Retinopathy

Ranibizumab or laser treatment for macular oedema?

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The RESTORE (Efficacy and Safety of Ranibizumab [Intravitreal Injections] in Patients with Visual Impairment due to Diabetic Macular Edema) study (2011; summarised alongside) provides compelling evidence for the use of intravitreal ranibizumab (an antivascular endothelial growth factor) in the management of diabetic maculopathy, following on from the large Diabetic Retinopathy Clinical Research Network (DRCRnet et al, 2010) study involving 52 clinical sites in the USA. The DRCRnet had compared the effectiveness of laser treatment (prompt or deferred), intravitreal triamcinolone and intravitreal ranibizumab and reported an improvement in best-corrected visual acuity (BCVA) – an average of nine-letter gain over 12 months – in participants treated with ranibizumab, either alone or combined with laser therapy.

RESTORE was a multicentre (73 centres in 13 countries – 10 European, Turkey, Canada and Australia), double-masked, sham-controlled, randomised trial with three treatment arms: ranibizumab plus sham laser, ranibizumab plus laser, and laser plus sham injection. The primary outcome was the mean change in BCVA in the treated eye at the 12-month follow-up visit. The investigators also measured vision- and health-related quality of life (QOL). Participants already had visual impairment caused by diabetic macular oedema.

Participants in the ranibizumab-alone and combined-therapy arms received a mean of 7.0 and 6.8 injections, respectively, in the first year. In both the active and sham arms participants received an average of two laser treatments.

From baseline to 12 months, there was a significant improvement in BCVA in the ranibizumab-treated (alone or in combination) group of approximately six letters (approximately one line on the vision chart) compared with only one letter in the laser-alone group. A clinically significant change in vision is usually defined as a gain or loss of ≥15 letters. In this study, approximately 23% participants receiving ranibizumab gained ≥15 letters, compared with only 8% in those receiving laser alone; and only 2% of ranibizumab-treated participants lost ≥15 letters compared with 8% in the laser-alone group. Ranibizumab-treated participants with improved vision showed a corresponding improvement in QOL measures.

All treatments were effective in stabilising vision, although it is clear that treatment with ranibizumab was associated with a better visual outcome than treatment with laser alone.

> ***"Every effort must be made to ensure that people with maculopathy are identified early (by screening) and treatment is applied before the vision has significantly deteriorated."***

Despite these findings, NICE (2011) has recently published a final appraisal determination and has concluded that treatment with ranibizumab is not an effective use of NHS resources and cannot be recommended in people with diabetic macular oedema. Laser clearly remains an effective and cost-effective treatment for macular oedema, but cannot restore vision once lost. Therefore, every effort must be made to ensure that people with maculopathy are identified early (by screening) and treatment is applied before the vision has significantly deteriorated. The reality is that there will always be people who present late or in whom laser has failed, and at the very least ranibizumab should be available to treat these individuals.

Diabetic Retinopathy Clinical Research Network, Elman MJ, Aiello LP et al (2010) Randomized trial evaluating ranibizumab plus prompt or deferred laser or triamcinolone plus prompt laser for diabetic macular oedema. *Ophthalmology* **117**: 1064–77

NICE (2011) *Final Appraisal Determination: Ranibizumab for the Treatment of Diabetic Macular Oedema*. NICE, London. Available at: http://bit.ly/ow5Wiv (accessed 31.08.11)

OPHTHALMOLOGY

Ranibizumab therapy improves visual acuity and quality of life

Readability	✓✓✓
Applicability to practice	✓✓✓✓✓
WOW! factor	✓✓✓

1 Ranibizumab combined with laser therapy has been shown to improve vision in people with diabetic macular oedema.

2 The current authors assessed whether ranibizumab alone or in combination with laser therapy was superior to laser therapy alone for diabetic macular oedema.

3 A total of 345 people aged ≥18 years with diabetes and visual impairment caused by macular oedema were included in the study.

4 Participants were randomised to receive ranibizumab plus sham laser therapy (n=116), ranibizumab plus laser therapy(n=118) or sham injection plus laser therapy (n=111).

5 The mean change in best-corrected visual acuity letter score from baseline to 12 months (the primary outcome) was significantly greater with ranibizumab than without (+6.1 and +5.9 for ranibizumab alone and with laser, respectively, compared with +0.8 for laser alone; P<0.0001).

6 Ranibizumab treatment was also associated with improvement in health-related quality of life (HRQOL) assessed using a visual function questionnaire compared with laser therapy alone (P<0.05) after 12 months.

7 The authors concluded that 12 months of ranibizumab treatment in people with diabetic macular oedema was associated with improved visual acuity and HRQOL.

Mitchell P, Bandello F, Schmidt-Erfurth U et al (2011) The RESTORE study: ranibizumab monotherapy or combined with laser versus laser monotherapy for diabetic macular edema. *Ophthalmology* **118**: 615–25

ACTA OPHTHALMOLOGICA

Stable refraction and visual acuity

Readability	✓✓✓✓
Applicability to practice	✓✓✓
WOW! factor	✓

1 The aim of this study was to determine if refraction and visual acuity (VA) varies in people with diabetes under routine care.

