

Subthreshold Laser Not Protective in Eyes With Drusen

Results from the PTAMD study showed a modest treatment benefit, particularly in eyes with pretreatment visual acuity between 20/32 and 20/63.

BY CONNI BERGMANN KOURY, EDITOR-IN-CHIEF

Subthreshold laser treatment — per the protocol for the Prophylactic Treatment of AMD Multi-Centered Trial (PTAMD) — was not protective against subsequent choroidal neovascularization in eyes with drusen.¹ Thomas R. Friberg, MD, for the PTAMD Study Group, presented this conclusion at the Association for Research in Vision and Ophthalmology 2006 Annual Meeting in Fort Lauderdale, Fla.

Results from the bilateral study arm of PTAMD showed a modest treatment benefit, particularly in eyes that had a visual acuity between 20/32 and 20/63 before application of the laser. The objective of this portion of the PTAMD was to determine in a randomized trial whether a grid of prophylactic subthreshold laser placed in an eye with drusen would have a prophylactic benefit or a therapeutic benefit compared with the untreated fellow eye. Dr. Friberg is a professor in the department of ophthalmology at the University of Pittsburgh School of Medicine and chief of the Retina Service.

There were 639 patients randomized to subthreshold laser treatment in one eye in a one-time application from 22 centers. The treatment consisted of the application of a 810-nm laser with a 125- μ m spot size. The patients had to have a visual acuity of at least 20/63 in both eyes and at least five large drusen ($\geq 63 \mu$ m) in each eye.

EYES WITH BETTER VISUAL ACUITY FOLLOWED SEPARATELY

Patients were followed by fundus photography, fluorescein angiography and Early Treatment of Diabetic Retinopathy Study (ETDRS) BCVA for up to 5 years, Dr. Friberg reported. Eyes with good visual acuity at baseline might not be expected to improve, he said, so patients

with pretreatment visual acuity of 20/32 to 20/63 were evaluated as a separate subgroup in a planned analysis.

Rates of choroidal neovascularization did not differ between treated and untreated eyes at 3 years, Dr. Friberg said. A reduction of 50% or more drusen following treatment was observed in 44.5% of eyes that had laser application versus 4.5% of eyes that were untreated and observed at 12 months and 47.1% versus 9.0% at 24 months ($P < .001$ for each). When all study patients were analyzed as a group, 24-month visual acuity reflected a one and one-half letter benefit compared with the observation eyes ($P = .04$), and treated eyes showed a higher percentage of two lines of visual acuity gain (12% vs 8%).

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In the subgroup of patients with baseline vision from 20/32 to 20/63, treated eyes showed a four-letter (one line = five letters) benefit over observed eyes at 24 months. Eyes that were treated also showed a higher percentage that had two or more lines of visual acuity gain (31% vs 19%, $P = .025$) and less visual acuity loss (13% vs 22% losing two or more lines, $P = .04$), Dr. Friberg reported.

The conclusion of this study arm was that subthreshold laser treatment applied to eyes with drusen, as per the protocol, was not protective. It did, however, have a modest therapeutic benefit.

BACKGROUND

The first report from the PTAMD was published in *Ophthalmology*.² Those findings from unilaterally eligible patients found that prophylactic subthreshold 810-nm diode laser treatment to an eye with multiple large drusen — in a patient whose fellow eye has already suffered a neovascular event — places the treated eye at a higher risk of developing choroidal neovascularization. The investigators advised against using prophylactic subthreshold diode treatment in such eyes.

The primary endpoint of the first portion of PTAMD was to determine the effects of subthreshold 810-nm diode laser treatment on the rate of development of choroidal neovascularization and the effect on visual acuity in patients with multiple large drusen in one eye and preexisting neovascular AMD in the other. The multicenter, randomized, prospective, controlled trial included 244 patients aged ≥ 50 years with neovascular or advanced AMD in one eye. The fellow eye had to have (1) at least five drusen ≥ 63 nm in diameter, (2) ETDRS BCVA of 20/63 or better, and (3) no evidence of neovascularization at baseline.

Patients were randomized to treatment or observation of their study eye, and at each visit, BCVA, a complete retinal exam and fluorescein angiography was documented. The treatment consisted of a grid of 48 extrafoveal, subthreshold diode laser spots, 125 μm in diameter, placed in an annulus outside of the foveola. Patients were evaluated at baseline, and at 3, 6, 12, 18, 24, 30 and 36 months after randomization. There were no retreatments allowed as per the protocol.

The investigators reported that, throughout follow-up, the rate of choroidal neovascularization events in treated eyes consistently exceeded that in observed eyes. At 1 year, the difference was 15.8% versus 1.4% ($P=.05$). Most of the differences, the investigators wrote, occurred during the first 2 years of follow-up. Treated eyes also had a higher rate of visual acuity loss (greater than or equal to three lines) at 3- and 6-month follow-up relative to observed eyes (8.3% vs 1% and 11.4% vs 4%, respectively; $P=.02, .07$). ■

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1. Friberg TR, PTAMD Study Group. The Prophylactic Treatment of AMD Multi-Centered Trial (PTAMD): Results from the bilateral study arm. Presented at the Association for Research in Vision and Ophthalmology 2006 Annual Meeting. May 3, 2006. Fort Lauderdale, Fla.
2. Friberg TR, Musch DC, Lim JJ, et al. Prophylactic treatment of age-related macular degeneration report number 1: 810-nanometer laser to eyes with drusen. Unilaterally eligible patients. *Ophthalmology*. 2006;113:6221

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