
TO THE EDITOR: We read with some concern the recent article by Ikuno et al. on intravitreal aflibercept in patients with myopic choroidal neovascularization (CNV). The authors report a 3:1 randomization of intravitreal aflibercept and sham in patients with sight-threatening CNV owing to myopia. Patients in the sham (control) group “were given 1 sham injection followed by repeated sham injections every 4 weeks through week 24 regardless of whether re-treatment criteria were fulfilled or not.” Control patients were only offered treatment at week 24. Predictably, these patients did worse than those who received therapy at the time of active CNV. The control group lost a mean of 2.0 letters from baseline at week 24, whereas the treatment group gained a mean of 12.1 letters. Additionally, even after initiation of treatment, the control group only improved marginally and experienced significantly poorer visual outcomes than the treatment group at 48 weeks (9.6-letter difference). This latter result is not surprising and entirely foreseeable based on our understanding of CNV and the risk of subsequent atrophy with delay of treatment.

This study was conducted between November 2010 and August 2013. The authors comment on the use of a sham control, referencing the lack of approved therapy for the treatment of myopic CNV in the primary study country (Japan) at the time of study enrollment. Although technically true, by November 2010 there were several established treatment options available including photodynamic therapy and anti-vascular endothelial growth factor for myopic CNV. In fact, intravitreal bevacizumab was widely used for the treatment for CNV of all etiologies by this time, including those secondary to degenerative myopia. A quick review of PubMed indicates approximately 52 independent reports in press between 2006 and November 2010 specifically evaluating treatment of myopic CNV with intravitreal bevacizumab, including 5 from the first author of this report demonstrating its safety and effectiveness.

Given all this, we would like to voice our concern regarding the ethical consequences of denying treatment to patients for 6 months when viable treatment options are available. Although certainly not the first prospective, randomized study to do this, the lack of any mechanism to offer earlier treatment to control eyes seems regrettable because the therapeutic benefit of aflibercept was evident very early in the 6-month observation period and the visual outcomes were so disparate between control and treatment eyes.

Although we recognize and appreciate the importance of proper controls in any study design, the safety and welfare of patients should always be a priority. In this study, a shorter observation period and an option to use bevacizumab may have limited some of the vision loss in control eyes, compared with treatment eyes, without jeopardizing the credibility or robustness of the study outcomes. We encourage such efforts and consideration in future controlled trials.

SHRIJI PATEL, MD
STEPHEN JAE KIM, MD
Department of Ophthalmology, Vanderbilt University, Nashville, Tennessee

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Correspondence: Stephen J. Kim, MD, Vanderbilt Eye Institute, 2311 Pierce Avenue, Nashville, TN 37232. E-mail: skim30@gmail.com.

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