Accuracy of the ICare rebound tonometer in glaucomatous eyes with topical ocular hypotensive medication

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Abstract

Background: The purpose of this study was to assess the accuracy of the ICare tonometer, using the Perkins applanation tonometer (AT) as the reference, in a sample population being treated with travaprost 0.004% for glaucoma.

Material and methods: Twenty-eight consecutive patients with open-angle glaucoma or ocular hypertension who had been receiving travaprost 0.004% to control elevated intraocular pressure (IOP) were included in the study. IOP was measured in the entire sample with ICare and Perkins AT. The difference between the methods was plotted against the mean to compare the tonometers. The hypothesis of zero bias was examined by a paired $t$-test. The 95% limits of agreement (LoA) were also calculated.

Results: As previously found in young healthy subjects, ICare showed a tendency to overestimate Perkins IOP measurements by a mean of 3.57 mmHg. The agreement between the two methods is shown by the 95% LoA which was from $-9.37$ to $+2.23$ mmHg: 53% of the IOP differences fell within $\pm3$ mmHg.

Conclusions: The performance of the ICare tonometer in glaucomatous patients being treated with travaprost 0.004% to lower the IOP appears to be similar to that of young healthy patients. The tendency of ICare to overestimate the IOP readings should be considered when the instrument is used in the follow-up of glaucomatous patients.

Keywords: glaucoma, ICare, intraocular pressure, Perkins tonometry, portable tonometers, rebound tonometry

Introduction

Glaucoma is a progressive neuropathy of the optic nerve that may cause irreversible blindness (Tuulonen et al., 2003), so early detection is critical. Risk factors include age (Tuck and Crick, 1998; Wensor et al., 1998), family history (Wolf’s et al., 1998) and the presence of myopia (Grodum et al., 2001). Intraocular pressure (IOP) is an important risk factor for developing glaucomatous damage (Racette et al., 2003) and the risk increases with IOP (Sommer et al., 1991). Furthermore, lowering IOP is the only treatment for glaucoma (Tuulonen et al., 2003).

There are currently a number of tonometers for the assessment of IOP, although the Goldmann applanation tonometer (GAT) is still considered the gold standard for IOP measurement (Hansen, 1995; Wingert et al., 1995; Cho and Lui, 1997; Jorge et al., 2002; Fernandez et al., 2005; Garcia et al., 2005; van der Jagt and Jansonius, 2005).

In order to assess IOP outside the consulting room, such as in bedridden patients or for screening purposes, a portable version of the GAT was conceived (Perkins AT, Clement Clarke International Ltd, Harlow, UK), and this has been considered as a reference standard for
portable tonometers because of the close agreement found between Goldmann and Perkins AT (Chiara et al., 1989; Wingert et al., 1995; Jorge et al., 2002).

Over the last few years, new tonometers have been developed with the aim of simplifying the IOP measurement process and to allow their use by non-specialist personnel. These are non-contact tonometers (NCT) (Hansen, 1995; Cho and Lui, 1997; Jorge et al., 2002; García et al., 2005); portable tonometers such as Tono-Pen XL (Wingert et al., 1995; García et al., 2005; van der Jagt and Jansonius, 2005); or the palpebral TGdc-01 (García et al., 2005; van der Jagt and Jansonius, 2005). Those instruments have been compared with Goldmann or Perkins AT to determine their suitability, but mainly in normal subjects (Cho and Lui, 1997; Jorge et al., 2002; Fernandes et al., 2005; García et al., 2005).

The ICare (Tiolat Oy, Helsinki, Finland) is a new portable tonometer that measures the IOP based on processing the rebound movement of a rod probe, resulting from its interaction with the eye (van der Jagt and Jansonius, 2005; García-Resua et al., 2006). This tonometer has been described in detail by García-Resua et al. (2006). These authors tested the accuracy of the ICare tonometer in a young healthy population by comparing its results with those obtained with the Perkins AT (García-Resua et al., 2006). The study also included another portable tonometer, the Tono Pen-XL. Results showed systematic overestimation of IOP with the ICare and a moderate trend for differences between Perkins and ICare to increase as IOP increases (García-Resua et al., 2006). However, the commonest application of tonometry is the detection and follow-up of patients undergoing medication to control elevated IOP, and comparisons of new tonometers with AT in glaucomatous patients are not often reported.

