Colour vision testing for diabetic retinopathy: a systematic review of diagnostic accuracy and economic evaluation


CRD summary
This well-conducted review concluded that there was insufficient evidence to support the use of colour vision testing alone, or in combination with retinal photography, as a method for screening for retinopathy in patients with diabetes. Given the paucity of good quality evidence, the authors' conclusion seems appropriate and reliable.

Authors' objectives
To determine the diagnostic performance and cost-effectiveness of colour vision testing to identify and monitor the progression of diabetic retinopathy.

Searching
The following databases were searched without language restrictions from inception to September 2008: MEDLINE, EMBASE, CINAHL, Science Citation Index, the Cochrane Library, DARE, HTA, LILACS, BIOSIS Previews, Pascal, Inside Conferences, Dissertation Abstracts, NTIS, ClinicalTrials.gov, ReFeR, NHS EED, ClinicalStudyResults.org, and Clinical Trial Results. The search strategy was reported. Seven relevant organisation websites, four relevant library websites, and conference proceedings of four societies spanning 1999 to 2007 were also searched.

Study selection
Diagnostic cohort and case-control studies (with at least 20 participants of any age with type 1 or type 2 diabetes, with either at least five patients with evidence of retinopathy, or all patients with diabetes) that compared any test of colour vision with a reference standard (fundus examination by fluorescein angiography, digital retinal photography, biomicroscopy or ophthalmoscopy) were eligible for inclusion. Sufficient data to construct 2x2 tables of test performance had to be reported to be included in the analyses. Studies of attitudes or preferences of patients with diabetes in relation to colour vision testing and ‘phase I’ studies comparing the range of test results in patients with and without retinopathy, or across stages of retinopathy, were also included.

Where reported, the mean age of participants ranged from 14 to 57.7 years, the proportion males ranged from 37 to 62%, and the proportion of participants with insulin dependent diabetes from 0% to 100%.

Two reviewers independently selected studies for retrieval. One reviewer screened full papers, with the decision checked by a second reviewer. Disagreements were resolved by consensus.

Assessment of study quality
One reviewer assessed study quality using the 14-item QUADAS (Quality Assessment of Diagnostic Accuracy Studies) tool; the results were checked by a second reviewer.

Data extraction
Data to construct 2x2 tables of test performance were extracted by one reviewer, from which sensitivity, specificity and likelihood ratios with 95% confidence intervals (CIs) were calculated. Data extraction was checked by a second reviewer.

Methods of synthesis
Results were combined in a narrative synthesis. The range in sensitivity, specificity and likelihood ratios, with 95% confidence intervals, were presented. Differences between studies were discussed in the text and study details tabulated. Sensitivity and specificity estimates were plotted in receiver operating characteristic (ROC) space.

Results of the review
Twenty five studies, reporting 30 comparisons, met the inclusion criteria (n=7,959 patients; range 24 to 2,857). Study
quality was generally poor. Of the 30 comparisons: two recruited an appropriate patient spectrum; 26 avoided incorporation bias; 24 avoided partial and differential verification bias; five avoided clinical review bias; five avoided diagnostic review bias; three avoided test review bias; six avoided progression bias; 19 reported adequate details of the index test and/or reference standard; 10 reported uninterpretable results; and 12 reported on withdrawals.

**Test diagnostic accuracies:** Farnsworth-Munsell 100 hue test (five studies): sensitivity ranged from 11 to 74%, and specificity from 45 to 100%. Lanthony desaturated D-15 test (five studies): sensitivity ranged from 4 to 87%, and specificity from 10 to 90%. Lanthony New Colour Test (one study): sensitivity was 79 or 86%, and specificity 60 or 34% depending on reference standard. Automated/computerised tests (four studies): sensitivity ranged from 30 to 97%, and specificity from 40 to 100%. Anomaloscopes (one study): sensitivity was 0% and specificity 100%.

Alternative outcomes were reported in the remaining included studies: pseudoisochromatic plates (three studies), Farnsworth-Munsell 100 hue test (five studies), Lanthony desaturated D-15 test (one study), Lanthony New Colour Test (one study), Mollon-Reffin Minimalist Test (one study), automated/computerised tests (two studies), and anomaloscopes (one study).

**Cost information**
The economic evaluation suggested that the addition of colour vision testing to the current national screening programme would be relatively inexpensive and could be cost-effective if it adequately increased sensitivity. The cost per quality-adjusted life-year gained was £6,364 for type 1 diabetes and £12,432 for type 2 diabetes, but sensitivity analysis highlighted the substantial probability that colour vision testing was not diagnostically accurate enough to be either an effective or a cost-effective addition to current screening methods.

**Authors' conclusions**
There was insufficient evidence to support the use of colour vision testing alone, or in combination with retinal photography, as a method for screening for retinopathy in patients with diabetes.

**CRD commentary**
The authors addressed a clear research question supported by appropriate inclusion criteria. The search was extensive with attempts made to reduce publication and language bias. Each stage of the review was conducted in duplicate reducing the potential for error and bias.

Study quality was assessed using appropriate criteria and the results for each criterion were given. The decision to present a narrative synthesis seemed appropriate.

This was a well-conducted review, and given the paucity of good quality evidence, the authors' conclusion seems appropriate and reliable.

**Implications of the review for practice and research**
**Practice:** The authors did not state implications for practice beyond the main conclusion.

**Research:** The authors identified a number of research priorities: optical coherence tomography; diagnostic accuracy of colour vision testing combined with retinal photography; cost-effectiveness of colour vision testing; and activity-based cost analyses detailing resource use of the various manual and automated colour vision testing strategies.

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**Bibliographic details**
Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.