Optical coherence tomography versus stereoscopic fundus photography or biomicroscopy for diagnosing diabetic macular edema: a systematic review
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CRD summary
This review, which assessed the use of optical coherence tomography for diagnosing macular oedema attributable to diabetic retinopathy, concluded that optical coherence tomography performs well in comparison with fundus stereophotography or biomicroscopy. The authors' rather optimistic conclusions are, nevertheless, likely to be reliable.

Authors' objectives
To review the sensitivity and specificity of optical coherence tomography (OCT), compared with well-established 'gold' standard tests, for diagnosing macular oedema attributable to diabetic retinopathy.

Searching
MEDLINE (from 1966 to 2006) and EMBASE (from 2002 to 2006) were searched for relevant studies; the search terms were reported. The indices of the following journals were also handsearched from 1998 to 2006: Ophthalmology, Archives of Ophthalmology, American Journal of Ophthalmology, Investigative Ophthalmology and Visual Science, British Journal of Ophthalmology and Retina. The references of the retrieved full articles were also screened.

Study selection
Studies of diabetic participants with clinically significant macular oedema, according to Early Treatment of Diabetic Retinopathy Study criteria, were eligible for inclusion. Eligible studies also had to use OCT as an index test (either low or high resolution) and stereoscopic fundus photography, or contact lens or non contact lens biomicroscopy of the fundus, as the reference test.

The type of gold standard used in the included studies varied, and included stereophotography, contact lens or non contact lens biomicroscopy, and a combination of these. Nine studies used low resolution OCT and 6 studies used high resolution OCT. Most of the studies included participants with various levels of diabetic retinopathy; several studies used healthy participants in the control groups. The main outcomes reported were the sensitivity and specificity.

Two reviewers independently selected studies for inclusion, with any disagreements resolved by discussion.

Assessment of study quality
Study quality was assessed using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) checklist, which uses 14 criteria. Additional criteria, such as use of a sample size calculation, were also used.

Two reviewers independently assessed study quality, with any disagreements being resolved by a third reviewer.

Data extraction
Outcome data were extracted for each study. The sensitivity, specificity, positive and negative likelihood ratios (LRs), and diagnostic odds ratios (DORs) were calculated, along with 95% confidence intervals (CIs), when data were available to do so.

The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

Methods of synthesis
Meta-analyses examining pooled DORs were performed, using a fixed-effect model if three or fewer studies were found and a random-effects model if more than 3 studies were found. Pairs of sensitivity and specificity were pooled,
based on a random-effects bivariate model, to produce a summary receiver operating characteristic (ROC) curve. A test for threshold effect was also performed. Heterogeneity was assessed using \( \chi^2 \) tests and sources of heterogeneity in the DOR were investigated using multilevel logistic regression.

**Results of the review**

Fifteen studies (n=1,321) were included in the review, of which 11 were prospective cohort studies (n=912), two were retrospective cohort studies (n=150) and one was a retrospective case-control study (n=70); it was unclear whether or not the remaining study (n=189) was prospective in design.

Study quality was generally good, although the reporting and handling of uninterpretable test results was unclear or poorly reported in the majority of studies. No studies reported the use of a sample size calculation.

Sensitivity and specificity data could only be extracted from 6 studies. In five of these studies, central retinal thickness cut-offs between 230 and 300 μm were used to define abnormal OCT results and considered the central type of clinically significant macular oedema only. The expected operating point on the summary ROC corresponded to a sensitivity of 0.79 (5 studies; 95% CI: 0.71, 0.86) and a specificity of 0.88 (95% CI: 0.80, 0.93), with a positive LR of 6.5 (95% CI: 4.0, 10.7) and a negative LR of 0.24 (95% CI: 0.17, 0.32). No statistically significant heterogeneity was found between the pooled cohort studies. Further results were reported.

**Authors' conclusions**

OCT is a useful tool for diagnosing suspect central diabetic macular oedema, and performs well in comparison with fundus stereophotography or biomicroscopy.

**CRD commentary**

This review addressed a clear question and was supported by appropriate inclusion criteria. Attempts to identify relevant studies were undertaken using several methods, although language restrictions were not reported. Appropriate methods were used to minimise reviewer error and bias when selecting studies and assessing study quality, but were not stipulated for the data extraction stage. Study quality was assessed and was considered when interpreting the results of the review. Sufficient study details were provided and an appropriate synthesis of the data was undertaken, although the general lack of data precluded much investigation of heterogeneity. The authors' conclusions appear rather optimistic given the small number of studies analysed and the pooled LRs obtained, but they are likely to be reliable.

**Implications of the review for practice and research**

Practice: The authors suggested that OCT can be used to diagnose clinically significant macular oedema, particularly its central type or central diabetic macular oedema, and to decide on laser photocoagulation in patients with intermediate suspicion of disease. However, the strength of this statement is limited by the poor reporting of data in many of the included studies, and the failure to take into account correlation between eyes of the same patient in all included studies.

Research: The authors made several suggestions for further research, most of which were based around the quality of reporting data and study details. The authors also stated that after diagnostic accuracy has been established with respect to traditional gold standards, longitudinal studies of outcome impact are needed to enable the incorporation of a new diagnostic test into prognostic and therapeutic clinical pathways.

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