

Reproducibility and Clinical Evaluation of Rebound Tonometry

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PURPOSE. To establish the reproducibility of a rebound tonometer in humans and the effect of corneal thickness on measurements, comparing it with Goldmann applanation tonometer.

METHODS. In a first study designed to examine the reliability of the RBT, three experienced ophthalmologists undertook three consecutive intraocular pressure (IOP) measurements in 12 eyes of 12 normal subjects. A cross-sectional study was then performed to compare measurements obtained using the two tonometers in 147 eyes of 85 patients with ocular hypertension or glaucoma.

RESULTS. Intraobserver coefficients of correlation obtained in the reproducibility study were 0.82, 0.73, and 0.87. Interobserver correlation was 0.82. There was a good correlation between IOP readings obtained by the RBT and the GAT ($r = 0.865$, $P < 0.0001$). RBT readings were consistently higher than GAT measurements (median difference, 1.8 ± 2.8 mm Hg). A Bland-Altman plot indicated the 95% limits of agreement between the two methods were -3.7 to 7.3 mm Hg (slope = -0.022 , $P = 0.618$). Using RBT, the point that best discriminated between patients with an IOP ≤ 21 mm Hg and those with >21 mm Hg, as determined by the GAT was >23 mm Hg (sensitivity, 70.5%; specificity, 95.1%). In terms of pachymetry, the two tonometers behaved in a similar way, with correlation observed between IOP measurements and central corneal thickness.

CONCLUSIONS. Rebound tonometry is a reproducible method of determining IOP in humans. In general, it tends to overestimate IOP compared with Goldmann applanation tonometry. The tonometers used in both methods are similarly affected by pachymetry. (*Invest Ophthalmol Vis Sci.* 2005;46:4578–4580) DOI:10.1167/iovs.05-0586

High intraocular pressure (IOP) is the main known risk factor for the development and progression of glaucomatous optic neuropathy.¹ It is also the only risk factor on which we can efficiently act by using drugs, laser, or surgery, and therefore efforts to find a tool capable of accurately and reproducibly measuring IOP have been constant for more than a century.

A recently developed method of establishing IOP, rebound tonometry, has been used mainly in experimental models of

glaucoma for noninvasive pressure measurements in animals. This method has provided good results in ease of use and the precision and reproducibility of its results.²⁻⁵ The rebound method has also led to the marketing of a handheld tonometer for use in humans (ICare; Tiolat Oy, Helsinki, Finland).

The rebound tonometer (RBT) is an assembly of two coils coaxial to a probe shaft that bounce a magnetized probe off the cornea and detect the deceleration of the probe caused by the eye. A moving magnet within a coil induces changes in the voltage at the two ends of the coil generating a magnetic field with a given voltage, which is detected by the tonometer sensor. The voltage produced is proportional to the probe speed. Of all the variables linked to the probe's movement, the inverse of its deceleration speed seems to correlate best with IOP.² The probes used by the tonometer are disposable and are 24 mm long and weigh 11 mg. The probe tip has a 1-mm-diameter plastic cover, to minimize corneal damage.

To date, there have been no attempts to evaluate the reproducibility and reliability of the measurements provided by this instrument in humans. The present study was thus designed to evaluate the use of rebound tonometry in clinical practice, by comparing the reproducibility of the measures obtained to those provided by conventional applanation tonometry, and by examining the effect of corneal thickness on IOPs determined using the ICare RBT.

METHODS

The study was divided into two parts. In the first, we determined the reliability of the RBT by three consecutive measurements in each of 12 eyes of 12 normal subjects conducted by three experienced ophthalmologists, leaving a 5-minute interval between examinations. Intra- and interobserver coefficients of variation were estimated, and the number of attempts needed to obtain a valid measure was recorded.

