

Randomized Controlled Trial Comparing the Effects on Eye Pressure of Intravitreal Triamcinolone Injection versus Intravitreal Dexamethasone (Ozurdex) Implant in Patients with Diabetic Macular Edema: The TRIDEX TRIAL

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Purpose

The primary objective of this study is to compare the effects on intraocular pressure (IOP) change and the need for hypotensive eye drops on IOP reduction between the Dexamethasone Implant (Ozurdex) and triamcinolone 4 mg in patients with diabetic macular edema (DME). Secondary objectives: To compare the effects on Optical Coherence Tomography (OCT) during 24 weeks of intravitreal on central macular thickness (CMT) and best corrected visual acuity (BCVA).

Methods

A prospective study of Patients 18 to 85 years of age diagnosed with bilateral DME (CMT greater than 300 μm) without significant cataract whose both eyes were randomized into 2 groups. Exclusion criteria is IOP > 25mmHg. Comprehensive Ophthalmic evaluations included complete ophthalmologic assessment with BCVA assessment, IOP measurement using Goldman Applanation tonometry (mean of 3 measurements), color fundus pictures, fluorescein angiography and SD-OCT that were performed at baseline and 4, 8, 12, 16, and 24 weeks after the procedure. Predictive Analytics SoftWare Statistics version 20.0 was used. Kruskal Wallis, Mann Whitney and Kaplan-Meier were performed.

Results

Twenty-two patients with bilateral DME completed the 24-week study period. Mean IOP change was similar in both groups during the 6-month period, since glaucoma eyedrops were used promptly after IOP increase in both groups. However, the failure of proper intraocular pressure by the eye, defined as an increase on intraocular pressure and consequent use of eye drop was measured by a Kaplan-Meier curve and was significantly higher (p-value < 0.001) in the triamcinolone treated group (Figure 1). CMT (Figure 2) and BCVA (figure 3) showed no difference between groups.

