

10<sup>th</sup> International Conference on

# Clinical & Experimental Ophthalmology

November 21-23, 2016 Dubai, UAE

## Bevacizumab monotherapy or combined with laser versus laser monotherapy in Mongolian patients with diabetic macular edema

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**Objectives:** To evaluate the efficacy and safety of bevacizumab monotherapy or combined with laser versus laser monotherapy in Mongolian patients with visual impairment due to diabetic macular edema.

**Design:** Prospective, randomized, single-center, a 12 month, laser-controlled, clinical trial.

**Participants:** One hundred twelve patients aged  $\geq 18$  years, with type 1 or 2 diabetes mellitus and best corrected visual acuity (BCVA) in the study eye of 35 to 69 Early Treatment Diabetic Retinopathy Study (ETDRS) letters at 4m (Snellen equivalent: 6/60 or 6/12), with visual impairment due to center-involved diabetic macular edema (DME).

**Methods:** Patients were randomized to one of the three treatment arms: intra-vitreous bevacizumab (n=42), and intra-vitreous bevacizumab with laser (n=35), or laser alone (n=35). Bevacizumab injections were given for 3 initial monthly doses and then pro re nata (PRN) thereafter based on BCVA stability and DME progression. Laser photocoagulation was given at baseline then PRN as per ETDRS guidelines.

**Main Outcome Measures:** Average change in BCVA from baseline to months 1 through 12, central subfield thickness (CST) and safety over 12 months.

**Results:** Bevacizumab monotherapy or combined with laser were superior to laser monotherapy in improving mean change in BCVA letter score from baseline to months 1 through 12 (+8.3 and +11.3 vs. +0.06 letters; both  $p < 0.0001$ ). Although the improvement was greater with bevacizumab combined with laser than with the other two arms ( $p < 0.0001$  for bevacizumab combined with laser vs. laser monotherapy and  $p < 0.006$  for bevacizumab combined with laser vs. bevacizumab monotherapy). At month 12, greater proportion of patients gained  $\geq 10$  and  $\geq 15$  letters and with BCVA letter score  $> 73$  with bevacizumab monotherapy (23.8% and 7.1% and 4.8%, respectively) and bevacizumab + laser (57.1% and 28.6% and 14.3%, respectively) versus laser monotherapy (0% and 0% and 0%). The mean central subfield thickness was significantly reduced from baseline to month 12 with bevacizumab ( $-124.4 \mu\text{m}$ ) and bevacizumab + laser ( $-129.0 \mu\text{m}$ ) versus laser ( $-62.0 \mu\text{m}$ ; both  $p < 0.002$ ). Patients received a mean of 8.1 and 6.3 bevacizumab injections in the bevacizumab and bevacizumab + laser arms. Conjunctival hemorrhage was the most common ocular events. No endophthalmitis cases occurred. Bevacizumab monotherapy or combined with laser was not associated with an increased risk of cardiovascular or cerebrovascular events in this study.

**Conclusion:** Bevacizumab monotherapy or combined with laser showed superior BCVA improvements over macular laser treatment alone in Mongolian patients with visual impairment due to diabetic macular edema.

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