Diagnostic Accuracy of Monitoring Tests of Fellow Eyes in Patients with Unilateral Neovascular Age-Related Macular Degeneration
Early Detection of Neovascular Age-Related Macular Degeneration Study (EDNA)

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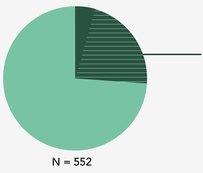
EDNA was a 3-year multicenter, prospective, cohort, comparative diagnostic accuracy study conducted in a monitoring setting in 24 ophthalmology departments within National Health Service (NHS) hospitals across the United Kingdom. The aim of EDNA was to evaluate the diagnostic accuracy of routinely used tests of visual function and retinal morphology compared with fundus fluorescein angiography (FFA) to detect onset of active macular neovascularization in unaffected fellow eyes of patients with unilateral neovascular age-related macular degeneration (nAMD). Over the course of the study, 552 participants were monitored for up to 3 years, with commonly performed index testing of self reported vision, Amsler-testing, visual acuity, fundus clinical examination and optical coherence tomography (OCT) compared with the reference standard of FFA.

During the study, 145 participants developed active nAMD in the EDNA study eye. In 120 participants (83.0%), a confirmatory FFA was available and read by the site clinician.

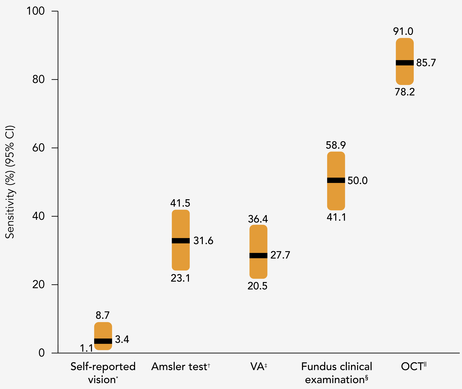


26.3% of participants (145/552) developed active nAMD in the EDNA study eye. Of those who developed active nAMD, 83.0% (120/145) had an FFA detection; this constituted the primary analysis cohort

- Active nAMD
- Active nAMD with FFA detection

The sensitivity of OCT was markedly higher compared with those of all other tests.

Sensitivity of Index Tests Against the Enhanced Reference Standard (Reading Center Determination of Conversion Based in FFA)



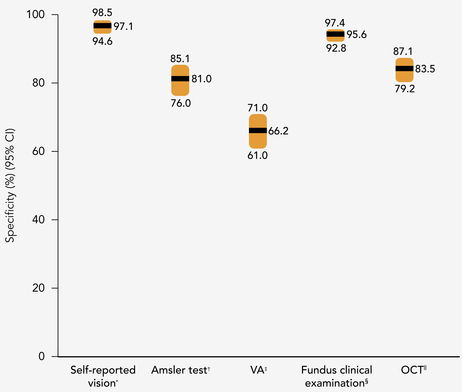
A total of 460 participants were included in the analysis, 83 were excluded because of missing data; 119 study eyes developed nAMD, and 341 did not.

*2 missing. †2 missing. ‡2 missing. §1 missing. ‖1 missing.

CI = Confidence interval; VA = Visual acuity

All 5 index test specificities were high.

Specificity of Index Tests Against the Enhanced Reference Standard (Reading Center Determination of Conversion Based in FFA)



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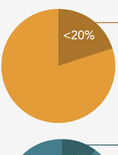
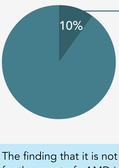
An important finding of some concern in EDNA was the poor diagnostic accuracy of self-reported visual function.



Less than one-fifth of the participants reported a change in vision that was worse or much worse at detection of onset of nAMD in the EDNA study eye.



Additionally, approximately 10% of patients had worsening of vision that was shown not to be due to the onset of nAMD.

The finding that it is not possible to rely on self-reported visual deterioration as a marker for the onset of nAMD is particularly disturbing because the study eye was required to have a VA of 68 or more ETDRS letters (Snellen 20/40 or better) at enrollment.

>95%

This degree of function represents driving-level VA, and it is notable that in more than 95% of participants the study eye was the eye with better acuity.

Thus, the inability of our patient population to recognize a change in function in the EDNA study eye around the time of onset of nAMD is both surprising and worrying because it is common clinical practice to ask patients to self-monitor for worsening of vision or the onset of distortion.

The other self-administered test, which involves recording the appearance of a scotoma or a distortion on the Amsler chart, also had poor sensitivity and specificity, which is a recognized drawback of this tool.

ETDRS = Early Treatment Diabetic Retinopathy Study.

Conclusions

Tests of self-reported change in vision, unmasking of new distortion, measurements of acuity, and fundus checks to diagnose active nAMD performed poorly in contrast to OCT. Our findings support a change to guidelines in clinical practice to monitor for onset of nAMD.