

Comparison of IOPen rebound tonometer with Goldmann applanation tonometer at different IOP levels

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Abstract

• **AIM:** To compare the accuracy of IOPen rebound tonometer with Goldmann applanation tonometer (GAT) in individuals with low, normal and high intraocular pressure (IOP) and to evaluate the effect of central corneal thickness (CCT) on IOP measurements.

• **METHODS:** This cross-sectional study consisted of 159 participants. IOP of one eye of each subject was measured consecutively with IOPen and GAT. Then CCT was measured using an ultrasonic pachymeter. Based on GAT IOP readings, participants were divided into low, normal and high IOP groups. Correlation between tonometers and CCT was calculated by spearman's correlation coefficient. Agreement between tonometers was evaluated using Bland-Altman method.

• **RESULTS:** Non-significant underestimation of IOP by IOPen was observed in low IOP group (Mean difference: 0.20mmHg; $P=0.454$) and also in normal IOP group (Mean difference: 0.56mmHg; $P=0.065$). However, IOPen significantly overestimated IOP in high IOP group (Mean difference: 1.06mmHg; $P=0.038$). The 95% limits of agreement (LoA) width between IOPen and GAT IOPs were 7.84, 8.57 and 14.27mmHg in low, normal and high IOP groups, respectively. Low IOP group had thinner corneas compared to high IOP group ($P=0.034$). IOP measurements taken by IOPen were not influenced by CCT ($P=0.099$) while poor correlation between CCT and GAT was found ($R=0.17$, $P=0.032$). Using receiver operating characteristic (ROC) curve, cutoff value of 18.75mmHg was determined for IOPen with sensitivity of 98.1 and specificity of 97.2%.

• **CONCLUSION:** Accuracy of IOPen is comparable to GAT in patients with low or normal IOP but IOPen

overestimates IOP at high IOP levels. CCT does not affect IOP readings with IOPen.

• **KEYWORDS:** rebound tonometry; IOPen; Goldmann applanation tonometry; intraocular pressure

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INTRODUCTION

Measurement of intraocular pressure (IOP) is one of the most important parts of ocular examination especially in patients at risk of glaucoma. Although manometry is the most accurate method for IOP measurement, it is not used in routine practice because of its invasive nature^[1,2].

The current gold standard for IOP measurement is the Goldmann applanation tonometer (GAT), against which other methods of IOP measurement are compared^[1].

Several factors including examiner's experience, central corneal thickness (CCT), corneal scar or edema, corneal biomechanics, amount of fluorescein, and blinking can affect the accuracy of IOP measurement with GAT^[3-6]. Disadvantages of GAT include the use of topical anesthesia and direct contact with the cornea which increases the risk of corneal infection and injury^[7,8].

Other methods for measurement of IOP include Tono-Pen, ocular blood flow tonograph, ocular response analyzer and non-contact tonometers. Since these methods are based on applanation technique for IOP measurements, they are subject to measurement errors due to the effect of corneal thickness on IOP measurement^[9,10].

During the recent years, researchers have shown interest in less invasive methods for IOP measurement unaffected by corneal thickness^[11].

Dynamic tonometry also called impact or rebound tonometry (RBT) measures IOP by detecting the deceleration of a magnetized probe with a disposable tip when it bounces off the cornea. A voltage proportional to the probe speed is generated. The instrument is held at a distance of 5mm-9mm from the eye. This instrument is portable, easy-to-use, needs no topical anesthesia with minimal risk of infection and ocular injury and may be used for home tonometry^[12-16].

Table 1 Comparison of measured IOP by GAT and IOPen in study groups

Group	Age (a)	Mean GAT (mmHg)	Mean RBT (mmHg)	Mean difference RBT-GAT (mmHg)	95%CI of difference	P
Low IOP	40.6±20.5	5.42±2.52	5.21±2.66	-0.20±2.00	-0.75~0.34	0.454
Normal IOP	43.1±16.2	14.71±2.50	14.15±2.99	-0.56±2.18	-1.16~0.03	0.065
High IOP	47.8±16.5	33.03±6.49	34.10±8.46	+1.06±3.63	0.06~2.06	0.038

IOP: Intraocular pressure; GAT: Goldmann applanation tonometry; RBT: Rebound tonometry; CI: Confidence interval.

