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Randomized Trial Evaluating Ranibizumab Plus Prompt or Deferred Laser or Triamcinolone Plus Prompt Laser for Diabetic Macular Edema

The Diabetic Retinopathy Clinical Research Network * • Michael J. Elman, MD • Lloyd Paul Aiello, MD, PhD • ... Ingrid U. Scott, MD, MPH • Cynthia R. Stockdale, MSPH • Jennifer K. Sun, MD, MPH • Show all authors • Show footnotes

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Objective

Evaluate intravitreal 0.5 mg ranibizumab or 4 mg triamcinolone combined with focal/grid laser compared with focal/grid laser alone for treatment of diabetic macular edema (DME).

Design

Multicenter, randomized clinical trial.

Participants

A total of 854 study eyes of 691 participants with visual acuity (approximate Snellen equivalent) of 20/32 to 20/320 and DME involving the fovea.

Methods

Eyes were randomized to sham injection + prompt laser (n=293), 0.5 mg ranibizumab + prompt laser (n=187), 0.5 mg ranibizumab + deferred (≥24 weeks) laser (n=188), or 4 mg triamcinolone + prompt laser (n=186). Retreatment followed an algorithm facilitated by a web-based, real-time data-entry system.

Main Outcome Measures

Best-corrected visual acuity and safety at 1 year.

Results

The 1-year mean change (±standard deviation) in the visual acuity letter score from baseline was significantly greater in the ranibizumab + prompt laser group (+9±11, P<0.001) and ranibizumab + deferred laser group (+9±12, P<0.001) but not in the triamcinolone + prompt laser group (+4±13, P=0.31) compared with the sham + prompt laser group (+3±13). Reduction in mean central subfield thickness in the triamcinolone + prompt laser group was similar to both ranibizumab groups and greater than in the sham + prompt laser group. In the subset of pseudophakic eyes at baseline (n=273), visual acuity improvement in the triamcinolone + prompt laser group appeared comparable to that in the ranibizumab groups. No systemic events attributable to study treatment were apparent. Three eyes (0.8%) had injection-related endophthalmitis in the ranibizumab groups, whereas elevated intraocular pressure and cataract surgery were more frequent in the triamcinolone + prompt laser group. Two-year visual acuity outcomes were similar to 1-year outcomes.

Conclusions

Intravitreal ranibizumab with prompt or deferred laser is more effective through at least 1 year compared with prompt laser alone for the treatment of DME involving the central macula. Ranibizumab as applied in this study, although uncommonly associated with endophthalmitis, should be considered for patients with DME and characteristics similar to those in this clinical trial. In pseudophakic eyes, intravitreal triamcinolone + prompt laser seems more effective than laser alone but frequently increases the risk of intraocular pressure elevation.

Financial Disclosure(s)

Proprietary or commercial disclosure may be found after the references.

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Correspondence: Protocol I Correspondence, Jaeb Center for Health Research, 15310 Amberly Drive, Suite 350, Tampa, FL 33647. E-mail: drcrstat4@jaeb.org

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