In the second part of the study, we compared the RBT and the Goldmann applanation tonometer (GAT; Haag-Streit, Köniz, Switzerland) by performing a cross-sectional study of 85 consecutive patients (with ocular hypertension and glaucoma) examined at the Department of Glaucoma, Hospital Clínico San Carlos (Madrid, Spain). Eyes with normal corneas and no history of previous ocular trauma or surgery were evaluated. Informed consent according to the tenets of the Declaration of Helsinki was obtained from each patient. In all patients, central corneal thickness was determined by ultrasound pachymetry (Dicon P55; Paradigm Medical Industries Inc., Salt Lake City, UT). Intraocular pressure was then determined with both the RBT and the GAT. Patients were randomly divided into two groups. Those in group 1 were first examined with the GAT, to obtain the mean of three measurements for the analysis, and the same procedure was repeated with the RBT, to obtain a further three measurements. The patients in the second group were examined with the two tonometers in reverse order. All IOP measurements were made by the same examiner, who was blind to the readings obtained with the first tonometer.

All statistical tests were performed on computer (SPSS 12.0 software for Windows; SPSS Inc., Chicago, IL). The Kolmogorov-Smirnov test was used to check for a normal distribution of quantitative data, which are expressed as the mean \pm SD. Differences between the measurements obtained with the two instruments were evaluated by

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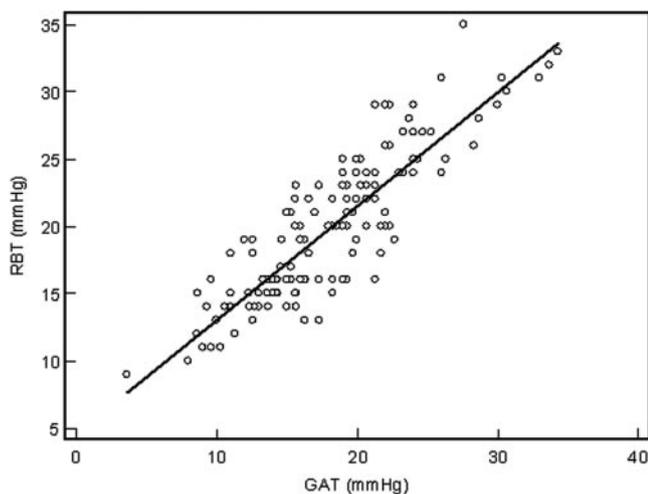


FIGURE 1. Correlation between IOP measurements obtained by GAT and RBT. $RBT\ IOP = 0.85 \times GAT\ reading + 4.6\ mm\ Hg$.

Student's paired *t*-test, and intra- and interobserver and intermethod reliabilities were established by calculating intraclass correlation coefficients (*r*). A Bland-Altman plot⁶ of the difference between RBT and GAT readings against the average of the two was drawn, to assess the agreement between the two methods and the presence of systemic bias. To examine the possible effects of pachymetry on the tonometer measurements, the pressures obtained were correlated with central corneal thickness. The validity of the two instruments was compared by constructing an ROC curve and setting a cutoff value of GAT IOP ≥ 21 mm Hg. We calculated the point of greatest sensitivity and specificity for detection with the RBT of an IOP > 21 mm Hg determined by GAT. The level of significance for each contrast was set at $P < 0.05$.

RESULTS

The reproducibility study was performed on 12 eyes of 12 normal subjects showing a mean pachymetry reading of $544.58 \pm 27.8\ \mu m$. Intraobserver correlation coefficients were 0.82 (range, 0.62–0.94) for the first examiner, 0.73 (0.46–0.90) for the second, and 0.87 (0.72–0.96) for the third. The interobserver correlation coefficient was 0.82 (0.62–0.94), and the intrasubject variation coefficient was 8.9%. A mean of 1.58 ± 0.67 attempts were needed to obtain a valid measurement. (A valid measurement was obtained after the first attempt in 50% of cases, after the second attempt in 42% of cases, and after the third attempt in only one (8%) case.)

