Spring 2014 : Edition 9

Macular*NEWS*

Welcome to the 9th edition of Macular*News*.

In this newsletter we report on our research findings one year into a comparative assessment of different approaches to treating Diabetic Macular Oedema.

Given that up to 10% of Australian people are affected by diabetes during their lifetime (substantially higher in some communities) this research has direct impact on the visual outcomes of many people.

Prof. Mark Gillies
Macular Research Group

The Clincal Research Unit

The Clinical Research Unit of the Macular Research Group is an internationally recognised clinical trial unit that conducts randomised clinical trials in macular and retinal diseases.

Research clinics are held in the Out Patients Department of the Sydney Eye Hospital and utilise testing equipment and resources across the campus including those of the Save Sight Institute.

The Clinical Research Unit is directed by the professorial head, Mark Gillies. The professorial associate Samantha Fraser-Bell and two international visiting fellows form the remainder of the medical team. Daily operations are overseen by a clinical research manager. Research patient visits are conducted with a staff of clinical research orthoptists, clinical research nurses and a clinical research officer.

Patients enrolled in therapeutic clinical trials are treated and closely monitored by the research team.

The Macular Clinical Team (from left): Susan Chin, Stephanie Goodwin, Christine Gaston-Aroney, Ajay Jadhav, Haipha Ali, Mark Gillies, Maria Williams

Diary Date: Friday 14th November
10am - 12 midday

Macular Information and Research Update

To register call (02) 9382 7316 or

visit https://maculardegeneration2014.eventbrite.com.au

Contact Us:
Laboratory Team (02) 9382 7270
Clinical Team (02) 9382 7309
FRB! Team (02) 9382 7272

Comparing two different treatments for diabetic macular oedema

The second most common macular disease after Macular Degeneration is “Diabetic Macular Oedema” (DMO).

This involves swelling of the macula because of damage to the macular blood vessels, something which commonly occurs in people with diabetes (see Figure 1).

DMO is believed to occur in around 7% of people with diabetes.

Given that diabetes affects 5-10 % of Australians (in some indigenous communities the rates are up to 50%), DMO is a common cause of loss of vision.

In the past, laser treatment was primarily used to treat DMO. However, this did not improve vision in most eyes, and many people continued to lose vision.

More recently, injections of specific medications into the eye have been developed to better control the swelling and damage.

There are currently two main types of injections that are used to treat DMO:

- Steroids
- Vascular Endothelial Growth Factor (VEGF) inhibitors.

The Save Sight Institute and Sydney Eye Hospital pioneered the development of steroid eye injections in the 1990s.

Since 1997 the Clinical Research Unit of the Macula Research Group has conducted a series of major clinical trials to assess the visual outcomes of steroid injections for macular disease.

VEGF inhibitors, such as Avastin, Lucentis or Eylea, were first developed to treat wet Macular Degeneration, but it turns out that they are also effective for DMO.

Although VEGF inhibitors and steroids are both reported to be effective in treating DMO, they also both have risks and side-effects. In order to better understand these, and to help medical practitioners make informed treatment choices for their patients, we decided to conduct a major clinical trial to directly compare VEGF inhibitors and steroids in the treatment of DMO.

The VEGF inhibitor analysed was Bevacizumab (‘Avastin’) and the steroid was a slow-release formulation of Dexamethasone (‘Dex-Implant’). The study was therefore called ‘BEVORDEX’.

Preliminary Results

Here we present the one year results of the BEVORDEX study (half way through its duration) which have recently been published in *Ophthalmology*, the leading professional journal in the field.

In 2010 we secured start-up funding from the National Health and Medical Research Council and, with the added assistance of our private patient donors, we were able to commence the study.

We enrolled 66 patients (88 eyes) over the following two years.

