Single-field fundus photography for diabetic retinopathy screening: a report by the American Academy of Ophthalmology

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CRD summary
The authors concluded that single-field fundus photography can be used as a screening tool to identify patients with diabetic retinopathy who require referral for ophthalmic evaluation and management, but it is not a substitute for a comprehensive examination. Limitations in the literature search and reporting of the review mean that these conclusions should be viewed with caution.

Authors’ objectives
To assess the effectiveness of single-field fundus photography as a screening tool to identify patients with diabetic retinopathy for referral for further ophthalmic care.

Searching
MEDLINE was searched from 1968 to 2001; update searches were conducted in September 2003. The Cochrane Controlled Trials Register was also searched. The search terms were reported. The search was limited to articles published in the English language.

Study selection
Study designs of evaluations included in the review
No inclusion criteria for the study design were specified. The included studies appeared to be diagnostic cohorts and were of both consecutive series and non-consecutively recruited patients.

Specific interventions included in the review
Studies of single-field fundus photography were eligible for inclusion. The examination techniques varied and were described in detail in the text. Where reported, the referral thresholds varied from moderate to severe non-proliferative disease to maculopathy. Some studies used mydriatics where the initial photographs without mydriatics were ungradable, while some studies excluded ungradable photographs.

Reference standard test against which the new test was compared
No inclusion criteria for the reference standard were specified. The included studies used either dilated ophthalmoscopy performed by an ophthalmologist or stereoscopic colour fundus photographs in seven standard fields, as defined by the Early Treatment of Diabetic Retinopathy Study Group (see Other Publications of Related Interest), as the reference standard.

Participants included in the review
Studies of patients with diabetes mellitus undergoing screening for diabetic retinopathy were eligible for inclusion.

Outcomes assessed in the review
No inclusion criteria for the outcome measures were specified. Sensitivity and specificity estimates from the included studies were reported.

How were decisions on the relevance of primary studies made?
The authors reviewed the abstracts of retrieved articles and selected those of possible clinical relevance for the review. It was unclear how many reviewers were involved in the selection process.

Assessment of study quality
A methodologist assigned evidence level ratings (I, II, or III) to all studies that the authors considered to be potentially
clinically relevant.

Level I studies were independent, blind comparisons in an appropriate spectrum (mix of disease severity, treated and untreated, other similar conditions) of consecutively recruited patients, all of whom received both the index test and the reference standard. Level II studies were those conducted in non-consecutive series of patients, or in a restricted spectrum of disease. Studies with an appropriate patient spectrum, where the reference standard was not performed in all patients, were also classified as level II. Level III studies were those in which an unobjective reference standard was performed without blinding, where the index test formed part of the reference standard, or where different reference standards were applied in the case of positive and negative test results. Diagnostic case-control studies were also rated level III.

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

Methods of synthesis
How were the studies combined?
The studies were combined in a narrative.

How were differences between studies investigated?
Level I and level II studies were discussed separately. No formal assessment of between-study heterogeneity was reported. Individual included studies were described in the text and table, but differences between the studies were not explicitly discussed.

Results of the review
Seven studies, three level I (n=667) and four level II (n=331), were included in the review.

Level I studies, comparing single-field fundus photography interpreted by trained readers with the reference standard of stereophotographs of seven fields, reported sensitivities for retinopathy ranging from 61% (specificity 85%) to 90% (specificity 97%) and specificities ranging from 85% (sensitivity 61%) to 97% (sensitivity 85% and 90%).

Level II studies, comparing single-field fundus photography interpreted by trained readers with the reference standard of dilated ophthalmoscopy by an ophthalmologist, reported sensitivities for retinopathy ranging from 38% (specificity 96%) to 100% (specificity 75% and 96%) and specificities ranging from 75% (sensitivity 100%) to 100% (sensitivity 82%).

Authors’ conclusions
Single-field fundus photography is not a substitute for a comprehensive ophthalmic examination, but there is evidence that it is a useful screening tool to identify patients with diabetic retinopathy who require referral for ophthalmic evaluation and management. The advantages of single-field fundus photography interpreted by trained readers are ease of use (only one photograph required), convenience and the ability to detect retinopathy.

CRD commentary
The review clearly stated the research question to be addressed. However, the inclusion criteria used to define the relevant data set were not clearly defined. The search strategy was limited to two bibliographic databases, one of which (the Cochrane Controlled Trials Register) was unlikely to identify the type of studies apparently being sought (diagnostic cohorts) since these are essentially observational studies. The search was further restricted to studies published in English and it is therefore possible that relevant data were missed. The review methods were incompletely reported, so it is not certain whether adequate efforts were made to reduce reviewer errors and bias.
Relevant details of the included studies and their results, in terms of reported test performance, were reported in the text and a table. Due to the lack of details of the data extraction process and inclusion criteria relating to the outcome measures, it is not possible to assess whether the authors derived the reported results from 2x2 contingency data, or took them directly from reports of the included studies; the inclusion of erroneously calculated estimates of diagnostic performance cannot, therefore, be ruled out. The methodological quality of the included studies was assessed using criteria relevant to studies of test accuracy and the studies were assigned an evidence level (I, II, or II). Level III studies appear to have been excluded from the review, although evidence level was not specified as an inclusion criterion.

The authors' conclusion, that single-field fundus photography can be used as a screening tool for diabetic retinopathy, is very much dependent upon what is considered the lower threshold for satisfactory test performance in a screening programme of this type (an area identified by the authors as needing further research).

**Implications of the review for practice and research**
Practice: The authors stated that single-field fundus photography could serve as a screening tool for diabetic retinopathy, but should not be considered a substitute for comprehensive ophthalmic examination. Caution should be exercised in applying the test performance characteristics from reported studies to real world situations.

Research: The authors stated that further studies are needed to assess the implementation of programmes based on single-field fundus photography and to confirm their clinical and cost-effectiveness in real clinical settings. They further stated that future research should include the establishment of standard protocols and satisfactory performance standards for diabetic retinopathy screening programmes.

**Bibliographic details**

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**Other publications of related interest**

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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.