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Quality of Life in Patients with Age-related Macular Degeneration: Results from the VI.S.I.O.N. Trial

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PURPOSE

Patients with AMD are more likely to need help with daily activities, experience more emotional distress, and report a reduced quality of life than those without AMD. Pegaptanib sodium is the first pharmacological treatment for subfoveal neovascular AMD. This study assessed the extent to which treatment of AMD with pegaptanib improves patient quality of life.

METHODS

Patients with all angiographic subtypes of AMD were included in 2 prospective, randomized, double-masked, sham-controlled, multicenter studies. Three doses of pegaptanib (0.3, 1, 3 mg) were compared to usual care with respect to change in visual functioning as indicated by the National Eye Institute Visual Function Questionnaire 25 (NEI-VFQ 25). In all, 569 patients enrolled in the U.S. and Canada completed the NEI-VFQ 25 at baseline and weeks 30 and 54. Four of the 12 subscales were prospectively designated as primary: Near Vision, Distance Vision, Role Limitations, Dependency. Between-group differences were assessed using an ANCOVA model with age, gender, and baseline score as covariates.

RESULTS

Subjects for whom NEI-VFQ data were available were equally distributed among the 4 study arms. Although patients were similar on many characteristics, proportion of patients with best eye treated was largest in the sham group (45%) compared to the 0.3, 1, and 3 mg treatment groups with 40%, 40%, and 35%, respectively. At week 54, scores on the Distance Vision and Role Limitations domains were consistently higher with active treatment. No trend favored usual care on any of the 12 domains or the Composite score. For Ocular Pain, differences between patients treated with any dose of pegaptanib and those receiving usual care were not statistically significant confirming that pegaptanib injections do not increase ocular pain. Analysis of responders (patients losing <15 letters at 54 weeks) showed a statistically significant ($P<0.05$) benefit for responders in 8 of the 12 NEI-VFQ subscales, including the primary 4 subscales.

CONCLUSION

The V.I.S.I.O.N. trial provided evidence of trends in VRQoL benefit associated with effective treatment of AMD using pegaptanib. All three active doses were similar in their effect. Treatment with pegaptanib is expected to contribute significantly to VRQoL improvement for responder patients.

* Financial interest disclosed