Experimental and clinical studies

Following the initial successful administration of this drug in the management of exudative AMD in May 2005, numerous case series were published illustrating the effectiveness of this treatment in a high proportion of patients(92).

Almost all of the evidence supporting the use on neovascular AMD comes from off-label usage in short-term uncontrolled clinical case series, which suggests that intravitreal administration is apparently locally and systemically well tolerated and is associated with vision stabilization or improvement in most treated eyes(85, 86, 87, 91, 94).

One of the earlier large retrospective case series in the literature included 81 consecutive eyes
(79 patients) with subfoveal choroidal neovascularization treated with 1.25 mg (0.05 cc) intravitreal bevacizumab, at baseline and 1 month later if morphologic changes attributable to the CNV persisted (subretinal fluid, pigment epithelial detachment, retinal thickening).

Seventy-eight percent had prior treatment with pegaptanib, photodynamic therapy (PDT), or both.

After one IVB injection, 30 of 81 eyes had resolution of their subretinal fluid. At 2 months, 50% demonstrated resolution of leakage.

The mean best corrected visual acuity (BCVA) improved from 20/200 to 20/125 at week 8
($p < 0.0001$)(91).

Spaide et al. in a subsequent study evaluated 266 eyes, 70% of which had prior treatment for exudative AMD (PDT or pegaptanib).

At the 3-month follow-up (data available for 141 patients) 38.3% patients improved by 2 or more Snellen lines.

Mean BCVA improved from 20/184 to 20/109 at 3 months ($p<0.001$).

Central retinal thickness measured by OCT improved over 3 months from a mean of 340 microns to a mean of 213 microns ($p<0.001$)(95).

A greater visual acuity effect has been reported in naïve eyes compared to those that have received previous treatment, for example in a study of 50 eyes (48 patients) treated with bevacizumab for exudative AMD found that naïve eyes responded more favorably than previously treated eyes.

Six of the 14 (43%) of naïve eyes gained 3 lines or more of vision versus 17% of eyes that had undergone prior treatment.

The naïve group's mean visual acuity improved from 20/160 at baseline to 20/63 ($p<0.001$) at week 24[(96)].

Such visual acuity gains were not reported with PDT or pegaptanib treatment and were comparable to the results of the phase III studies of ranibizumab.

However, those with longstanding exudative AMD have also been shown to improve with treatment.

One retrospective study in 48 eyes with exudative AMD for 5 months or longer (mean 17.9 months) showed that 25% of those improved at least 3 lines with bevacizumab intravitreous injection after a mean follow-up of 27 weeks[(96)].

In another prospective case series, Bashshur et al. injected 2.5 mg (0.1ml) of bevacizumab (twice the dose most frequently used) into the vitreous in 17 eyes with wet AMD patients and followed by two additional injections at four-week intervals.

Mean best-corrected visual acuity was 20/252 at baseline and 20/76 at week 12 ($P < 0.001$).

Mean central subfield retinal thickness also improved between baseline and week 12 in all 17 patients.

No systemic or ocular side effects were noted[(85)].

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