

New severity scale facilitates planning and analysis of treatment trials for diabetic macular oedema

Pippa Wysong
in Fort Lauderdale

A NEW severity scale for diabetic macular oedema developed using data from the Early Treatment Diabetic Retinopathy Study research group (ETDRS) should facilitate planning and analysis of treatment trials for the condition, according to Matthew Davis MD, University of Wisconsin, Madison, Wisconsin, US.

The five-step scale uses different measures of retinal thickness assessed in stereo photographic images and can be used to help assess risk factors and other features of the natural history of the disease, said Dr Davis who is part of the Diabetic Retinopathy Clinical Research Network and who presented a description of the severity scale in a poster at the annual meeting of Association for Research in Vision and Ophthalmology (ARVO).

“The study was done before we knew photocoagulation was an effective treatment for diabetic macular oedema. There won’t ever be a group of patients like that again.”

The ETDRS was a multi-centre randomised clinical trial started in 1979 designed to evaluate argon laser photocoagulation plus aspirin treatment in the management of non-proliferative, or early proliferative, diabetic retinopathy.

“The study was done before we knew photocoagulation was an effective treatment for diabetic macular oedema. There won’t ever be a group of patients like that again. Now that we know photocoagulation is helpful, we would never commit patients to follow-up without the chance of treatment for three years,” Dr Davis told *EuroTimes* in an interview.

But much can be learned from the information gleaned from the study, he emphasised.

“Much of the reason for the scale is to allow us to describe the natural history of diabetic retinopathy in these eyes, with the best method we had then. We want to provide information that may help in planning trials and in managing diabetic retinopathy.”



Matthew Davis

Data for the severity scale were derived from 3,711 patients in the ETDRS trial in whom one eye was assigned to no treatment of macular oedema, while the other eye received photocoagulation. Trained lay readers graded the degree of retinal thickening at the centre of

the macula and the area of thickening within one disc diameter from the centre using stereo photographic images.

Mean baseline visual acuity scores were tabulated for each eye and cross-referenced with both the retinal thickening grades. Groups with similar visual acuity scores were grouped together. Mean visual acuity scores at baseline and three-year follow-up were compared.

Baseline findings showed that as macular oedema increased on the scale, median visual acuity decreased from 87 to 65 letters (20/20 to 20/50).

Correlation between retinal thickening and loss of vision

Overall, it was found that visual acuity was associated with the area of retinal thickening within one disc diameter of the centre of the macula and the degree of retinal thickening at the centre of the macula. Researchers noted that eyes with the same degree of thickening in the centre of the macula have a decreasing visual acuity as the area of retinal thickening near the centre increased.

Essentially, the scale shows that there is a correlation between visual acuity and the thickness at and near the centre of the macula, and that longer duration of severe retinal thickening is associated with a greater decrease in visual acuity.

Dr Davis explained that the scale facilitates the concurrent tracking of changes in morphology and visual acuity. It will be useful in analysing further material from the ETDRS, as well as in the planning and analysis of other clinical trials.



Eye Exam

New diagnostic techniques under investigation

The researchers from the Network also presented a second, related poster at ARVO, comparing optical coherence tomography (OCT) and stereoscopic colour fundus photographs for measuring the severity of diabetic macular oedema.

This study is part of an ongoing 78-centre study comparing two different photocoagulation techniques for the treatment of diabetic macular oedema. The data were based on findings from 227 study eyes and 133 fellow eyes.

Patients enrolled in the study had visual acuity of at least 20/400, plus central or paracentral retinal thickening. The study compared retinal thickening as determined by OCT and the ETDRS scale.

The researchers found that there was good, but not excellent correlation between retinal thickening as determined by fundus photography and OCT, and that there was a fair correlation between retinal thickening and visual acuity. They concluded that OCT was better at measuring retinal thickness than the photographic method.

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Extent of Retinal Thickening	Mean Baseline Visual Acuity Score* in ETDRS eyes on a Macular Edema Severity Scale															Level			
	Thickness at Center																		
	None			Questionable			<1X Reference [†]			>=1X, <2X Ref [†]			>=2X Ref [†]				Total		
	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	
None in Field 2	86.8	5.8	2463													86.8	5.8	2463	Level 1A
None within 1 DD of center	86.2	6.2	761													86.2	6.2	761	Level 1B
Questionable within 1 DD of center	85.0	7.1	401	82.2	8.5	216										84.0	7.7	617	Level 1C
Definite, <1/2 DA within 1 DD of center	85.2	6.7	522	82.5	8.9	315	81.2	8.5	175	81.8	8.2	102	75.0	NA	1	83.5	8.0	1115	Level 2
>=1/2 DA, <1 DA within 1 DD of center	83.2	8.2	145	81.1	10.2	216	78.9	9.6	235	77.2	10.9	223	72.5	14.1	6	79.8	10.1	825	Level 3A
>=1 DA, < 2 DA within 1 DD of center	82.2	9.0	30	79.6	11.9	90	75.1	12.3	282	72.8	12.4	571	66.7	15.0	34	74.1	12.7	1007	Level 3B
>=2 DA within 1 DD of center	60.7	13.9	3	87.0	8.5	7	72.1	13.3	58	64.3	14.6	467	59.8	13.6	99	64.5	14.7	634	Level 4
Total	86.2	6.3	4325	81.8	9.5	844	77.5	11.1	750	71.3	13.9	1363	62.2	14.4	140	81.6	11.2	7422	Level 5A

*Sneller equivalents: 100 = 20/10, 85 = 20/20, 70 = 20/40, 65 = 20/50, 60 = 20/63

[†]Reference thickness is the maximum thickness of normal retina 0.5 to 1.0 disc diameter from the center of the macula.

Table 1. Extent of retinal thickening and thickness at center of macula cross-classified and cells with similar baseline visual acuity combined as indicated by color code. Note diagonal connection of many cells, as might be expected when two additive risk factors are cross-classified.