TITLE: Optical Coherence Tomography versus Heidelberg Retinal Tomography for Monitoring and Diagnosing Eye Diseases: Comparative Clinical and Cost-Effectiveness and Guidelines for Use

DATE: 20 November 2008

RESEARCH QUESTIONS:

1. What is the comparative clinical effectiveness of optical coherence tomography versus Heidelberg retinal tomography?

2. What is the comparative cost-effectiveness of optical coherence tomography versus Heidelberg retinal tomography?

3. What are the guidelines for use of optical coherence tomography and Heidelberg retinal tomography?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, the Cochrane Library (Issue 4, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2003 and November 2008, and are limited to English language publications only. No filters were applied to limit the retrieval by study type. Internet links are provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.
RESULTS:

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by economic evaluations, randomized controlled trials (RCTs), controlled clinical trials, observational studies, and evidence-based guidelines.

Two controlled clinical trials and five observational studies were identified pertaining to the clinical effectiveness of optical coherence tomography versus Heidelberg retinal tomography. No relevant health technology assessments, economic evaluations, RCTs, or evidence-based guidelines were identified.

OVERALL SUMMARY OF FINDINGS:

Controlled clinical trials

Caprioli et al. compared the ability of optic disc and retinal nerve fiber layer (RNFL) imaging to discriminate between the unaffected eyes of glaucoma patients (n=46) and normal eyes from patients without glaucoma (n=46).\(^1\) Stratus Optical Coherence Tomography (OCT) and Heidelberg Retina Tomography (HRT) II performance was compared using receiver operator characteristic (ROC) curves. Parameters with the largest area under the ROC curves were inferior average RNFL thickness (0.92±0.03) for OCT and linear cup-to-disc ratio (0.82±0.05) for HRT II. OCT identified more perimetrically normal glaucomatous eyes as having some abnormality compared to normal eyes than did HRT II (P=0.001). Authors concluded that optical coherence tomography may detect evidence of glaucoma damage earlier than HRT II.

Iliev et al. compared the diagnostic performance of OCT with that of HRT.\(^2\) Patients with ocular hypertension, glaucoma-like discs, glaucoma, and healthy controls were imaged with OCT disc mode and HRT II. A total of 49 eyes were evaluated. With regard to the accuracy in determining optic nerve head borders, OCT performed well. HRT performed better than OCT in discs with large cups and OCT values were consistently larger than those of HRT of the disc and cup area. Small rim areas and volumes were minimized and larger ones magnified by OCT when compared with HRT. Authors concluded Stratus OCT disc protocol performed well overall, however, disc border recognition frequently failed.

Observational studies

In a retrospective cross-sectional study, Badala et al. compared optic disc and RNFL imaging methods to discriminate normal eyes from eyes with early glaucoma.\(^3\) Ninety-two patients (92 eyes) participated, 46 of which had early perimetric open-angle glaucoma and 46 of which were controls. Diagnostic performance of OCT (Stratus OCT) and HRT (Heidelberg retinal tomograph III) were compared. Area under receiver operator characteristic curves (AUCs) and sensitivities at fixed sensitivities were measured and classification and regression tree (CART) analysis was used to evaluate combinations of quantitative parameters. Parameters with largest AUCs (± standard error) were average RNFL thickness for StratusOCT (0.96 ± 0.02) and Frederick S. Mikelberg (FSM) discriminant function for HRT III (0.91 ± 0.03). CART showed a 91% sensitivity and 96% specificity when Stratus OCT average RNFL thickness and HRT III cup-to-disc area were combined. Authors concluded that high diagnostic precision could be obtained using a combination of OCT and HRT.
Naithani et al. sought to evaluate the relationship between optic nerve head (ONH) and peripapillary retinal nerve fiber layer (RNFL) parameters by OCT and confocal scanning laser ophthalmoscopy (HRT) in early and moderate glaucoma. As well, they compared several OCT-based automated classifiers with those inbuilt in HRT for detection of glaucomatous damage. Sixty eyes of 60 patients with glaucoma (30 early and 30 moderate visual field defects) and 60 eyes of 60 healthy subjects were studied. Patients were evaluated first using Fast Optic Disc and Fast Peripapillary RNFL scans on the OCT and subsequently with HRT to evaluate ONH. Values from OCT and HRT related to glaucoma were analyzed among groups. To classify eyes as either glaucomatous or normal, ROC curves were generated using linear discriminant analysis (LDA), artificial neural networks (ANN) and CART on OCT-based parameters were compared with the Moorfield regression analysis (MRA), R Bathija (RB), and FS Mickelberg (FSM) functions in the HRT. With respect to disc area, no statistically significant difference was found between OCT and HRT within study groups (P>0.05). The areas under ROC curves were 0.9822 (LDF), 0.9791 (CART), and 0.9383 (ANN) as compared with 0.859 (FSM), 0.842 (RB) and 0.767 (MRA). Authors concluded that OCT-based classifiers were superior to HRT-based classifiers when distinguishing between healthy and glaucomatous eyes.