To compare the two instruments, 147 eyes of 85 patients were examined. Of these patients, 72 had primary open-angle glaucoma and 13 had ocular hypertension. The mean age of the patients was 63.8 ± 15.6 years.

In the entire series of 147 eyes, the mean IOP obtained with the GAT was 18.1 ± 5.4 mm Hg and with the RBT was 19.9 ± 5.3 mm Hg ($P < 0.001$). Excellent correlation was shown between the two instruments ($r = 0.865$, $P < 0.001$; Fig. 1). In most cases (107 eyes, 72.8%), IOPs provided by the RBT were higher than those obtained by the GAT ($0.85 \times GAT\ reading + 4.6$ mm Hg). The mean difference between the two instruments was 1.8 ± 2.8 mm Hg. The maximum difference among the patients in whom the IOP reading given by the GAT was higher, was 5.3 mm Hg, whereas in patients showing a higher IOP when examined with the RBT, the difference was as high as 7.7 mm Hg (Fig. 2). In 48.9% of cases, the difference between readings taken with the two tonometers was < 2 mm Hg.

With the RBT, the point that best discriminated between patients with an IOP \leq and > 21 mm Hg by GAT was 23 mm Hg (sensitivity, 70.5%; specificity, 95.1%).

The behavior of both tonometers was found to correlate with corneal thickness. With each instrument, a statistically significant correlation was detected between the pachymetry measurements and IOP (GAT: $r = 0.172$, $P = 0.037$; RBT: $r = 0.225$, $P = 0.006$).

No complications arising from the use of either tonometer were recorded.

DISCUSSION

Since it was described by Kontiola² in 1997, the technique of RBT has been mostly used to establish IOP in animal models of glaucoma.⁷ In the rat, this noninvasive method has been easy, quick, and reliable for measuring IOP.^{4,7}

The RBT has shown good reproducibility when used in animals. Measurements are hardly affected by the distance the probe is placed from the eye (in the range of 3 to 5 mm), or by the angle at which the probe impacts the eye (if $< 25^\circ$ with respect to the visual axis).⁴ Daniais et al.⁵ noted a strong correlation between the true pressure established manometrically in cannulated rats' eyes and measurements obtained using the RBT. Our results indicate that this tonometer also provides reproducible readings when used in humans, showing high intra- and inter-observer correlation coefficients. The data recorded in the current study are comparable to results obtained with other tonometers,^{8–10} our intrasubject variation being 8.9%.

At present, there are scarce available data on the precision of measurements taken with the RBT. When comparing the RBT with the Tonopen (Medtronic, Jacksonville, FL) in rats, Goldblum et al.⁷ found that measurements obtained using the RBT did not vary significantly from true (manometric) pressures, whereas the values provided by the Tonopen tended to overestimate the real IOP.

Kontiola³ performed a clinical study comparing rebound tonometry with conventional tonometry in 36 patients and obtained a correlation coefficient of 0.82 between the two instruments, which is similar to the 0.86 recorded in our study. Other investigators have demonstrated similar correlation coefficients between different tonometers and the GAT, which is taken as the "gold standard."¹¹

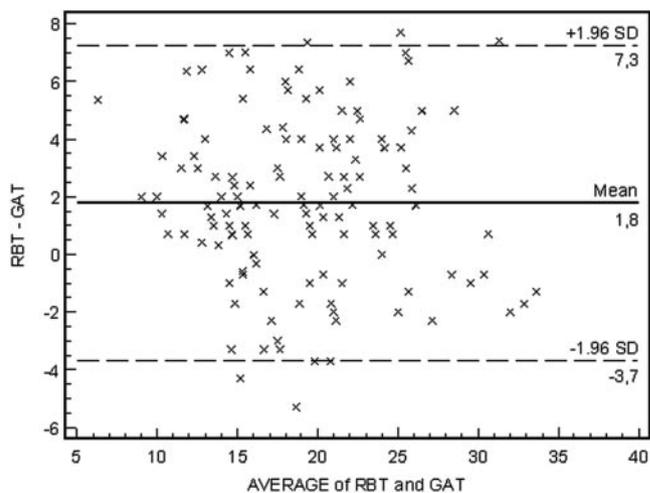


FIGURE 2. Bland-Altman plot. $RBT\ IOP - GAT\ IOP$ versus the mean of both (slope = -0.022 , $P = 0.618$).

