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Prevention of Macular Edema in Patients With Diabetic Retinopathy Undergoing Cataract Surgery: The PROMISE Trial.

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BACKGROUND AND OBJECTIVE: To determine the safety and efficacy of intravitreal aflibercept injection (IAI) in patients with diabetic retinopathy (DR) in the prevention of macular edema (ME) following cataract surgery. **PATIENTS AND METHODS:** This phase 2, prospective, interventional, single-masked, randomized trial at a single academic center included 30 patients who were 18 years of age or older with nonproliferative DR and undergoing cataract surgery with phacoemulsification. Patients received 2 mg intravitreal aflibercept (0.05 mL) or sham injection during cataract surgery. Main outcome measures included treatment adverse events (AEs), best-corrected visual acuity (BCVA), and incidence of ME (defined as presence of cystoid abnormalities as detected by optical coherence tomography at any follow-up visit), a 30% or greater increase from preoperative baseline in central subfield macular thickness, or a BCVA decrease of more than 5 ETDRS letters from Day 7 due to retinal thickening. **RESULTS:** There were similar incidences of AEs between the two groups and no clinically serious ocular AEs in either group. The IAI group had fewer ME events at Day 14 (13% vs. 53%; $P = .022$), but there was no significant difference in ME events at Day 30 (27% vs. 60%; $P = .057$), Day 60 (27% vs. 60%; $P = .057$), or Day 90 (40% vs. 67%; $P = .161$). Compared to the study group, the control group had a significantly greater increase in central subfield thickness (CST) at Day 30 (50.05 μm vs. 7.95 μm ; $P = .040$) and Day 60 (56.45 μm vs. 3.02 μm ; $P = .010$). However, the difference in CST between groups was no longer significant at Day 90 (50.31 μm vs. 18.48 μm ; $P = .12$). There were no significant differences in BCVA gains between the IAI and sham group at the end of the follow-up period (Day 90, ETDRS letters: 9.88 vs. 8.52; $P = .66$). **CONCLUSIONS:** Use of IAI in patients with DR for prevention of ME following cataract surgery showed no significant AEs. Although there were significant differences in ME incidence and retinal thickness at periods of time, there was no clinically meaningful benefit in terms of VA. Further larger trials are needed to validate these findings. [Ophthalmic Surg Lasers Imaging Retina. 2020;51:170-178].

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