The effects of different topical glaucoma treatments on the human cornea have been reported previously. Four-week treatment with timolol (0.5%) resulted in a decreased tear volume on the ocular surface and modified corneal epithelial barrier function (Ishibashi et al., 2003). Therefore, IOP measurements could be affected as Whitacre and Stein (1993) have reported. Glaucoma treatment with travaprost 0.004% has been associated with central corneal thinning (Harasymowycz et al., 2007), and this could affect the applanation resistance of the cornea (Harasymowycz et al., 2007). Previous studies generally displayed poor agreement when other types of tonometers were compared with AT in glaucomatous patients (Mackie et al., 1996), although at present, the upgraded version of NCT seems to offer good reliability in patients affected by glaucoma (Jorge et al., 2003).

The purpose of this study was to establish the level of confidence of the new portable ICare tonometer in a glaucomatous population being treated with Travatan® (travaprost 0.004%) as this glaucoma treatment could affect corneal thickness. The Perkins applanation tonometer was used as a reference.

Material and methods
Following informed consent, measurements of IOP were obtained from 28 consecutive patients (35.5% men and 64.5% women) with open-angle glaucoma or ocular hypertension who had been receiving topical administration of Travatan® (travaprost 0.004%; Alcon Laboratories Inc., Fort Worth, TX, USA) from a private ophthalmology clinic in Galicia (Spain). The age of patients ranged from 34 to 84 years (mean 67.31 ± 13.55 years) and those subjects with either irregular astigmatism or regular astigmatism greater than 3 DC were excluded (Whitacre and Stein, 1993). All procedures followed the Declaration of Helsinki and were approved by the Ethics Committee of the University of Santiago de Compostela.

To reduce between-observer bias, all measurements were carried out by the same clinician. The order in which the two tonometers were used was intended to avoid an increase of aqueous outflow by corneal compression, which might contaminate subsequent IOP readings, (Krakau and Wilke, 1971). The ICare tonometer was always used first because it did not require anaesthetic, followed by the Perkins tonometer. An interval of 5 min was allowed between the application of techniques to recover from potential corneal compression. All the measurements were performed between 11:00 and 13:00 hours to minimize the diurnal variation in IOP (Wilensky et al., 1993).

ICare Tonometer
The ICare tonometer uses disposable probes that interact with the central cornea quickly and gently. The subject was asked to look straight ahead to a far point while the examiner placed the tonometer near the subject’s eye. Care was taken to ensure that the distance from the tip of the probe to the cornea of the eye was 4–8 mm, adjusting the forehead-support when necessary, as recommended by the manufacturer. Once the tonometer was correctly adjusted, six repeated IOP readings with a limit of precision of 1 mmHg were acquired by pressing the tonometer acquisition button.

Perkins applanation tonometer
This instrument uses the same measurement principle as the GAT. Before acquisition, one drop of fluorescein
anaesthetic solution (2.5 mg mL⁻¹ oxibuprocaine and 4 mg mL⁻¹ fluorescein) was instilled. Care was taken to obtain an appropriate width for the fluorescein rings. Too broad fluorescein rings could lead to an overestimation of the IOP reading by up to 4.6 mmHg, and low fluorescein concentration can underestimate the IOP by 1.5 to 9 mmHg (Whitacre and Stein, 1993). Two successive measurements with a precision limit of 1 mmHg were obtained and then averaged. The biprism was disinfected with 3% hydrogen peroxide and rinsed with saline solution between subjects.

