Retinal Nonperfusion (RNP) Extent and its Relationship with Visual, Anatomic, and Disease State Outcomes Among Eyes Treated for Diabetic Macular Edema (DME)

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Purpose:
Evaluate the relationship between macular RNP area quantified in mm$^2$ and visual and anatomic outcomes as well as the impact of baseline RNP area on the incidence of proliferative diabetic retinopathy (PDR) events in eyes treated for DME through 2 years in VISTA.

Methods:
Post hoc analysis included 178 of 466 eyes randomized in VISTA with baseline and weeks 52 and 100 7-field fluorescein angiography images, quantifiable RNP (mm$^2$) at baseline, and received intravitreal aflibercept injection (IAI) 2 mg q4 weeks (2q4, n=60), IAI 2 mg q8 weeks following 5 monthly doses (2q8, n=55), or laser control (n=63). RNP was quantified in mm$^2$ at baseline and weeks 24, 52, and 100 by a masked reading center. PDR events were defined as PDR, panretinal photocoagulation, or vitrectomy.

Results:
At baseline, mean RNP areas were 1.7, 1.5, and 1.5 mm$^2$ with 2q4, 2q8, and laser, respectively. At week 100, the corresponding mean change (95% CI) from baseline RNP area was –0.7 (–1.0, –0.2), –0.6 (–1.1, –0.3), and –0.2 (–0.6, 0.2) mm$^2$, respectively. At week 100, reductions in RNP from baseline with 2q4 and 2q8 correlated with changes from baseline in BCVA (r=–0.6 and –0.5, P<0.05; respectively) and CRT (r=0.7 and 0.4, P<0.05; respectively), but not with changes from baseline in DRSS score (r=0.4 and 0.1). With laser, there was no correlation between changes from baseline in RNP with BCVA, CRT, and DRSS score. Overall, 2.8% (3/108; combined IAI) and 14% (8/57; laser) of eyes with baseline RNP developed a PDR event through week 100. Compared to eyes with baseline RNP of ≤0.615 mm$^2$, PDR events (HR [95% CI]) occurred 2.1 (0.2, 22.7) times and 9.2 (1.2, 73.6) times higher in eyes with baseline RNP >0.615 – ≤1.255 mm$^2$ and >1.255 mm$^2$, respectively.

Conclusions:
Significant reductions in macular RNP with IAI correlated with improvements in BCVA and CRT. Greater baseline RNP area was associated with greater likelihood of developing a PDR event through week 100.