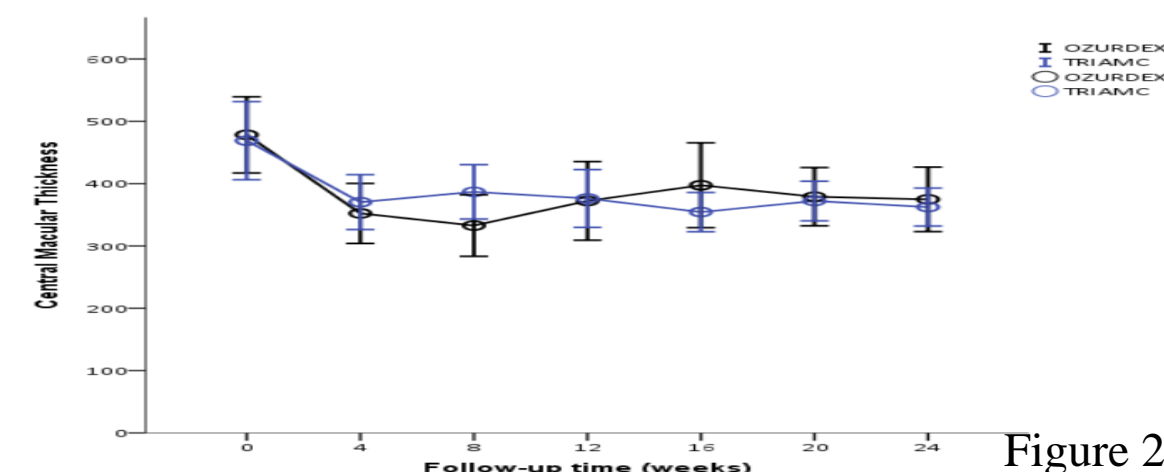


Figure 2

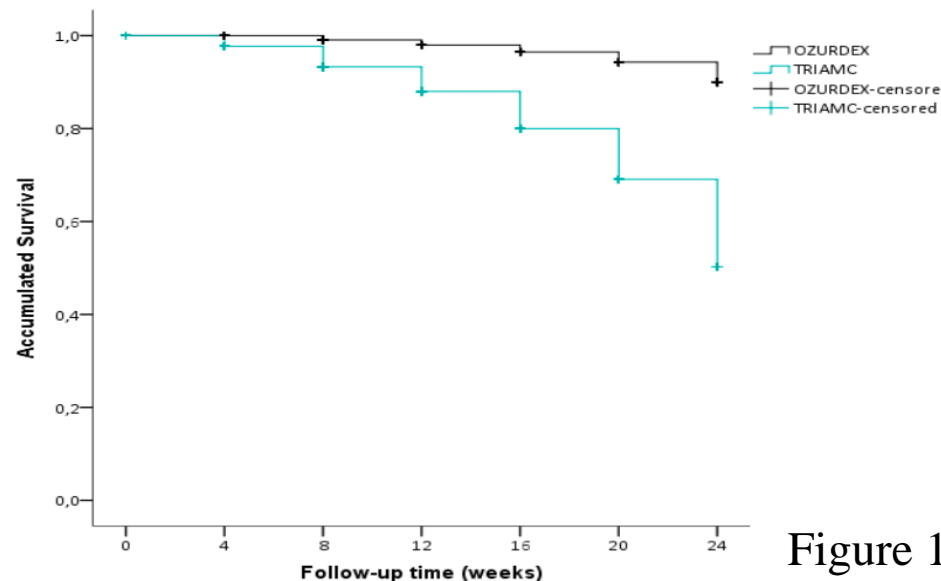
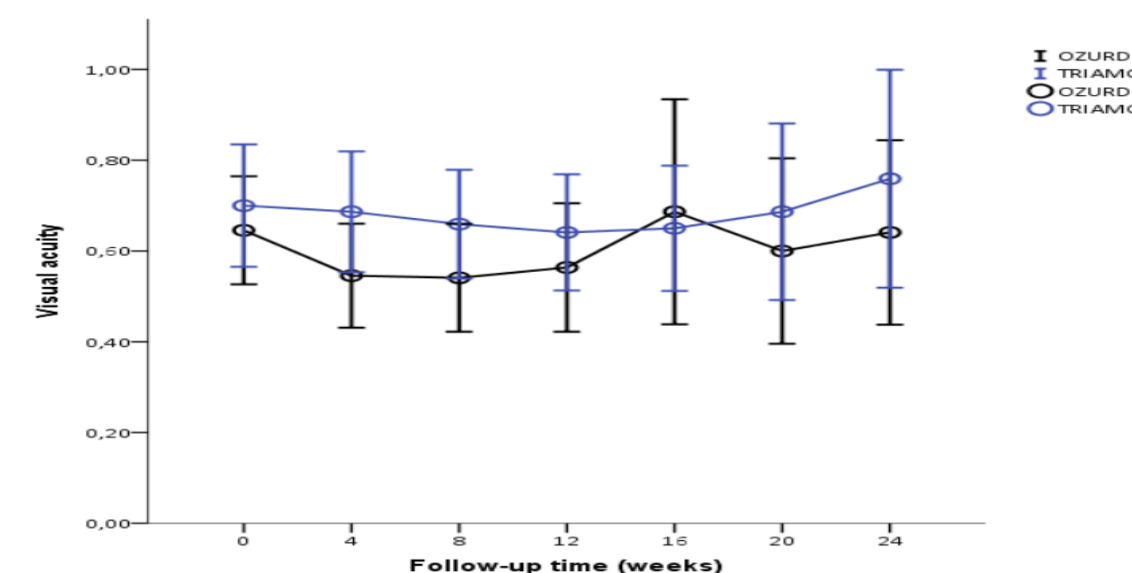


Figure 1

Discussion

Triamcinolone has a significantly higher effect on eye pressure autoregulation and need for hypotensive eyedrops when compared to Ozurdex. To our knowledge, no previous study has assessed the need of eyedrops as primary outcome using cumulative survival analysis. Patient's both eyes were treated, and it is a study limitation.