**Statistical analysis**

Data were analysed using the statistical package SPSS v. 12.0.1 for Windows (SPSS Inc., Chicago, IL, USA). Mean and standard deviation (S.D.) were calculated for each parameter. A regression analysis was used to evaluate the level of concordance between IOP measurements from each tonometer in the study. The coefficient of correlation is a measure of the relation, rather than the agreement between two values. Bland and Altman (1986) described a method of measuring test agreement using plots of differences against mean values as the best way to compare measurements with different instruments, when the actual measurement is unknown. The bias was assessed statistically as the mean of the differences compared with zero. The hypothesis of zero bias was examined by a paired t-test. The 95% limit of agreement (LoA; mean of the difference ±1.96 S.D. of the differences) was also calculated.

**Results**

The mean difference in Perkins IOP between right and left eyes was statistically significant (paired t-test; Perkins IOP right eye – Perkins IOP left eye = −1.89 ± 4.66 mmHg; p = 0.041), whereas ICare did not show a statistically significant difference between both eyes (p = 0.214). These IOP asymmetries, which are significantly larger when considering glaucoma populations (Mackie et al., 1996), supports the use of each eye as a separate sample.

Table 1 shows the results for IOP measured with both tonometers in the 56 eyes of the 28 patients. Mean, S.D., and maximum and minimum values of IOP measurements are shown. ICare overestimated the mean IOP obtained by Perkins AT and the difference was statistically significant at 3.57 ± 2.98 mmHg (paired t-test; t = −9.01, p < 0.001) showing a LoA from −9.37 to +2.23 mmHg. Although the mean difference was −3.57, with the LoA covering a range of ±5.80 mmHg, the maximum difference in IOP could be as much as −9.37 mmHg.

A strong correlation between ICare and Perkins tonometers was found, showing a good relationship between both tonometers as indicated by a correlation coefficient of r = 0.71 and a determination coefficient of r² = 0.51, which were statistically significant (p < 0.001). Figure 1 shows the scatterplot and regression line for that comparison whose equation is:

ICare = 0.95Perkins + 4.36.

Approximately 53% of the IOP differences between Perkins and ICare fell within ±3 mmHg and 75% fell between ±5 mmHg.

Plots of differences against mean for each comparison, as advocated by Bland and Altman, are displayed in Figure 2, where the mean of differences and the 95% LoA are also shown. Linear regression analysis of the difference vs mean showed a statistically significant trend towards a greater difference between Perkins and ICare as IOP increased (r = 0.38, r² = 0.14; p = 0.004).

**Discussion**

The present study shows the validity of IOP measurements obtained by the new ICare rebound portable
tonometer on a glaucomatous population being treated with travaprost 0.004%. This, in other words, shows us the efficacy of the ICare tonometer to follow up patients undergoing medical treatment to control elevated IOP, when that glaucoma treatment could affect corneal thickness and ocular surface (Ishibashi et al., 2003; Harasymowycz et al., 2007).

Commonly, the assessment of IOP is generally based on the use of Goldmann or Perkins tonometers which represent the ‘gold standard’ for applanation tonometry (Hansen, 1995; Wingert et al., 1995; Cho and Lui, 1997; Jorge et al., 2002; Fernandes et al., 2005; Garcia et al., 2005; van der Jagt and Jansonius, 2005; Garcia-Resua et al., 2006). However, these devices can only be used by specialized personnel and, in the case of the Goldmann AT, not outside the consulting room. The advent of safe, reliable and easy-to-use new tonometers could allow monitoring of IOP outside the clinic hours and even in the patient’s home. This type of tonometry, commonly called self-tonometry (Kothy et al., 2003; Naruse et al., 2005), does not disturb the usual daily routine of the glaucoma patient, and makes it possible to measure IOP during the night and early morning hours without the need for hospitalization of the patient. This is important taking into account the diurnal variation of the IOP (Wilensky et al., 1993), because patients with well-controlled glaucoma can experience diurnal IOP peaks higher than 22 mmHg outside regular office hours (Wilensky et al., 1987; Asrani et al., 2000). The ICare tonometer does not require the use of anaesthetic and hence, because of its safe and easy method of acquisition, it could be used by the patient’s relatives at home (Garcia-Resua et al., 2006).

