Abstract

What Happens to Diabetic Retinopathy Severity With Less Frequent Treatment? A Post Hoc Analysis of the RISE/RIDE Open-Label Extension Study

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Purpose:

To characterize the effect of baseline Diabetic Retinopathy Severity Score (DRSS) on DRSS response when less-than-monthly treatment is initiated after a period of monthly ranibizumab. The present analysis compares patients from the RISE/RIDE (NCT00473330/NCT00473382) open-label extension (OLE) who experienced DRSS improvement, stability, or worsening during OLE when analyzed by original treatment assignment.

Methods:

Patients from RISE and RIDE 36-month (M) phase 3 clinical trials who enrolled in OLE (M36–M48) and received ranibizumab 0.5 mg as-needed (PRN) were analyzed through M48. PRN criteria during OLE included diabetic macular edema on optical coherence tomography and/or best-corrected visual acuity worsening of ≥ 5 ETDRS letters from M36. Patients receiving sham treatment during core studies were also analyzed. DRSS response was defined as: improved/maintained (≥ 0-step improvement from M36–M48); returned to baseline (worsened but not beyond baseline DRSS); or worsened (M48 DRSS worse than baseline DRSS). The analysis examined the association between baseline DRSS and DRSS response during OLE, and injection frequency during OLE.

Results:

When stratified by baseline DRSS, 60%, 58%, and 50% of ranibizumab-treated patients with DRSS 35/43, 47/53, and 60–75 (without prior PRP), respectively, improved or maintained DRSS during OLE; 31%, 38%, and 45%, respectively, worsened but not beyond baseline DRSS; and 9%, 5%, and 5% worsened beyond their baseline DRSS. On average, patients with baseline DRSS 35/43, 47/53, and 60–75 (without prior PRP) received 5.0, 4.5, and 4.2 ranibizumab injections, respectively, during OLE. Among sham-treated patients with baseline DRSS 35/43, 47/53, and 60–85 (without prior PRP), respectively, 75%, 86%, and 86% improved or maintained their baseline DRSS through M12. Average change in DRSS over time for sham-treated patients was minimal and similar across baseline DR severity subgroups.

Conclusions:

Half or more of ranibizumab-treated patients maintained DRSS improvements through OLE. Regardless of baseline DRSS, patients received an average of 4–5 injections during OLE, suggesting that continuous long-term monitoring and treatment may be necessary to maintain DRSS stability. More severe baseline DR may be indicative of reduced ability to maintain or improve DRSS gains, and greater susceptibility to regress to baseline DRSS with intermittent dosing.