

Better Vision, Less Need for Photocoagulation with Pegaptanib

Larger trials are needed to confirm its efficacy in a broader range of diabetic eye diseases.

BY CONNI BERGMANN KOURY, EDITOR-IN-CHIEF

Diabetic macular edema (DME) patients treated with pegaptanib sodium had better vision, decreased retinal volume and less need for laser surgery, according to a study presented at the American Academy of Ophthalmology (AAO) 2005 Annual Meeting in Chicago.

Thomas R. Friberg, MD, professor of ophthalmology and bioengineering at the University of Pittsburgh Medical Center Eye Center, and colleagues conducted a phase 2 trial in 39 centers in the United States. They randomized 44 patients to receive 0.3 mg of the anti-vascular endothelial growth factor (VEGF) medication (Macugen, EyeTech/Pfizer) through intravitreal injections. Forty-four patients received 1.0 mg, 42 received 3.0 mg and a group of 42 patients received a sham injection.

Patients were treated every 6 weeks for 12 weeks, and were to receive at least three injections. The mean number of injections patients received was 3.7. Steven D. Schwartz, MD, presented the findings from the Macugen Diabetic Retinopathy Study Group during the Retina Subspecialty Day portion of the AAO meeting. Dr. Schwartz is chief of the Retina Division at Jules Stein Institute/David Geffen School of Medicine at the University of California Los Angeles.

The primary outcome for the study was change in visual acuity and change in retinal thickness on optical coherence tomography (OCT), from baseline to week 36. The investigators also recorded the number of patients who were deemed to need photocoagulation. Patients in the study had diffuse DME greater than one half of a disc area in the foveal center and best corrected visual acuity between 20/50 and 20/320 in the affected eye and 20/100 or better in the fellow eye.

The results were as follows: At 36 weeks of follow-up a larger proportion of those receiving 0.3 pegaptanib compared to sham maintained and gained visual acuity (73% vs 51% [$P=.02$]). With regard to mean change in retinal volume, patients treated with the 0.3-mg

dose pegaptanib showed a reduction versus an increase with sham ($P=.021$).

"There was an absolute change in retinal thickness in the treated eyes that showed a mean decrease of 68 microns compared with an increase of 4 microns in the sham-treated group," Dr. Schwartz said.

Fewer patients who were treated with the anti-VEGF injection ended up needing laser photocoagulation (25% in the treatment group vs 48% in the sham group, $P=.04$)

The researchers concluded pegaptanib for diabetic macular edema treatment was well tolerated and patients had better vision, decreased retinal volume and less need for laser therapy. They recommended that larger, prospective, randomized, controlled trials should be conducted to confirm the safety and tolerability of the agent and its efficacy in a broader range of diabetic eye diseases. ■

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3. Macugen Diabetic Retinopathy Study Group. A phase 2 randomized double-masked trial of pegaptanib, an anti-vascular endothelial growth factor aptamer, for diabetic macular edema. *Ophthalmology*. 2005;112:1747-1757.