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Incidence of New Diabetic Macular Edema in Fellow Eyes of Patients in the VISTA and VIVID studies

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Purpose:
Post hoc analysis of VISTA and VIVID data to evaluate the incidence, time to development, and baseline factors predicting occurrence of diabetic macular edema (DME) in fellow eyes of patients treated for DME in the study eye.

Methods:
VISTA and VIVID randomized 872 DME patients to receive either intravitreal aflibercept injection (IAI) 2 mg every 4 weeks (2q4), IAI 2 mg every 8 weeks after 5 monthly doses (2q8), or macular laser photocoagulation (laser control) through week 100. This ad hoc analysis evaluated 755 fellow eyes (laser control, n=252; 2q4, n=245; and 2q8, n=258) without DME at baseline (defined as 6 weeks before through 4 weeks after first study eye treatment) for DME development determined by reported DME-related adverse events and the use of treatments for DME (intravitreal agents, laser). The effect of select baseline factors on incidence of DME in fellow eyes was evaluated by Cox regression model.

Results:
Over 100 weeks, 44.9%, 44.2%, and 42.9% of fellow eyes developed DME in the 2q4, 2q8, and laser control groups, respectively. No significant differences were observed in the mean time to development of DME across treatment groups. The mean time to DME development in all treatment groups combined was 199 days. Univariate analysis identified worse Diabetic Retinopathy Severity Scale severity, and worse best-corrected visual acuity (BCVA) in study eye, shorter duration of diabetes, and lack of insulin usage as baseline factors associated with higher rate of DME development in the fellow eye. Multivariate regression analysis confirmed that patients with shorter duration of diabetes (hazard ratio (HR) [95% CI] per 10 years: 0.850 [0.755, 0.957], P=0.0074) and worse baseline BCVA in the study eye (HR [95% CI] per 10 letters: 0.876 [0.789, 0.973], P=0.0131) were at higher risk of developing DME in the fellow eye.

Conclusions:
Almost half of patients with DME in one eye, developed DME in the fellow eye with a mean of approximately 6 months over 2 years of follow-up. Duration of diabetes and baseline BCVA in the study eye were predictors for DME development in the fellow eye.