Previous studies comparing ICare rebound tonometer with applanation tonometer have shown different results [17-21]. IOPen is a new rebound tonometer, the accuracy of which has been less investigated [22,23].

As a new instrument, the accuracy of IOPen must be compared with GAT as the current standard, so this study was conducted to compare the accuracy of IOPen with GAT at different levels of IOP including low, normal and high IOPs.

SUBJECTS AND METHODS

This cross-sectional study was performed at the Department of Ophthalmology, Imam Khomeini Hospital, Ahvaz, Iran. The study was approved by the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences and adheres to the tenets of Declaration of Helsinki.

Subjects Inclusion criteria included mental and physical health and willingness for participation in the study. Patients with a history of systemic diseases, eye trauma, corneal abrasion, corneal or ocular surgery except for trabeculectomy (for low IOP group), corneal astigmatism (1D, and use of any ocular medication except for antiglaucoma drugs in glaucoma patients were excluded from the study.

Methods Overall, 159 participants were recruited from patients of glaucoma clinic and their healthy relatives who met inclusion criteria. They were put in three equal groups each consisting of 53 patients based on GAT. IOP readings included: group 1 with low IOP (<10mmHg); group 2 with normal IOP (≥10mmHg to <21mmHg); and group 3 with high IOP (≥21mmHg).

After thoroughly explaining the study design and its objectives, informed consents were obtained from all the participants. All individuals underwent complete ophthalmic examination including refraction, slit-lamp biomicroscopy and fundus examination. Only one eye of each subject who met the above-mentioned criteria was considered for the study, otherwise the left eye was chosen.

IOP was measured twice by a single ophthalmologist using rebound tonometer (IOPen, MediceL AG, Wolfhalden, Switzerland) and the mean of the two readings were used for statistical analysis. Topical anesthesia was not necessary.

IOPen software is programmed for six measurements. After the sixth measurement, the letter P appears on the monitor of the device and the IOP value is read. The software deletes the highest and lowest IOP readings automatically and calculates the mean of the measured IOPs. Measurement quality is rated on a scale ranging from 0 (best quality) to 5 (worst quality).

Only high quality measurements (0 to 3) were recorded.

Five minutes after IOP measurement with IOPen, IOP was re-measured using calibrated GAT (Haag-Streit, Bern, Switzerland) by another ophthalmologist masked to the IOPen readings. For each patient IOP was measured two times by GAT and the mean of the two measurements was used for further analysis.

Then central corneal thickness of the eye was measured with ultrasonic pachymetry (Pachymeter SP-3000, Tomey, Nagoya, Japan).

Statistical Analysis Statistical analysis was performed using SPSS software (version 17, SPSS Inc, Chicago, IL, USA). Mean±standard deviation (SD) and 95% confidence interval (CI) were used to describe the data. Spearman's correlation coefficient was used to evaluate the correlation between IOP taken by GAT or IOPen and CCT. The agreement of the obtained IOP values by the two tonometers was evaluated using Bland-Altman method. The 95% limits of agreement (LoA) were also calculated. Considering IOP of 21mmHg as the normal cutoff value for GAT, a receiver operating Characteristic (ROC) curve was constructed to determine the cutoff point for IOPen and the area under the ROC curve (AUC) was calculated. P values less than 0.05 were considered as significant.

RESULTS

Overall, 159 eyes of 159 participants including 79 men and 80 women aged 43.8±18.03 years were enrolled in this study. The groups were matched in terms of age (P=0.11, One-way ANOVA). Table 1 summarizes the results of tonometry by GAT and IOPen in the study groups.

IOP measured with IOPen was slightly lower than GAT readings in groups 1 and 2 (with low and normal IOPs), however, the differences were not statistically significant. In high IOP group, IOPen overestimated IOP compared to GAT (P=0.038).

