The value of digital imaging in diabetic retinopathy

PF Sharp[1*]
J Olson[2]
F Strachan[3,4]
J Hipwell[3]
A Ludbrook[5]
M O'Donnell[6]
S Wallace[6]
K Goatman[3]
A Grant[6]
N Waugh[7]
K McHardy[8]
JV Forrester[9]

[1] Department of Medical Physics, University of Aberdeen, UK
[2] Department of Ophthalmology, Grampian Universities NHS Trust, UK
[3] Department of Biomedical Physics and Bioengineering, University of Aberdeen, UK
[4] Departments of Ophthalmology and Diabetes, Grampian Universities NHS Trust
[5] Health Economics Research Unit, University of Aberdeen, UK
[6] Health Services Research Unit, University of Aberdeen, UK
[7] Scottish Health Purchasing Information Centre, Grampian Health Board, UK
[8] Consultant, Grampian University Hospitals NHS Trust, UK
[9] Department of Ophthalmology, University of Aberdeen, UK

*Corresponding author

Executive summary

Health Technology Assessment 2003; Vol. 7: No. 30

Health Technology Assessment
NHS R&D HTA Programme

Executive summary

Objectives

To undertake a systematic literature review followed by a primary study to assess the performance of digital imaging, compared with other modalities, in screening for, and monitoring the development of, diabetic retinopathy.

The study addressed three questions:

1. Can a digital imaging system detect retinopathy irrespective of sort or level?
2. Can a digital imaging system detect progression of retinopathy?
3. Can a digital imaging system determine when treatment is required?

Design

Question 1

All imaging was acquired at a hospital assessment clinic. Subsequently, study optometrists examined the patients in their own premises.

Questions 2 and 3

In addition to the above, a subset of patients had fluorescein angiography performed every 6 months.

The gold standard was clinical examination by an ophthalmologist.

All questions were also addressed using automated analysis of digital red-free images.

Subjects

The study invited 1114 patients undergoing direct ophthalmoscopy at the diabetic clinic in Aberdeen; of these, 727 agreed and 387 declined. Of the former 586 attended. Of these 103 patients had type 1 diabetes mellitus, 481 had type 2 diabetes mellitus and two had secondary diabetes mellitus; 157 (26.8%) had some form of retinopathy ('any') and 58 (9.9%) had referable retinopathy.

Results

Question 1: can a digital imaging system detect retinopathy irrespective of sort or level?

Any retinopathy

Manual grading of 35-mm colour slides produced the highest sensitivity (89%) and specificity (89%) figures, with optometrist examination recording most false negatives (sensitivity 75%). Manual and automated analysis of digital images had intermediate sensitivity.

Referable retinopathy

Both manual grading of 35-mm colour slides and digital images gave sensitivities of over 90% with few false positives (specificity 89 and 87%, respectively).

Digital imaging produced 50% fewer ungradable images than colour slides.

Question 2: can a digital imaging system detect progression of retinopathy?

This part of the study was limited as patients with the more severe levels of retinopathy opted for treatment.

There was an increase in the number of microaneurysms in those patients who developed from mild to moderate.

There was no difference between the turnover rate of either new or regressed microaneurysms for patients with mild or with sight-threatening retinopathy.

Question 3: can a digital imaging system determine when treatment is warranted?

Since there was no definite answer to question 2, then the answer must be 'no' at present.

Conclusions

Implications for healthcare

Digital imaging

In the context of a national screening programme for referable retinopathy, digital imaging is an effective method. In addition, technical failure rates are lower with digital imaging than conventional photography. Digital imaging is also a more sensitive technique than slit-lamp examination by optometrists.

Automated grading of digital images

Automated grading can improve efficiency by correctly identifying just under half the population as having no retinopathy.

Recommendations for future research

1. Is the nasal field required for grading? Our study would suggest not. Single-field imaging could potentially reduce the time taken to perform retinal screening and the number of technical failures.
2. Can automated grading safely perform as a first-level grader? Our study would suggest 'yes', but this needs to be confirmed in a large screening programme.
3. Does colour improve the performance of grading digital images? Although high-resolution colour digital images are now routinely available, their role in screening for diabetic retinopathy has yet to be assessed.
4. Can patient recruitment be improved? Future research is required to ensure effective uptake in a diabetic retinopathy screening programme.

Publication

Sharp PF, Olson J, Strachan F, Hipwell J, Ludbrook A, O'Donnell M, *et al*. The value of digital imaging in diabetic retinopathy. *Health Technol Assess* 2003;**7**(30).

NHS R&D HTA Programme

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Initially, six HTA panels (pharmaceuticals, acute sector, primary and community care, diagnostics and imaging, population screening, methodology) helped to set the research priorities for the HTA Programme. However, during the past few years there have been a number of changes in and around NHS R&D, such as the establishment of the National Institute for Clinical Excellence (NICE) and the creation of three new research programmes: Service Delivery and Organisation (SDO); New and Emerging Applications of Technology (NEAT); and the Methodology Programme.

This has meant that the HTA panels can now focus more explicitly on health technologies ('health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care) rather than settings of care. Therefore the panel structure was replaced in 2000 by three new panels: Pharmaceuticals; Therapeutic Procedures (including devices and operations); and Diagnostic Technologies and Screening.

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The research reported in this monograph was funded as project number 94/18/05.

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ISSN 1366-5278

Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.
Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.