Patient Characteristics Affecting Incidence of Vision-Threatening Events (VTC) and Center-Involved Diabetic Macular Edema (CI-DME) in Moderately Severe-to-Severe Nonproliferative Diabetic Retinopathy (NPDR)

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Purpose:
To evaluate the incidence of VTC (defined as the occurrence of proliferative diabetic retinopathy or anterior segment neovascularization) and CI-DME by baseline characteristic factors in patients with moderately severe-to-severe NPDR who received sham in the PANORAMA trial.

Methods:
PANORAMA (ClinicalTrials.gov NCT02718326) randomized eyes with Diabetic Retinopathy Severity Scale (DRSS) levels 47 or 53 in patients without CI-DME to receive either intravitreal aflibercept (n=269) or sham (n=133) through week 52. Adjusted Mantel-Haenszel weighting scheme was used to evaluate differences across the following subgroups of baseline factors in the incidence of VTC and CI-DME in eyes that received sham: age tertiles (≤53, >53 – ≤62, >62 years), ethnicity (Hispanic or non-Hispanic), body mass index subgroups (≤30, >30 – ≤35, >35 kg/m²), hemoglobin A1c (HbA1c) tertiles (≤7.8%, >7.8% – ≤9.0%, >9.0%) diabetes duration tertiles (≤10.8, >10.8 – ≤19.2, >19.2 years), and DRSS level (47 vs 53).

Results:
At week 52, VTC and CI-DME occurred in 20.3% and 25.6%, respectively, of eyes that received sham. An adjusted difference (95% CI) of ≥10% in the incidence of VTC across baseline factor subgroups was found between age tertiles of ≤53 years vs >62 years (13.3% [–3.7, 30.4]), HbA1c tertiles of ≤7.8% vs >9.0% (17% [–0.4, 34.4]), and baseline DRSS levels of 47 vs 53 (–12.2% [–29.3, 4.8]). The corresponding adjusted difference of ≥10% in the incidence of CI-DME was found between age tertiles of ≤53 years vs >62 years (–15.7% [–34.4, 3.0]) and >53–≤62 years vs >62 years (–13.5% [–33.2, 6.3]), Hispanic vs non-Hispanic (18.9% [3.6, 34.2]), HbA1c tertiles of ≤7.8% vs >9.0% (–10.8% [–28.9, 7.2]), and diabetes duration tertiles of ≤10.8 years vs >19.2 years (–12.3% [–31.2, 6.5]) and >10.8–≤19.2 years vs >19.2 years (–13.8% [–32.5, 4.9]).

Conclusions:
Although a number of baseline characteristic factors including age, HbA1c, and disease severity showed trends towards association with the risk of VTC and CI-DME, these associations were not statistically significant. Hispanic ethnicity was associated with significantly greater incidence of CI-DME in this population of patients that received sham for moderately severe-to-severe NPDR.