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Prospective Randomised Trial of Intravitreal Bevacizumab vs. Triamcinolone for Patients with Diabetic Macular Edema at the Time of Cataract Surgery (The DiMECAT Trial)

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Abstract

Purpose: Cataract surgery in diabetic patients often results in poor visual outcomes from the progression of diabetic retinopathy and accelerated

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development of Diabetic Macular Edema (DME). This study compares the final visual and anatomical outcomes after the use of either intravitreal bevacizumab (BVB, Avastin™), or triamcinolone (TA, Triescence™) at the time of cataract surgery in patients with DME.

Methods: Prospective randomized clinical trial of an intravitreal injection of either 1.25mg of BVB or 4mg of TA at the time of cataract surgery, and at subsequent review if required, in diabetics with visually significant cataract and one of: i) refractory DME at the time of surgery, ii) treated DME within the 12 months prior to surgery, or iii) microaneurysms within the foveal avascular zone not amenable to focal macular laser. End points were best-corrected visual acuity, change in central macular thickness (CMT) on SD-OCT from baseline, number of injections and ocular complications at 6 months post-operatively.

Results: To date, 47 patients have been recruited at the Royal Victorian Eye and Ear Hospital, Melbourne, Australia, 31 of whom have had surgery (17 in the TA group). At baseline, the BVB group with 56 ± 16 LogMAR letters and CMT of $366 \pm 108 \mu\text{m}$, was similar to the TA group with 50 ± 17 LogMAR letters and CMT $386 \pm 152 \mu\text{m}$ ($p=0.28$ and 0.69 respectively). Ten TA and 7 BVB subjects have currently reached the 6-month time point. At 6 months, both BVB and TA groups gained vision from baseline (mean 26.2 letter gain in TA group, 17.4 letter gain in BVB, $p=0.40$). However, only the TA group had a sustained reduction in CMT that was significantly better than the BVB group ($315 \mu\text{m}$ TA vs. $433 \mu\text{m}$, $p=0.011$). The BVB group received an average of 4.2 ± 1.6 injections over 6 months, compared to a total of 2 injections in the TA group. There was one case of raised intraocular pressure ($\geq 22 \text{mmHg}$) in the TA group (10%).

Conclusions: When administered at the time of cataract surgery in patients with DME, both TA and BVB result in improved visual acuity at 6 months post operatively - however only TA resulted in a sustained reduction in central macular thickness. Further follow up will determine whether this translates into better long term visual outcomes in the TA group.

Keywords: 499 diabetic retinopathy • 466 clinical (human) or epidemiologic studies: treatment/prevention assessment/controlled clinical trials • 743 treatment outcomes of cataract surgery



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