Impact of Baseline Diabetic Retinopathy Severity Scale Score on Visual Outcomes in VIVID-DME/VISTA-DME

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Introduction: VIVID-DME/VISTA-DME evaluated intravitreal aflibercept (IVT-AFL) versus laser in patients with diabetic macular edema (DME). Purpose: Assess the impact of baseline diabetic retinopathy severity scale (DRSS) score on visual acuity (VA) at Week (W)100. Methods: Post-hoc analysis. Patients were randomized to IVT-AFL 2mg every 4 weeks + sham laser (2q4), IVT-AFL 2mg every 8 weeks (after 5 monthly doses) + sham laser (2q8), or laser + sham injections. Patients were grouped according to baseline DRSS score: low risk (≤43; mild or moderate non-proliferative diabetic retinopathy [NPDR]), moderate risk (47; moderately severe NPDR), and high risk (≥53; severe NPDR). VIVID-DME/VISTA-DME data were integrated. Results: Proportions of patients with gradable baseline DRSS scores of low, moderate, and high risk in the IVT-AFL pooled 2q4 and 2q8 group (N=576) were 33.5%, 17.9%, and 35.2%, respectively and 37.8%, 17.5%, and 31.8% in the laser group (N=286), respectively. At W100, least squares mean treatment difference (IVT-AFL–laser) within each risk group (adjusted for baseline VA) was 8.9 letters (low), 9.7 letters (moderate), and 11.0 letters (high). Conjunctival haemorrhage was the most common ocular treatment-emergent adverse event in IVT-AFL-treated patients in the pooled 2q4/2q8 population of VIVID-DME (25.5% [n=271]) and VISTA-DME (36.2%; n=307)). Conclusion: Improvements in VA at W100 were greater in IVT-AFL-treated patients compared with laser, regardless of baseline DRSS score. There was a numerical increasing trend in treatment difference compared with laser as baseline DRSS score increased from low to high, adjusted for baseline visual acuity. Financial Disclosure: Professor Marta Misiuk-Hojlo is a consultant to Bayer HealthCare and was a principal investigator in the VIVID-DME Clinical Trial; Professor David Brown is a consultant to Bayer HealthCare and Regeneron Pharmaceuticals; Todd Katz is an employee of Bayer HealthCare.