CLINICAL JUDGMENT OF GDX vcc VERSUS GDX gss

in the detection of nerve fibre layer thinning for glaucoma patients

A PRELIMINARY STUDY

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ABSTRACT

The aim of this preliminary study was to compare retinal nerve fibre layer (RNFL) thinning in patients with either established or suspected glaucoma using the two nerve fibre analysers (GDx gss and GDx vcc) manufactured by Laser Diagnostics Technologies Inc (San Diego). The results obtained were compared with conventional clinical data of 33 patients attending glaucoma clinic. The results demonstrated that both analysers were useful for detecting RNFL loss in established glaucoma and have a positive correspondence with conventional clinical data. The GDx vcc was superior in detecting RNFL loss, which corresponded with the clinical data in 23% of glaucoma suspects compared with a lesser outcome from the original GDx gss. However, from the results there is a significant possibility that 41% of glaucoma suspects may go undetected irrespective of which GDx analyser is used.

Key words: Retinal nerve fibre layer, GDx, glaucoma.

INTRODUCTION

In recent decades ophthalmology has seen many advances in the early detection of glaucoma, primarily assisted by new and improved methods for detection of retinal nerve fibre layer (RNFL) damage. It is now recognised that RNFL damage is visible up to 6 years prior to visual field damage[1]. Nerve fibre analysis using polarimetry is believed to "show damage that leads to glaucoma" as opposed to optic disc and visual field findings that show the damage resulting from glaucoma.[2]

The GDx analyser technology, which is based on scanning laser polarimetry, measures the thickness of the RNFL rather than the surface topography of the retina. The birefringent properties of the nerve fibres cause the polarized laser light to split into two parallel rays that travel at different velocities. The light undergoes a wavelength shift proportional to the thickness of the RNFL. The retardation of the parallel rays as they emerge from the RNFL, directly correlates to the nerve fibre layer thickness.

As the cornea and lens also have birefringent properties, the original GDx Glaucoma scanning system (GDx gss) incorporated a " corneal compensator" to correct for the effect this may have on the retardation measurements. The compensator is set for the average cornea, and is considered to be satisfactory for 80% of patients; however, some patients significantly deviate from the average. When the corneal compensation falls outside 80%, the RNFL may appear thinner or thicker than normal, which leads to unreliable results[3].

To overcome the variability in results associated with the corneal birefringent property, the manufacturers have released the GDx Variable Corneal Compensation (vcc) or GDx Access. The new technology determines and corrects for anterior segment birefringence, from both the cornea and lens, based on individual eye determinations rather than an 'average' corneal birefringent database.

AIM

To determine if individual corneal birefringent compensation in the updated analyser made a difference to the RNFL measurements, staff from the Orthoptic Department undertook a one-month trial, where patients were scanned with both analysers. The results from the two analysers were compared with each other using the Temporal-Superior-Nasal-Inferior-Temporal (TSNIT) graph as the main benchmark. This method was selected because the range of the global indices used in the updated GDx vcc are not the same as those used in the GDx gss and hence not comparable.[2] The TSNIT graph compares 13 parameters with a normative database and highlights deviations from the average parameters. The TSNIT graphs were judged on the image quality of the printouts, retardation of the image, position of the plot relative to the distribution and symmetry of superior and inferior bundles and shape and maximum/minimum height of the TSNIT humps. To analyse the clinical benefit and use of the GDx analysers as glaucoma detection tools, the results of each TSNIT graph were compared with the other clinical data, which included the optic nerve head appearance, intra-ocular pressures and visual fields of each patient. The clinical data was extracted from the medical records of patients attending glaucoma specialty clinics.

METHOD

The clinical evaluation involved a judgment by two orthoptists who individually viewed each set of GDx data along with the ophthalmologists' clinical report. The orthoptists then pooled their findings to determine which subjects were to be included in the

study. Allowing each Orthoptist to analyse and compare the results independently before coming to a conclusion was designed to reduce bias in the study.

The study population was recruited from the hospital glaucoma clinics and subjects had either established glaucoma or were glaucoma suspects. In the initial analysis of the data, the results of 33 patients were randomly selected and reviewed. Subjects ranged between the ages of 33 - 91 years with 21 females and 14 males. Subjects were of Caucasian and Asian ethnicity.

Subjects excluded from the analysis included those whose visual field results were judged by the reliability parameters on Humphrey field printout to produce an inadequate outcome . Patients with conditions that cause optic nerve changes such as multiple sclerosis were also excluded. In addition, scans which showed large optic discs, which required an ellipse size outside the standard calculation area, were excluded.

Conventional clinical test results: all subjects were tested on the Humphrey field analyser using the SITA-Standard 24-2 program. When two or more adjacent areas were depressed by 5dB or more in an area at risk of glaucoma loss (i.e. glaucoma hemi-field areas) these fields were treated as suspect or glaucomatous and used for comparison with the RNFL image. This selection was based on the presumption that areas of field loss and loss of the RNFL should correspond.