2 Fifty-three participants had refraction and visual acuity in one eye and blood glucose measurements taken at four visits during 1 month.

3 Variability was the difference between the highest and lowest measurements for each individual.

4 Refraction was completely stable in 43 participants; in the remaining 10 refraction changed only slightly.

5 The mean intraindividual variability in best-corrected VA (expressed as logMAR units) was 0.08.

6 The median blood glucose intraindividual variability was 6.3 mmol/L (range, 0.5–18.1 mmol/L); there was no association between blood glucose levels or blood glucose variations and refraction or VA.

7 It was concluded that, in this cohort, VA and refraction remained stable despite variations in blood glucose levels in people with diabetes under routine care.

Agardh E, Hellgren KJ, Bengtsson B (2011) Stable refraction and visual acuity in diabetic patients with variable glucose levels under routine care. *Acta Ophthalmol* **89**: 107–10

GRAEFES ARCH CLIN EXP OPHTHALMOL

Regional distribution of DR lesions

Readability	✓✓✓✓
Applicability to practice	✓
WOW! factor	✓

1 The authors examined whether differences in the diameter responses of retinal arterioles cause regional differences in diabetic retinopathy (DR) lesions.

2 Participants with proliferative DR, diabetic maculopathy and healthy individuals were studied (n=17 for each group).

3 Diameter changes in a macular and a peripheral retinal arteriole were assessed during increased arterial blood pressure, increased retinal metabolism or both, simultaneously.

4 Diameter differences were only noted between the three groups during simultaneous stimulation.

5 It was concluded that different diameter responses may contribute to regional differences of DR lesions.

Skov Jensen P, Jeppesen P, Bek T (2011) Differential diameter responses in macular and peripheral retinal arterioles may contribute to the regional distribution of diabetic retinopathy lesions. *Graefes Arch Clin Exp Ophthalmol* **249**: 407–12

OPHTHALMOLOGY

Severe DR reduces quality of life

Readability	✓✓✓✓
Applicability to practice	✓✓
WOW! factor	✓✓

1 The authors examined the impact of diabetic retinopathy (DR) severity on health-related quality of life (HRQOL).

2 A total of 1064 Latino people with T2D were included: 578 with no DR, 166 with unilateral non-proliferative DR (NPDR), 268 with bilateral NPDR, 23 with unilateral proliferative (PDR) and 29 with bilateral PDR.

3 HRQOL was measured using a visual function questionnaire and a health survey and the relationship between HRQOL and DR severity was assessed.

4 Severe DR was associated with lower HRQOL scores (P<0.05).

5 The decline in HRQOL was greatest between the participants with grade 8 DR (unilateral moderate NPDR) and 9–15 (bilateral moderate NPDR to bilateral PDR).

6 The authors concluded that severe DR was associated with a decline in HRQOL.

Mazhar K, Varma R, Choudhary F et al (2011) Severity of diabetic retinopathy and health-related quality of life: the Los Angeles Latino Eye study. *Ophthalmology* **118**: 649–55

OPTHALMOLOGY

Prevalence of non-diabetic retinopathy is associated with CV risk factors

Readability	✓✓✓✓
Applicability to practice	✓✓
WOW! factor	✓✓

1 The aim of this study was to determine the prevalence of retinopathy and the association with cardiovascular (CV) risk factors among four different ethnic groups (white, black, Hispanic and Chinese) of people with no diabetes.

2 A total of 5173 people without diabetes (aged 45–84 years) and gradable retinal photographs were included in this study.

3 The prevalence of retinopathy was 12.5% (n=645) in this cohort.

4 The prevalence rates of retinopathy across the four ethnic groups were: 11.9% (white), 13.9% (black), 12.6% (Hispanic) and 17.2% (Chinese).

5 After adjusting for age, gender and race, hypertension was significantly associated with retinopathy (odds ratio [OR], 1.47; 95% confidence interval [CI], 1.23–1.75).

6 The presence of hypertension in black participants was strongly associated with retinopathy (OR, 1.78; 95% CI, 1.22–2.60; P=0.003).

7 After adjustments, smoking (OR, 1.50; 95% CI, 1.09–2.06) and internal carotid intima-media thickness (OR, 1.22; 95% CI, 1.05–1.41) were associated with retinopathy.

8 The authors concluded that features usually associated with diabetic retinopathy are common among different ethnic groups of people without diabetes and are associated with CV risk factors.

Ojaimi E, Nguyen TT, Klein R et al (2011) Retinopathy signs in people without diabetes: the multi-ethnic study of atherosclerosis. *Ophthalmology* **118**: 656–62

"Visual acuity and refraction was stable but blood glucose levels variable in people with diabetes under routine care."