Figures 1 and Table 2 show the Bland-Altman analysis and 95% LoAs in the study groups. The 95% LoA width between the IOPen and GAT IOPs was 7.84mmHg in low IOP group; 8.57mmHg in normal IOP group and 14.27mmHg in high IOP group.

Mean corneal thickness was compared among the groups using One-way ANOVA (P=0.032) and Tukey test. Low IOP group had significantly thinner corneas compared to high IOP group (529 vs 550μ, respectively; P=0.034).

Correlation between IOP measurements with IOPen and CCT was not statistically significant (Spearman correlation

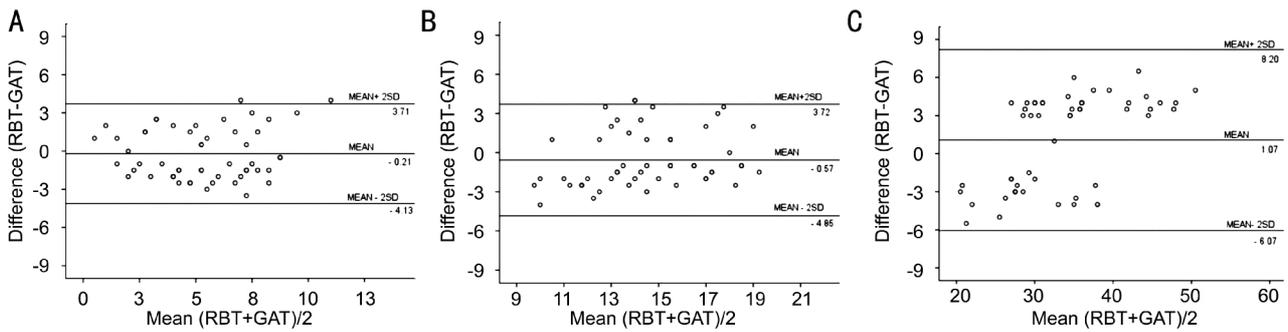


Figure 1 Agreement between IOPen and GAT using the Bland –Altman method, plotting the means against the differences between IOPen and GAT IOPs (mmHg) A: Low IOP group; B: Normal IOP group; C: High IOP group.

Table 2 Bland-Altman analysis of IOP measurements in the study groups using GAT and IOPen ($\bar{x} \pm s$, 95% LoAs)

Group	RBT-GAT IOPs (mmHg)	95% LoA			CCT (μ)
		Lower LoA (mmHg)	Upper LoA (mmHg)	Width of LoA (mmHg)	
Low IOP	-0.20±2.00	-4.13	3.71	7.84	529±41
Normal IOP	-0.56±2.18	-4.85	3.72	8.57	546±46
High IOP	+1.06±3.63	-6.07	8.20	14.27	550±43

IOP: Intraocular pressure; LoA: Limits of agreement; GAT: Goldmann applanation tonometer; RBT: Rebound tonometer; CCT: Central corneal thickness.

coefficient 0.13, $P=0.099$). A weak correlation was found between GAT readings and CCT (Spearman correlation coefficient 0.17, $P=0.032$).

ROC curve was constructed for IOP measurements by IOPen. AUC was calculated 0.999 (95%CI: 0.996-1.000). IOP of 18.75 was determined as cutoff value for IOPen with a sensitivity of 98.1% (95% CI: 91-99.9) and specificity of 97.2% (95%CI: 92.5-99.3). At this cutoff point, RBT had a positive predictive value of 94.5% (95%CI: 85.9-98.6) and a negative predictive value of 99% (95% CI: 95.4-1.000). Taking higher IOP values as threshold resulted in lower sensitivity.

DISCUSSION

This study showed that IOP reading with IOPen is comparable to GAT. IOPen slightly underestimated IOP at low and normal IOP levels compared to GAT and overestimated IOP at high IOP levels. CCT does not affect IOP readings by IOPen.

GAT is currently the gold standard for IOP measurement but an easy-to-use and accurate alternative method for measurement of IOP seems necessary in daily practice, because several corneal parameters, especially CCT, affect the accuracy of GAT^[1,11].