To compare the ability to discriminate between healthy and glaucomatous eyes, Pueyo et al. studied scanning laser plarimeter (GDx VCC) HRT and Stratus OCT measurements in 139 eyes from 139 subjects. Sixty-six of the patients had health eyes, 73 had intraocular pressure and standard automated perimetry measurement values that classified them as glaucomatous. The best criteria discriminating between healthy and glaucomatous eyes were Moorfields regression analysis out of the 95% confidence interval (HRT-II), OCT retinal nerve fiber layer average thickness <77 microm, and nerve fiber indicator >37 (GDx VCC) with sensitivities of 85%, 66%, and 48%, with specificity higher than 95%. Authors concluded that both OCT and HRT are useful in evaluating glaucomatous damage.

The diagnostic ability of HRT and OCT were also compared in 2006 by DeLeón-Ortega et al. The healthy (n=149) and glaucomatous (n=79) eyes of 228 participants were analysed using HRT-II, GDx VCC, OCT, and a subjective assessment of ONH stereographs. ROC curves were constructed for each device and sensitivity was estimated at 80% of specificity. Similar diagnostic ability was found for all imaging techniques; however, none demonstrated superiority to subjective assessment of optic nerve head stereographs.

Madeiros et al. used scanning laser polarimetry with variable corneal compensation (GDx VCC), confocal scanning laser ophthalmoscopy (HRT II [Heidelberg Retina Tomograph]), and optical coherence tomography (Stratus OCT) to discriminate between healthy eyes and eyes with glaucomatous visual field loss. One hundred and eighty-three patients were studied, 107 with visual field loss due to glaucoma and 76 healthy controls. After patients with unacceptable images were excluded, the GDx VCC, HRT II and OCT RNFL scans of 141 eyes of 141 subjects (66 healthy controls, 75 with glaucomatous visual field loss) were analyzed. There were no statistically significant differences between the areas under the ROC curves for the best parameters from OCT (RNFL thickness AUC=0.92) and HRT II (linear discriminant function AUC=0.86). Authors concluded that AUCs and sensitivities at high specificities were similar for the best parameters of each instrument.

Comparative evidence for the superiority of either OCT or HRT is mixed. OCT performs well in determining glaucomatous damage, as does HRT. Furthermore, one study claimed that best results could be obtained by taking both OCT and HRT measurements. Only one study concluded that optical coherence tomography has the potential detect evidence of glaucoma damage earlier than HRT II. Overall, both techniques have been shown to differentiate...
between glaucomatous and healthy eyes.\textsuperscript{1,3,5-6} No relevant cost information or guidelines were identified.
REFERENCES SUMMARIZED:

Health technology assessments
No literature identified.

Systematic reviews and meta-analyses
No literature identified.

Economic analyses and cost information
No literature identified.

Randomized controlled trials
No literature identified.

Controlled clinical trials


Observational studies


Guidelines and recommendations
No literature identified.

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APPENDIX – FURTHER INFORMATION:

Observational studies


Review articles


Product information