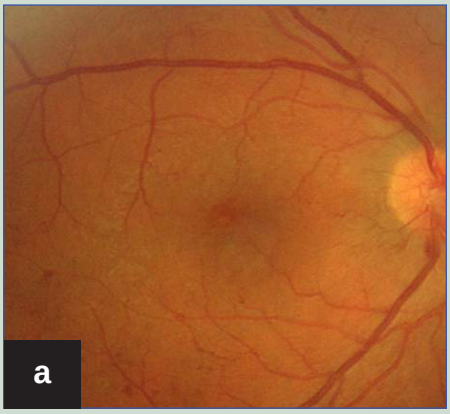
Half of the group received steroid injections while the other half received VEGF inhibitor injections.

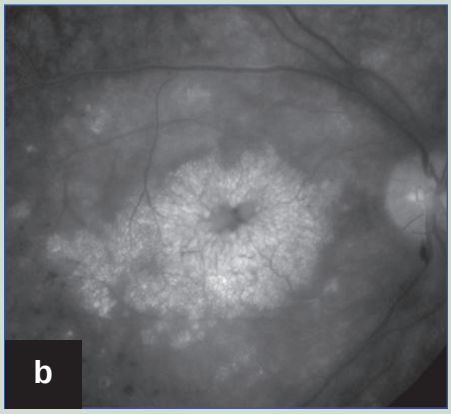
We were primarily interested in the proportion of patients in each group whose vision improved by two or more lines on an eye chart.

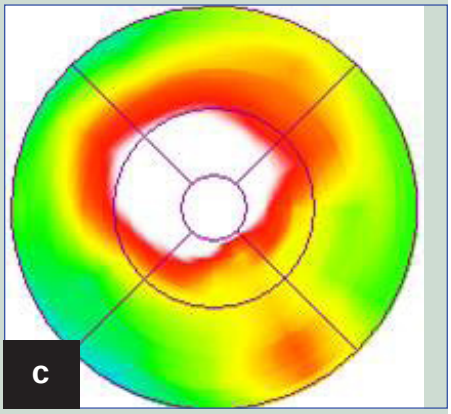
In both groups this has, to date, occurred in around 40% of eyes.

Vision did not deteriorate in any eyes treated with the VEGF inhibitor, whereas it did in some eyes receiving steroid injections. This was primarily

“This study provides good evidence that steroids may be considered a first-line treatment for people with Diabetic Macular Oedema if they have already had their cataracts removed”







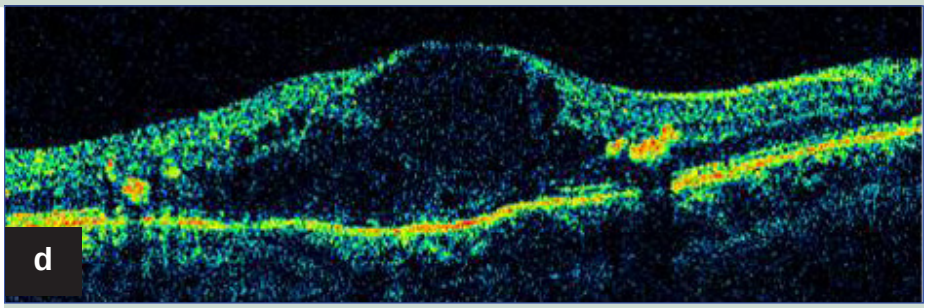


Figure 1: Images of diabetic macular oedema. A) colour photograph of a macula; B) retinal angiogram showing leakage of dye within the macula; C) Optical Coherence Tomography (OCT) thickness map; and D) OCT cross section of the macula showing marked swelling.

due to cataract formation, a well-know side effect of steroid injections.

Another common side-effect of steroid injections is increased intraocular pressure, which occurred in around half of the treated eyes.

While steroids have these increased risks, they have an advantage in that injections are required much less frequently and the effect on swelling appears to be stronger.

On average, eyes treated with steroids needed only three injections during the 12 month study. Eyes treated with the VEGF inhibitor required an average of eight injections during the same time period.

