

Abstracts

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The RESTORE Study Ranibizumab Monotherapy or Combined with Laser versus Laser Monotherapy for Diabetic Macular Edema

Mitchell P, Bandello F, Schmidt-Erfurth U, Lang GE, Massin P, Schlingemann RO, Sutter F, Simader C, Burian G, Gerstner O, Weichselberger A

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Mitchell et al have shown that treatment with ranibizumab as monotherapy and combined with laser treatment is superior to laser treatment alone in rapidly improving and sustaining visual acuity in patients with visual impairment due to diabetic macular edema (DME). The 12 - month RESTORE study involved 345 patients with diabetes mellitus and visual impairment due to DME. One hundred and sixteen patients were randomized to ranibizumab + sham laser, 118 to ranibizumab+laser, and 111 to sham injections+laser. Ranibizumab alone and combined with laser proved superior to laser monotherapy in improving the mean average change in best corrected visual acuity (BCVA) from baseline through Month 12 (+6.1 and +5.9 vs. +0.8). By Month 12, a significantly larger proportion of patients had a BCVA letter score ≥ 15 and BCVA letter score level >73 with ranibizumab and ranibizumab+laser vs. laser alone. In addition, these patients quality of life improved significantly during the study period. In conclusion Ranibizumab consistently improved BCVA across all patient subgroups, including patients with focal or diffuse DME.

Intravitreal Triamcinolone Prior to Laser Treatment of Diabetic Macular Edema; 24 - Month Results of a Randomized Controlled Trial

Gillies MC, McAllister IL, Zhu M, Wong W, Louis D, Arnold JJ, Wong TY

Mark et al conducted this study to report the 24 months outcome from a clinical trial of intravitreal triamcinolone acetonide (IVTA) plus laser versus laser treatment only in eyes with diabetic macular edema (DME). It was a prospective, double-masked,

randomized, placebo-controlled study. Eighty-four eyes of 54 participants were entered into the study, with 42 eyes randomly assigned to receive IVTA plus laser and 42 randomly assigned to receive laser treatment alone. Primary end point data were available for 71 (84.5%) eyes at 24 months, with last visual acuity observation carried forward for the remaining eyes. Best-corrected logarithm of minimum angle of resolution (logMAR) visual acuity and central macular thickness (CMT) by optical coherence tomography were measured after laser treatment preceded by either IVTA or sham. The primary outcome was the proportion of eyes with improvement in visual acuity of 10 letters or more at 24 months. The secondary outcomes were mean visual acuity, requirement for further treatment, change in CMT, and adverse events. At 24 months, improvement of 10 logMAR letters or more was seen in 15 (36%) of 42 eyes treated with IVTA plus laser compared with 7 (17%) of 42 eyes treated with laser only (P=0.047; odds ratio, 2.79; 95% confidence interval, 1.01-7.67). There was no difference in the mean CMT or mean logMAR visual acuity between 2 groups. At least 1 retreatment was required in the second year of the study in 29 (69%) of 42 IVTA plus laser-treated eyes compared with 19 (45%) of 42 laser only eyes (P=0.187). Cataracts were removed from 17 (61%) of 28 phakic IVTA plus laser-treated eyes versus 0 (0%) of 27 laser only eyes (P=0.001). Treatment for elevated intraocular pressure was required in 27 (64%) of 42 IVTA plus laser eyes compared with 10 (24%) of 42 laser only eyes (P=0.001). The study concluded that treatment with IVTA plus laser resulted in a doubling of improvement in vision by 10 letters or more compared with laser only over 2 years in eyes with DME, but is associated with cataract and raised intraocular pressure.

Preoperative Intravitreal Bevacizumab Use as an Adjuvant to Diabetic Vitrectomy: Histopathologic Findings and Clinical Implications

El-Sabagh HA, Abdelghaffar W, Labib AM, Mateo C, Hashem TM, Al-Tamimi DM, Selim AA.

Hazem et al conducted this study to evaluate the effects of intervals between preoperative intravitreal

injection of bevacizumab (IVB) and surgery on the components of removed diabetic fibrovascular proliferative membranes. It was a Interventional, consecutive, prospective, comparative case series. A total of 52 eyes of 49 patients with active diabetic fibrovascular proliferation with complications necessitating vitrectomy were enrolled. Participant eyes that had IVB were divided into 8 groups in which vitreoretinal surgery was performed at days 1,3,5,7,10, 15,20, and 30 post injection. A group of eyes with the same diagnosis and surgical intervention without IVB injection was used for comparison. In all eyes, proliferative membrane specimens obtained during vitrectomy were sent for histopathologic examination using hematoxylin–eosin stain, immunohistochemistry (CD34 and smooth muscle actin) and Masson’s trichrome stain and comparative analysis of different components of the fibrovascular proliferation (CD34, smooth muscle actin, and collagen) among the study groups was done.

The results showed that pan-endothelial marker CD34 expression levels starting from day 5 post injection were significantly less than in the control group (P-0.001) with minimum expression in all specimens removed at or after day 30 post injection. Positive staining for smooth muscle actin was barely detected in the control eyes at day 1, and consistently intense at day 15 and beyond (P - 0.001). The expression level of trichrome staining was significantly high at day 10, compared with control eyes (P - 0.001), and continued to increase at subsequent surgical time points. So this study concluded that a profibrotic switch was observed in diabetic fibrovascular proliferation after IVB and suggested that at approximately 10 days post-IVB the vascular component of proliferation is markedly reduced, whereas the contractile components (smooth muscle actin and collagen) are not yet abundant at the same time. Therefore after IVB, one should wait for atleast 10 days for the maximum effect before surgical intervention.