Despite the excellent correlation coefficients obtained when comparing the RBT with the GAT, the instruments show considerable discrepancy in their measurements. Thus, Kontiola³ observed that IOP measurements obtained with the RBT were generally lower than those provided by the GAT ($0.9 \times \text{GAT reading} - 4.8 \text{ mm Hg}$). In contrast, our readings indicate that although the measurements obtained with both instruments showed good correlation, the RBT systematically measured higher IOPs ($0.85 - \text{GAT reading} + 4.6 \text{ mm Hg}$). We are unable to explain this striking difference with the findings of Kontiola. Their clinical study formed part of a more extensive experimental study in which this type of tonometry was presented, and there is not much information on the population sample. It is also likely that the currently marketed RBT tonometer has been substantially modified since this initial study. In our study, the mean difference in readings between the two tonometers was $1.8 \pm 2.8 \text{ mm Hg}$, and only in 48.9% of cases was the difference below 2 mm Hg, so that the two instruments cannot be considered equivalent. The Bland-Altman plot indicates that the 95% confidence interval (CI) of the differences in measurements made with the two devices was between -3.7 and 7.3 mm Hg and that the differences did not vary significantly for the different ranges of pressure (slope = -0.022 , $P = 0.618$). That value is similar to that observed for the Tonopen (between -3 and 8 mm Hg).¹²

The RBT point that was best at discriminating between patients with an IOP \leq and $>21 \text{ mm Hg}$, as determined by GAT, was 23 mm Hg (sensitivity = 70.5%, specificity = 95.1%). This should not be taken to indicate that a reading $>23 \text{ mm Hg}$ obtained with the RBT would be best at discriminating between a normal and pathologic pressure. This determination could only be made by performing a population study that included RBT-determined IOP measurements in normal subjects.

Pachymetry results are known to affect applanation tonometry readings, overestimating IOP when the patient has a thick cornea and giving values below the real pressure in eyes with low pachymetric measurements. Several nomograms have been developed for normal patients, those with glaucoma, and patients undergoing corneal refractive surgery to compensate for the corneal thickness effect on IOP measurements,¹³⁻¹⁵ although none has been completely satisfactory. RBT measurements cannot be considered independently of the thickness of the cornea ($r = 0.225$, $P = 0.006$).

Currently, the main advantage of the RBT is that measurements can be taken without the need for topical anesthesia and with minimum discomfort. Kontiola and Puska¹⁶ compared readings obtained with the RBT and the Pulsair 3000 (Keeler, Ltd., Windsor, UK) on nonanesthetized corneas, to establish the degree of tolerance of each instrument. They obtained similar IOPs with each instrument, and both procedures were well tolerated. Another potential advantage of the RBT is that, because of the small size of its probe, the RBT is ideal for use in animal models. Besides the tonometer used in our study, which was optimized for use in humans, another tonometer designed to determine IOP in animals is available (TonoVet; Tiolat Oy, Helsinki, Finland). This model has a calibration chart to adapt its use to the different species (e.g., cat or dog and horse).

In conclusion, to our knowledge the present study is the first evaluation of the reproducibility of the RBT in humans. The ICare offers reproducible IOP measurements and can be easily applied, provided the clinician understands its limitations with respect to the applanation tonometer. Readings 1 to 2 mm Hg higher than those provided by conventional tonometry can be expected, although in some cases the difference could even exceed 7 mm Hg. Further work should include a controlled study based on manometry, to validate the results obtained with the RBT in humans in the range of measurements made in general clinical practice.

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