see in our randomized, controlled trials?" Dr. Prenner asked. "What are we doing wrong?"

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**Drs. Ciulla, Wykoff, and Prenner examine treatment outcomes for DME patients.**


Dr. Ciulla replied that the controlled circumstances of clinical trials could be a factor. Patients are not eligible for clinical trials if they have conditions such as severe ischemia, uncontrolled diabetes, or hypertension. Real-world DME patients with renal insufficiency or previous laser treatment would also be ineligible. The sicker real-world population would not be expected to do as well as the highly selected population of a randomized trial. Dr. Ciulla closed the discussion by noting that real-world visual outcomes after anti-VEGF therapy are better for DME than for neovascular AMD, based on a similar study he conducted previously. He also focused on the importance of careful patient monitoring and emphasized that patients with better vision from the start are at increased risk for vision loss and should be counseled on the need for follow-up. ■

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