The effectiveness of the Heidelberg Retina Tomograph and laser diagnostic glaucoma scanning system (GDx) in detecting and monitoring glaucoma

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Executive summary

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**Objectives**

The objectives of this study were:

- To compare the diagnostic accuracy of optic nerve head tomography [Heidelberg Retina Tomograph (HRT)] and scanning laser polarimetry (GDx) for identifying patients with glaucomatous visual field loss.
- To investigate the applicability of the instruments in an unselected population of hospital patients.
- To measure the length of time required for a full examination.
- To calculate between- and within-observer variability in HRT and GDx measurements.

**Design**

Examinations were performed with the HRT, GDx and Humphrey Field Analyzer (HFA). Glaucoma was defined by the presence of a field defect. Patients within the cross-sectional groups underwent a single examination, whereas patients in the longitudinal groups were examined 6 monthly, for an average of 3.5 years.

**Setting**

The study was carried out by the University of Manchester at Manchester Royal Eye Hospital.

**Participants**

Cross-sectional groups:

- 98 normal controls
- 152 patients with primary open angle glaucoma (POAG).

Longitudinal groups:

- 240 patients at risk of developing glaucoma (either due to high intraocular pressure, and/or a fellow eye with POAG)
- 75 patients with POAG.

**Main outcome measures**

For the cross-sectional groups, the diagnostic accuracies of the HRT and GDx were compared; specificity was set at 95%. The extent of agreement was determined. In the longitudinal cohorts, the rate of change was determined by linear regression. The ability of the techniques to identify cases showing deterioration was investigated.

To estimate the clinical application of the instruments, the proportion of an unselected group of patients on whom the examinations could be performed was calculated. Additionally, the time taken to perform and process each examination was measured.

**Results**

From the cross-sectional group, the maximum sensitivities of the HRT and GDx were 59% and 45%, respectively (at 95% specificity). From the two longitudinal cohorts, the level of agreement between the three instruments for identification of the development and deterioration of POAG was low.

The applicability of the techniques was 80% (HRT), 88% (GDx) and 98% (HFA). The length of time to perform a full examination with each instrument was 12.3, 11.8 and 28.3 minutes, respectively.

Agreement of HRT and GDx parameters between and within observers was largely good.

**Conclusions**

There is poor agreement for detection of glaucoma between the HFA, HRT and GDx. The techniques are amenable to use in the clinical environment, but no single examination has sufficient diagnostic precision to be used in isolation; also, the imaging techniques were not universally applicable. Neither the HRT nor GDx should be viewed as a replacement for visual field examination.
Implications for healthcare

All cases of suspect, incipient or progressing glaucoma cannot be detected by one form of examination (e.g. HRT, GDx or HFA) alone. Since agreement between the three techniques is low, several different tests are necessary to optimise diagnostic precision.

Further research

The following areas are recommended for further research:

- To determine why most patients within the longitudinal arms of the study showed very little deterioration.
- The determination of aspects of the structure versus function relationship in glaucoma, which may explain why any one technique fails to detect a proportion of cases.

Publication

The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the ‘National Knowledge Service’ that is being developed to improve the evidence of clinical practice throughout the NHS.

The HTA Programme was set up in 1993. Its role is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS. ‘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.

The HTA Programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, service-users groups and professional bodies such as Royal Colleges and NHS Trusts. Research suggestions are carefully considered by panels of independent experts (including service users) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or conducting a trial to produce new evidence where none currently exists.

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Reviews in *Health Technology Assessment* are termed ‘systematic’ when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this monograph was commissioned by the HTA Programme as project number 95/18/04. The contractual start date was in April 1998. The draft report began editorial review in July 2004 and was accepted for publication in March 2005. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors’ report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health.

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