Intravitreal Bevacizumab and Ranibizumab for Age-Related Macular Degeneration

A Multicenter, Retrospective Study

Donald S. Fong, MD, MPH,[1,2] Peter Custis, MD,[3] Jennifer Howes, PhD,[4] Jin-Wen Hsu, PhD[4]

Objective: To compare visual acuity (VA) outcomes after bevacizumab or ranibizumab treatment for AMD.

Design: Comparative, retrospective case series.

Participants: We followed 452 patients in a retrospective study of exudative AMD treated with anti-vascular endothelial growth factor drugs; 324 patients were treated with bevacizumab and 128 patients with ranibizumab.

Methods: All treatment-naïve patients who received either bevacizumab or ranibizumab were followed for 1 year. Baseline characteristics and VA were recorded using standard descriptive statistics.

Main Outcome Measures: Visual acuity.

Results: At 12 months, the distribution of VA improved in both groups with 22.9% of bevacizumab and 25.0% of ranibizumab attaining ≥20/40. Improvement in vision was observed in 27.3% of the bevacizumab group and 20.2% of the ranibizumab group. The mean number of injections at 12 months was 4.4 for bevacizumab and 6.2 for ranibizumab. There were 8 (2%) deaths in the bevacizumab group and 4 (3%) in the ranibizumab group. Two patients developed endophthalmitis in the bevacizumab group and the ranibizumab group. The bevacizumab group had slightly worse acuity at baseline, but both groups showed improvement and stability of vision over time.

Conclusions: Both treatments seem to be effective in stabilizing VA loss. There was no difference in VA outcome between the 2 treatment groups. Because the study is a nonrandomized comparison, selection bias could mask a true treatment difference. Results from the Comparison of the Age-related Macular Degeneration Treatment Trials will provide more definitive information about the comparative effectiveness of these drugs.

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Age-related macular degeneration (AMD) is the leading cause of severe vision loss in patients >60 years of age.[1] Because most cases of vision loss are due to the exudative form, the current treatments are targeted toward the treatment of neovascularization. In 2006, the United States Food and Drug Administration approved the use of ranibizumab (Lucentis; Genentech, South San Francisco, CA) for the treatment of exudative AMD. Before its approval, many ophthalmologists already were using bevacizumab (Avastin; Genentech), a drug very similar to ranibizumab. Bevacizumab is approved for the systemic treatment of certain cancers, but is not approved for injection into the eye. This "off-label" use of the drug has been reported to be effective at treating exudative AMD.[2–6] Although the safety and efficacy of ranibizumab is well established,[7,8] the cost per injection is high. However, bevacizumab is inexpensive, but it has not been well studied. The current study compares the efficacy of bevacizumab or ranibizumab in treating exudative AMD.

Methods

The study was conducted at Kaiser Permanente Southern California, which provides comprehensive prepaid medical care to 3.1 million residents of Southern California. This care is delivered by >6000 physicians working in 11 medical centers. The study population was composed of all persons, ≥18 years of age who have exudative AMD. Patients with choroidal neovascularization owing to conditions other than AMD were excluded. Only eyes with newly diagnosed choroidal neovascularization were eligible, and second eyes that subsequently developed choroidal neovascularization were excluded from the study.

Each of the 11 departments of ophthalmology maintained a log of all patients who received treatment with an anti-vascular endothelial growth factor agent. Using these logs, clinical information from patients with exudative AMD was used to create a registry. This registry was then used to identify all patients who had no prior treatment and who received a single anti-vascular endothelial growth factor agent. For eyes that were started on 1 therapy and then switched to another, visual acuity (VA) information was included until therapy was changed. Information after the change was not used. Charts of 100 randomly identified patients from the registry were reviewed by 2 reviewers to confirm inclusion and exclusion criteria. All 100 charts were found to meet the criteria. Age was determined at entry to the study. Race and socioeconomic status were obtained from geocoding using the patient's address and corresponding census block. Geocoding is a method to determine a person's race and socioeconomic status using census data. This method has been used and validated in a number of studies.[9]

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Visual acuity was abstracted from the chart at baseline and at 3-month intervals. To investigate the change during follow-up and perform statistical testing, Snellen acuities were converted into the logarithm of the mean angle of resolution (logMAR). This conversion is necessary to change the nonnormal distribution of the Snellen acuities into one that is normally distributed and testable statistically. Although the Snellen chart, when compared with the logMAR (Early Treatment Diabetic Retinopathy Study) chart, has different number of letters per line and different number of lines for the same change in acuity, this conversion was necessary to allow statistical testing. Analysis of change was conducted in a paired fashion; the change was computed not by group, but by eye. For example, logMAR change was based on computing the change between baseline and at 3, 6, 9, and 12 months by eye. These changes were then summarized for each time point.

Standard descriptive statistics were used to describe the baseline characteristics. *t*-tests or the Wilcoxon rank–sum test were used to compare continuous variables. The chi-square test or the Fisher exact test was used to compare categorical variables. All analyses were performed on the Statistical Analyses System (SAS Inc., Cary, NC). The study was reviewed and approved by the Kaiser Permanente Southern California Institutional Review Board.