DMO is assessed by measuring the Central Macular Thickness (CMT) with an Optical Coherence Tomography (OCT) machine.

In normal eyes, the CMT is less than 300 microns. In the BEVORDEX study, participants had an average CMT of 500 microns before they started treatment.

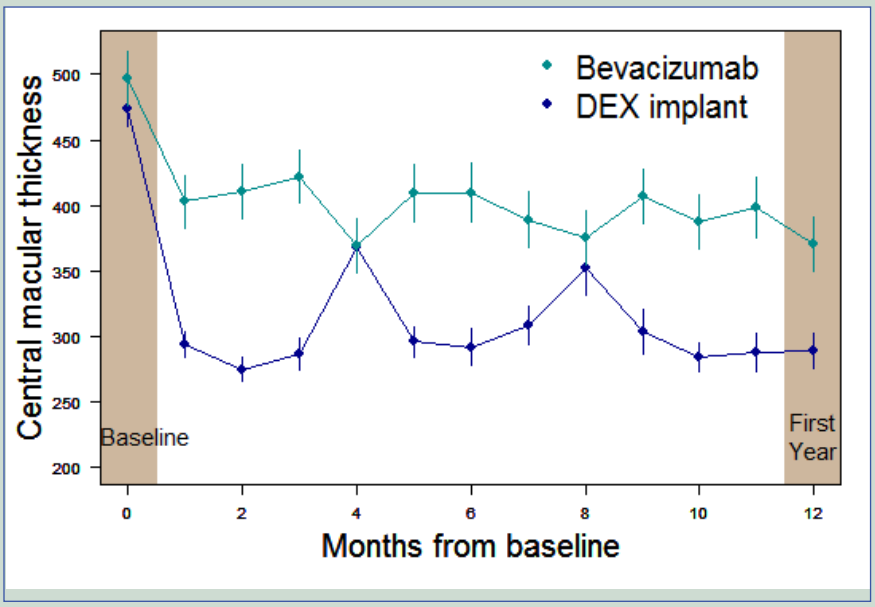


Figure 2: Mean central macular thickness by treatment type, for baseline and each of the 12 months of follow-up. Bevacizumab (Avastin) in green and Dexamethasone (Dex-Impant) in blue. The DEX implant reduced the macular thickness more effectively but was clearly wearing off after four months.

Figure 2 shows that eyes treated with steroid injections (Dex-Implant) had a much greater reduction in DMO (measured by CMT) than eyes treated with the VEGF inhibitor (Bevacizumab 'Avastin').

It also demonstrates for the first time that this particular steroid is only effective for four months. It was previously thought to last six months.

How does this trial reduce the risk of people going blind from macular disease? This is, of course, our primary objective in the Macula Research Group and we are proud of the progress we have made thus far and in being the first to conduct a study to compare these commonly used drugs directly.

In summary, our findings thus far indicate that steroid injections clearly have a stronger effect and last much longer than the VEGF inhibitor.

However steroids also frequently caused cataracts and can result in increased intraocular pressure.

This study provides good evidence that steroids may be considered as first line treatment of eyes with DMO for those people who have already had their cataracts removed.

Steroids might also be considered for patients who wish to have as few injections as possible, or cannot be seen monthly, perhaps for geographical reasons.

Contact Us

Laboratory Team
(02) 9382 7270

Clinical Team
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FRB! Team
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The BEVORDEX study will complete its final two-year follow-up of all patients in October 2014.

This study has relied on private donations because, as is often the case, the initial NHMRC start-up funding was not enough to cover all costs involved in the study which has spanned 8,800 separate patient visits over four years.

We thank and acknowledge our loyal supporters, without whom this important research could not take place.

Save Sight Institute is a centre of The University of Sydney.

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Macular Research Group, Save Sight Institute
South Block Sydney Hospital
8 Macquarie Street Sydney NSW 2000
Tel: (02) 9382 7316
macular.news@sydney.edu.au