

Ranibizumab found effective against diabetic retinopathy

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In a randomized clinical trial of more than 300 participants, researchers from Johns Hopkins and elsewhere have found that ranibizumab—a drug most commonly used to treat retinal swelling in people with diabetes—is an effective alternative to laser therapy for treating the most severe, potentially blinding form of diabetic retinal disease. Results of the government-sponsored study also show that the drug therapy carries fewer side effects than the currently used laser treatment.

"These findings mark an important advancement in the treatment of diabetes-related vision loss," says co-author Neil Bressler, M.D., professor of ophthalmology at The Johns Hopkins University School of Medicine, and chief of the retina division of Hopkins' Wilmer Eye Institute. "For almost four decades we have been searching for a treatment that is as effective as the [laser therapy](#) we currently use, but with fewer side effects, and we may have found it."

Since the 1970's, ophthalmologists have successfully used panretinal photocoagulation as the gold-standard treatment for so-called proliferative diabetic retinopathy, a disease that causes extensive harm to the blood vessels that nourish the light-sensitive tissue (the retina) that lines the inside back of the [eye](#). The laser therapy usually preserves central vision in the retina's macula, but often damages night and side vision.

In a report on the research, published online November 13, 2015, by the *Journal of the American Medical Association*, the researchers say

ranibizumab is one of several drugs that block the effects of vascular endothelial growth factor (VEGF), a substance long known to spur the development of excessive and abnormal blood vessels in the eyes of some people with diabetes.

Bressler says some 7.7 million people in the United States have some form of diabetic retinopathy, a frequent complication of diabetes, and, when left untreated, one of the leading causes of blindness. Of those with the condition, an estimated 1.5 percent suffer from proliferative diabetic retinopathy, in which lack of blood flow increases production of VEGF, which stimulates the growth of new, fragile [blood vessels](#). The new vessels are prone to bleeding into the center of the eye. This can cause scarring on the surface of the retina, which can detach the retina off the back wall of the eye.

For the new study, researchers analyzed data from 305 participants (and a total of 394 eyes) with proliferative diabetic retinopathy in one or both eyes at 55 clinical sites across the U.S. The damaged eyes were assigned randomly to treatment with ranibizumab or laser. For participants who agreed to have both eyes treated in the study, one eye was assigned to the laser group and the other to the ranibizumab group.

About half of the eyes assigned to the laser group required more than one round of laser treatment. In the other group, ranibizumab (at a standardized dose) was injected into the eye once per month for three consecutive months, and then as needed until the condition resolved or stabilized.

Tests after two years showed that vision in the ranibizumab group improved by about half a line on an eye chart compared with virtually no change in the laser group. There was little change in side vision with injection (an average worsening of 23 decibels), but a substantial loss of side vision with laser (a worsening of 422 decibels). Decibels, although

commonly known as a measurement of sound, are also used to measure the sensitivity of the retina to light. The greater the worsening (in decibels), the greater the loss of retinal sensitivity.

Under the approved protocol for the study, investigators also used ranibizumab to treat [diabetic macular edema](#)—a form of retinal swelling—in the laser group, as necessary. Slightly more than half (53 percent) of eyes in the laser group received ranibizumab injections for that purpose. Some 6 percent of eyes in the ranibizumab group also received laser therapy, mostly among eyes that underwent retinal surgery to treat complications of diabetic retinopathy.

The research team reported that rates of serious adverse events, including cardiac arrest and stroke, were similar in the two groups. Among the 216 study participants with only one study eye, 3 percent had a heart attack in the ranibizumab group compared with 2 percent in the laser group, while 2 percent had a stroke in the ranibizumab group compared with 4 percent in the laser group. The rate of vitrectomy, a surgical procedure that clears the middle cavity of the eye of blood or scar tissue causing retinal detachment, was lower in the ranibizumab group (8 of 191 eyes) than in the laser group (30 of 203 eyes). One patient in the ranibizumab group developed a serious infection in the eye as a result of an injection. Rates of other side effects, such as retinal detachment, neovascular glaucoma, iris neovascularization and ocular inflammation, were low, with little difference between treatment groups, Bressler says.

The research team also reported that their data suggest ranibizumab may help prevent diabetic macular edema from occurring. Among people without diabetic macular edema at the start of the study, only 9 percent of ranibizumab-treated eyes developed diabetic macular edema during the study, compared with 28 percent in the laser group.

Although promising as an alternative to laser therapy, the researchers

note that ranibizumab can cost an estimated \$2,000 per dose, although most insurances will cover the treatment for diabetic macular edema. The researchers also caution that they did not assess two other anti-VEGF drugs, aflibercept and bevacizumab, because when the study was designed, there was little data supporting the potential effectiveness of those two drugs in treating [proliferative diabetic retinopathy](#) compared with ranibizumab.

Plans are to continue to follow patients in this study for a total of five years, Bressler says.

Provided by Johns Hopkins University School of Medicine

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