EFFICACY AND SAFETY OF OZURDEX FOR THE TREATMENT OF MACULAR EDEMA RELATED TO BRANCH RETINAL VEIN OCCLUSION IN A 12-MONTH, PROSPECTIVE, OPEN-LABEL, MULTICENTER STUDY IN KOREA: THE COBALT STUDY

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Introduction: Evaluation of efficacy and safety of Ozurdex® dexamethasone intravitreal implant (0.7mg) in early treatment and retreatment of macular edema (ME) related to branch retinal vein occlusion (BRVO). Method: This non-comparative, open-label, 7-site, Korean trial enrolled 71 adults with center-involving BRVO-associated ME for 3 months with best-corrected visual acuity (BCVA) between 19 and 73 letters. Rescue treatment with laser photocoagulation was allowed if 3 months passed since last injection and BCVA dropped 10 letters from baseline. Ozurdex retreatment was allowed if 4 months passed since last injection, central retinal thickness (CRT) was 290µm or BCVA was 84 letters with recurrent ME; visual acuity decrease being attributable to ME. Results: At 12 months, patients (n=59; mean ± standard deviation [SD]) age 57.46±9.19 years; 53.52% male) had a mean±SD BCVA improvement of 15.27±14.99 letters (P0.0001) and mean±SD CRT decrease of 196.90±164.07µm (P0.000); 55.93% of patients gained ≥15 letters. Over 12 months, 32.39% of patients received 1 injection; 18.31% and 49.30% of patients received 2 and 3 injections, with a mean±SD interval of 20.78±6.02 and 19.20±3.09 weeks, respectively. No patient required rescue treatment. Fifty-two patients experienced 131 adverse events (AEs); 51.15% were drug-related. Most common (5%) AEs were increased intraocular pressure (IOP) (33.59%) and cataract (8.39%). IOP increase of 25 mmHg was experienced by 17.74% of patients, but was controlled with treatment. One patient required cataract extraction. Conclusion: Early Ozurdex administration significantly improves BCVA and reduces CRT at 12 months in patients with BRVO-associated ME. Optimal retreatment interval was adjudged to be 5 months.