Optic nerve head appearance judged as suspicious included a cup/disc ratio greater than 0.3 for both colour and contour and any disc abnormalities consistent with glaucoma such as peripapillary atrophy, rim notching/ thinning or shelving. Pressures measured by Goldmann tonometry were considered suspect when above 21mmHg ± 1.22mmHg. This range accounts for the known variations in central corneal thickness[5].

GDX tests : each subject was scanned on both GDx analysers by the same orthoptist. Three single images were obtained on the GDx gss and the highest quality picture was kept for analysis. Only one image of RNFL was taken on the GDx vcc, which is consistent with the acquisition guidelines for this analyser. The results analysed compared the subjects' paired eyes and not individual eyes, as this was determined to resemble the clinical picture more closely. Examining both eyes also allowed for comparison of any asymmetry in RNFL between the two eyes and to determine if this asymmetry was also detected in the subjective data (cupping of discs, visual fields and pressures).

RESULTS

The results were assessed by clinical judgement, as normally conducted in clinical practice. The use of clinical judgement was considered to be appropriate as the orthoptists involved in the evaluation have five years experience in the use and evaluation of the original GDx. Choplin and Sanchez-Galeana[6,7] investigated the "power of expert judgments of the GDx printouts for detecting glaucoma " and concluded that clinical judgment of printouts was superior to the automatically generated parameters, such as 'The Number'.

Thirty three patients fulfilled the criteria for this study. Eleven (33%) had established glaucoma, and were on single or combination dose glaucoma treatment. Twenty two (67%) were identified as glaucoma suspects, defined by suspicious results on either tonometry, optic nerve head appearance or visual fields, these patients were not on any glaucoma treatment. Of the 11 patients with established glaucoma, ten (91%) showed corresponding nerve fibre loss on the TSNIT graphs in both GDx printouts with the clinical data. In the remaining subject there was no correspondence between either GDx or the clinical evidence.

Of the 22 glaucoma suspects, eight (36%) showed similar nerve fibre loss on the TSNIT graph between the two analysers and the RNFL thinning correlated with the visual field loss and optic nerve head appearance. Five of the 22 (23%) subjects showed nerve fibre loss that correlated closely with the TSNIT graph of the GDx vcc and the clinical data. In these subjects there was no correlation with the GDx gss.

In nine (41%) of the glaucoma suspects it was difficult to decide which of the two GDx models was the more accurate. In these subjects there was no correspondence between the two TSNIT printouts of either analyser, with the analysers eliciting nerve fibre loss in different quadrants of the TSNIT. In addition, the RNFL loss of both was not consistent with the clinical data presented, so a benchmark could not be determined. Table 1 lists the results of the study.

Table 1.

Defect	No. of patients	Correspondence of both GDx with clinical data	Correspondence of GDx vcc only with clinical data	Correspondence of GDx gss only with clinical data	Neither
Established glaucoma	11	10 corresponded	0	0	1
Glaucoma suspects	22	8	5	0	9

Table 1. Comparison of GDx results with clinical data in subjects with established glaucoma and glaucoma suspects.

DISCUSSION

In this study, ten subjects with established glaucoma as determined by conventional clinical tests had nerve fibre loss present on both TSNIT graphs of the GDx gss and GDx vcc, which corresponded with the clinical data. Detection rates of RNFL loss were higher in advanced glaucoma as opposed to early glaucoma with both analysers. The results confirm that the GDx gss and GDx vcc are useful tools for detecting advanced cases of glaucoma in 91% of patients.

In the glaucoma suspects, the GDx vcc, which compensates for anterior segment birefringence was a more effective tool than the GDx gss in 23% more cases for diagnosing RNFL loss that corresponds with clinical evidence.

In spite of the increased diagnostic value of the GDx vcc, the role of nerve fibre analysers in glaucoma screening is still subject to some scepticism as to the clinical value. Essentially, the cost benefit of screening needs to be decided, keeping in mind that 41% of glaucoma suspects may be missed with both GDx analysers, and perhaps clinicians may have to according to Colen et al[8] "...accept that some early cases of glaucoma may be undetected". To determine the cost effectiveness of this technology further research needs to be undertaken. Comparisons of the TSNIT graphs to results from the SWAP visual fields and/or Frequency Doubling Technique, which are accepted as detecting early glaucomatous changes prior to any abnormality appearing on the SITA-Standard visual field techniques should be conducted. A statistical evaluation of both analysers for glaucoma suspects also needs to be performed, comparing the sensitivity and specificity of each analyser in early glaucoma compared with a control age-matched normal group.

In conclusion, the GDx gss and GDx vcc are effective clinical tools for detecting RNFL loss in established glaucoma and have a positive correlation with the clinical data. In glaucoma suspects, evidence of glaucoma comparable to the clinical data has a higher frequency of detection with the GDx vcc compared with the GDx gss. However, from the results there is a significant possibility that 41% of glaucoma suspects may go undetected irrespective of which GDx analyser is used. Given that over 300,000 Australians currently have glaucoma and this proportion will increase with our aging population[9], the improved early detection of RNFL loss with the GDx vcc deserves consideration. The medical benefit to the patient and saved financial cost to the community of early detection in 23% of glaucoma suspects with the GDx vcc warrants the inclusion of this equipment in the management of glaucoma.

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