In this study Perkins AT was considered the gold standard because it has the same measurement principle as GAT and close agreement has been found between the two devices (Chiara et al., 1989; Wingert et al., 1995; Jorge et al., 2002). Previous studies comparing portable techniques also considered Perkins as the gold standard (Lagerlof, 1990; Evans and Wishart, 1992; Garcia et al., 2005).

In the present study there were statistically significant differences of IOP between the two eyes as expected in glaucomatous populations. This asymmetry between right and left eye supports, as reported by other authors, the use of each eye from the same patient as a separate sample (Mackie et al., 1996; Jorge et al., 2003). However, this was only found with the Perkins AT, whereas ICare IOP measurement did not reveal such an asymmetry.

The mean Perkins IOP obtained in the present study was 15.63 mmHg. This is a low IOP mean value for a glaucomatous population, but all the subjects were receiving active treatment to reduce IOP before and during the study. Other studies of glaucomatous subjects who had been treated with topical medication showed higher mean AT IOP values (Wingert et al., 1995; Mackie et al., 1996; Jorge et al., 2003), which may be explained by the different modalities of treatment used in each study.

The mean IOP value using the ICare tonometer in this study was higher than that obtained by Perkins, and was similar to those obtained in glaucomatous populations with other type of tonometers (Wingert et al., 1995; Mackie et al., 1996; Jorge et al., 2003). This difference was statistically significant and reflects an overestimation of the ICare tonometer over Perkins AT by a mean of 3.57 mmHg. The plot of difference against mean IOP displayed in Figure 2 showed an overestimation of the IOP by the ICare tonometer on the entire range of IOP measured in the study. The LoA were ±5.80 mmHg and showed a statistically significant trend for differences between Perkins and ICare to increase as IOP increases ($r^2 = 0.14; p = 0.004$). In a previous study, the authors found similar results on young healthy subjects (Garcia-Resua et al., 2006). The LoA were slightly narrower (±4.47 mmHg) and showed a moderate trend for differences between Perkins and ICare to increase ($r^2 = 0.19; p < 0.001$) driven by the higher IOP values. When the IOP values ≥20 mmHg were removed from analysis, the LoA decreased (±3.97 mmHg), being similar to those LoA found by Fernandes et al. (2005) in a young healthy sample (±3.98 mmHg) where IOP AT sample values ranged.
from 8 to 18 mmHg. Furthermore, Fernandes et al. (2005) also found a significant overestimation of the ICare over the entire IOP range studied, with a similar trend of an increase in the difference as IOP increased. Conversely, van der Jagt and Jansonius (2005) did not find a statistically significant difference between ICare and AT measured by Goldmann. In their study the sample included 85 normal subjects and 17 patients with ocular hypertension or glaucoma. The age range was 24–86 years, similar to the sample reported here (58 ± 12 years). However, although there was no significant mean difference, the LoA showed a range of ±6.5 mmHg which was higher than that found by Garcia-Resua et al. (2006).

From the results reported in this study, there is a tendency for ICare to overestimate IOP measurements of patients receiving travoprost 0.004% topical medication for glaucoma. These results agree with those obtained in young healthy subjects, which indicate that the treatment with travoprost 0.004% does not affect the accuracy of the ICare IOP readings. The source of the differences in both tonometers, either in treated or healthy subjects, may be explained by the principle of measurement. Perkins AT uses a constant corneal compression which is more likely to lead to a decline in the IOP than is the case with the ICare tonometer, which touches the cornea more gently (Whitacre and Stein, 1993). From the results obtained here, it can be seen that low ICare readings are not likely to be higher when measured with the Perkins tonometer. However, in order to obtain an accurate measurement near to the true value of IOP, AT should be used when higher values have been obtained with ICare.

References