Results

From August 2005 to June 2008, 452 patients were entered into a registry of patients with exudative AMD treated with anti-vascular endothelial factor drugs. A total of 324 patients were treated with bevacizumab and 128 patients with ranibizumab. Table 1 shows the baseline characteristics of both groups. The ranibizumab group was slightly older, but had slightly better VA (mean VA, 20/160).

Of the 324 patients treated with bevacizumab, by 1 year, 8 (2.5%) patients had died, 37 (11.4%) were lost to follow-up, and 74 (22.8%) had changed treatments. Of the 128 patients in the ranibizumab group, 4 (3.1%) had died, 16 (12.5%) were lost to follow-up, and 4 (3.1%) had changed treatments. In most cases, the reason for patients changing treatment could not be determined. Endophthalmitis was seen in 2 patients treated in the bevacizumab group and 2 in the ranibizumab group. Only 1 case from each treated group was culture positive; both of these cases grew out *Staphylococcus epidermidis*. All 4 cases responded well to treatment with return to baseline vision within 1 month.

Table 1. Baseline Characteristic of Patients Treated with Bevacizumab and Ranibizumab

Demographic	Bevacizumab Group (n = 324)	Ranibizumab Group (n = 128)
Age (yrs)		
Mean (standard deviation)	78.2 (9.3)	81.8 (7.0)
<50	0.9%	0.0%
50–64	8.0%	1.6%
65–74	23.2%	15.6%
75–84	44.1%	49.2%
≥85	23.8%	33.6%
Gender		
Female	56.5%	60.9%
Male	43.5%	39.1%
Vision		
≤20/200	40.1%	33.6%
>20/200 to <20/40	46.3%	54.7%
≥20/40	13.6%	11.7%
Mean visual acuity (log mean angle of resolution)	0.9	0.8
Race (Geocoded)		
Asian	10.9%	7.8%
African American	2.9%	3.5%
Native American	0.4%	0.6%
Non-Hispanic white	52.1%	59.2%
Hispanic	30.8%	25.3%
Other	2.8%	3.7%

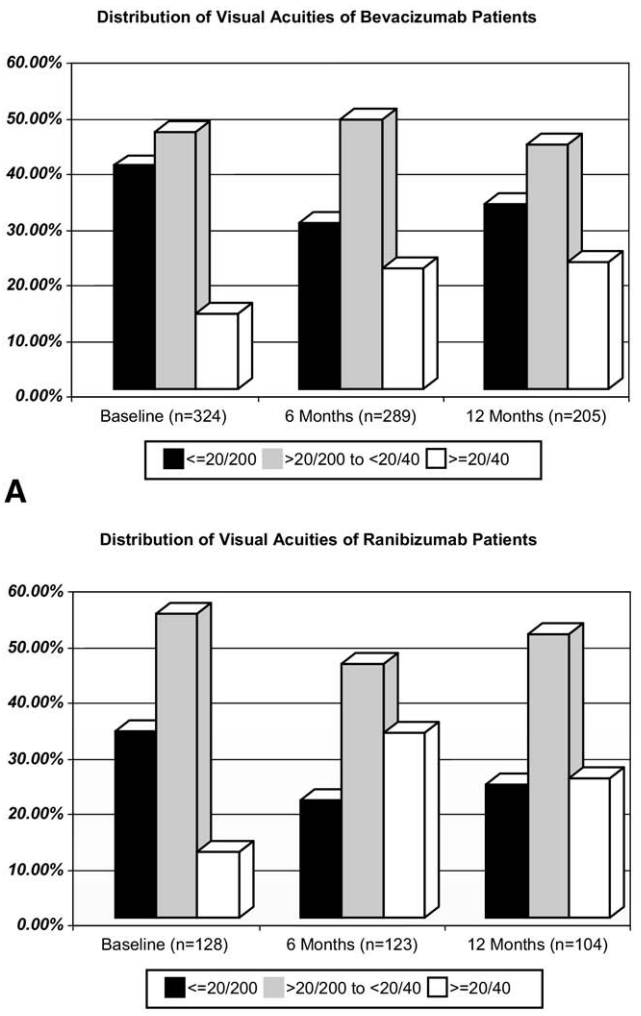

Figure 1. Distribution of visual acuity at baseline and after initial injection. **A**, Distribution for eyes treated with bevacizumab. **B**, Distribution for eyes treated with ranibizumab.

With follow-up, the distribution of visual acuities improved for both groups (Fig 1). At 1 year, the proportion of patients with VA ≥20/40 increased in the bevacizumab group from 13.6% at baseline to 22.9% at 12 months, and from 11.7% at baseline to 25.0% in the ranibizumab group. Although the bevacizumab group had slightly worse VA at the start, both groups showed improvement from baseline and stability of vision over time (Fig 2). Figure 3 shows a scatter plot of the VA at baseline and at 12 months after the first injection. We also looked at the number of eyes at each follow-up interval that had doubling of the visual angle and improvement of VA. Table 2 shows doubling of the visual angle (3-line loss of Early Treatment Diabetic Retinopathy Study acuity

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