## ABSTRACT

## Efficacy and Safety of Intravitreal Triamcinolone Acetonide in the Management of Recalcitrant Diabetic Macular Edema

**Purpose:** To evaluate the safety and efficacy of intravitreal triamcinolone acetonide in the management of recalcitrant diabetic macular edema unresponsive to laser photocoagulation and the intravitreal anti-VEGF agent, bevacizumab.

**Design:** Prospective, non-comparative, interventional study.

**Participants:** Twenty-one eyes of seventeen patients with clinically significant macular edema(CSME) that failed to respond to laser photocoagulation and 2 doses of intravitreal anti-VEGF agent, bevacizumab in which resolution of macular edema had not occurred within one month of treatment, as assessed by clinical examination and measured by optical coherence tomography (OCT) and are recalcitrant.

**Methods:** Eyes were diagnosed with recalcitrant diabetic macular edema which exhibited best corrected visual acuity (BCVA) of 6/18 or worse, with central macular thickness of more than 300  $\mu$ m (normal 200  $\mu$ m) were treated with 2 mg of intravitreal triamcinolone acetonide; and followed up for a period of 6months at intervals of 1 week, 1 month, 3 months and 6 months following the intravitreal injection. The visual and anatomic responses were observed as well as complications related to the injection procedure and corticosteroid medication.

**Main Outcome Measures:** The response to treatment was monitored functionally by best corrected visual acuity and anatomically by OCT by measuring central macular thickness quantitatively. Potential complications were monitored functionally by looking for decrease in visual acuity of one line by Snellen's chart, rise in intraocular pressure greater than 30mm of Hg not responding to antiglaucoma medications, progression of cataract, retinal detachment, vitreous hemorrhage, and endophthalmitis.

**Results:** All patients completed 6 months follow-up period. The mean best corrected visual acuity (BCVA) in the eyes that received triamcinolone acetonide (TA) was (in decimals)  $0.14 \pm 0.07$  (pre injection),  $0.26 \pm 0.12$  (one week after injection of TA),  $0.39 \pm 0.20$  (one month after injection of TA),  $0.32 \pm 0.15$  (3 months after injection of TA) and  $0.18 \pm 0.10$  (6months after injection of TA; these differences were statistically significant (one-way analysis of variance [ANOVA]; Fisher 'f' value = 11.804; P < 0.001). The mean central foveal thickness (CFT) in eyes with recalcitrant diabetic macular edema that received triamcinolone

acetonide was (in  $\mu$ m) 536.5 ± 115.3 (pre injection), 380.7 ± 95.6 (1 week post injection),  $280.9 \pm 71.6$  (one month post-injection),  $283.6 \pm 76.8$  (three months post-injection) and  $370.2 \pm 114.3$  (six months post-injection); these differences were statistically significant [one-way ANOVA; Fisher 'f' value = 24.4; P < 0.001]. The mean HbA<sub>1</sub>C value was 8.2% at baseline, 7.7% at 3 months and 7.7% at 6 months follow-up; this reduction in mean HbA<sub>1</sub>C values was not statistically significant.( P=0.06 ). The mean intraocular pressure (IOP) in the eyes with recalcitrant diabetic macular edema that received triamcinolone acetonide was (in mm Hg)  $17.4 \pm 2.2$  (pre injection),  $18.0 \pm 2.1$  (1 week post injection),  $18.4 \pm 2.2$  ( one month post-injection),  $18.6 \pm 5.12$  (three months post-injection) and  $20.3 \pm 5.12$ 11.8 (six months post-injection); these differences were not statistically significant (ANOVA; Fisher 'f' value = 0.689; P = 0.6). Of the 18 phakic eyes, four eyes ( 22.2%) developed cataract following intravitreal injection of triamcinolone acetonide for which cataract surgery and intraocular lens implantation were done. Severe complications, such as infectious endophthalmitis or retinal detachment, were not observed within the follow-up period in the present study.

**Conclusion:** Intravitreal triamcinolone acetonide appears to be effective in the management of recalcitrant diabetic macular edema and improvement in best corrected visual acuity was statistically significant in the short term (1 month and 3 months). The effect of intravitreal triamcinolone acetonide appears to be transient, necessitating repeat injections 6 months after the first dose. Intravitreal triamcinolone acetonide can still be a safe therapeutic option in patients who are resistant to conventional laser photo coagulation and intravitreal anti-VEGF agents. Further study is warranted to assess the long-term efficacy and safety of triamcinolone acetonide and the need for retreatment.

Keywords : Recalcitrant Diabetic Macular Edema, Intravitreal Triamcinolone Acetonide