In the literature there are a few studies evaluating the accuracy of IOPen^[22-25].

Moreno-Montañés *et al*^[22] reported that IOPen measures IOP about 3mmHg lower than GAT, however, in their study the two instruments were not compared at different IOP levels. Based on their study, CCT does not affect IOP measurements taken by IOPen.

Similarly, in our study, IOPen non-significantly underestimated IOP compared to GAT in low and normal IOPs and IOP readings were not affected by CCT. Although

the difference between IOPs obtained by IOPen and GAT at high IOP levels (34.10 ± 8.46 mmHg *vs* 33.03 ± 6.49 mmHg, respectively) was statistically significant, it seems not to be clinically significant.

These results are in contrast to Jorge *et al*^[24] study who reported statistically significant underestimation by IOPen[®] tonometer compared with GAT tonometer in glaucomatous population ($P<0.001$); mean differences were -4.81 ± 4.31 and -4.76 ± 5.76 mmHg for the right eye and left eye, respectively. Recently, Dahlmann-Noor *et al*^[25] reported significant overestimation of IOP by RBT compared to GAT in children with glaucoma which is in agreement with our results.

Several other studies have used ICare (older rebound tonometry instrument) with different results. Fernandes *et al*^[19] reported that ICare is helpful as a screening tool when GAT is not available but overestimates IOP about 1.34mmHg ($P<0.05$) compared to GAT. In their study mean GAT IOP was 13.42 ± 2.33 and mean ICare IOP was 14.76 ± 2.53 .

Garcia-Resua *et al*^[18] showed that ICare significantly overestimates IOP (3.35mmHg) compared to Perkins applanation tonometry. In another study by Levia *et al*^[20] in dogs, ICare underestimated IOP (1.90mmHg) compared to Tonopen XL applanation tonometer.

Sahin *et al*^[17] reported that ICare rebound tonometry overestimates IOP compared with GAT in glaucoma patients but still is a reliable, useful and easy-to-use method when GAT is not applicable and in children and disabled patients. In their study mean IOP with RBT and GAT were 18.70 and 18.27, respectively and the difference was not statistically significant. However, CCT showed great effect on RBT readings. Another study by Martinez-de-la-Casa *et al*^[15] showed that in patients with high IOP, ICare rebound tonometer overestimates IOP^[5]. Brusini *et al*^[21] found that

IOP measurements with ICare and GAT in glaucoma patients, are in quite agreement but affected by CCT. In a recent review, ElMallah and Asrani [11] concluded that IOP obtained by RBT is well correlated with GAT. Jorge *et al* [23] compared IOPen and ICare RBTs with GAT in normal individuals and observed significant underestimation of IOP by IOPen compared to GAT and ICare (2.94mmHg and 3.20mmHg, respectively).

In the current study, the 95% LoA width of differences between IOPen and GAT IOPs were 7.84, 8.57 and 14.27 mmHg in low, normal and high IOP groups, respectively. This shows a higher degree of agreement between IOP measurements by IOPen and GAT in low and normal IOPs than in high IOPs. In Moreno-Montanes study with IOPen in normal IOPs, the 95% LoA width was 13.92 and 15.99 [22].

ROC curve was created to find the best cutoff value for IOP measurements by IOPen to separate normal and high IOPs with the highest sensitivity and specificity. IOP of 18.75mmHg was determined as the threshold value with a sensitivity of 98.1% and specificity of 97.2%. Large AUC indicates high accuracy of RBT (*i.e.* sensitivity and specificity). Rebound tonometers are a new generation of tonometers that are comparable to GAT with promising results for use as an alternative for GAT when it is not available and also for home tonometry.

IOPen has some advantages over ICare in that it can be used at the slit lamp and is not affected by CCT. It measures IOP perpendicular to the center of the cornea to avoid incorrect rebound. If IOPen is not perpendicular to the cornea, a red light is reflected in the cornea and the IOP cannot be measured [1]. A major disadvantage of IOPen is that it cannot be used in supine position.

Our study showed that the accuracy of rebound tonometry with IOPen is comparable with GAT in patients with low or normal IOP but it overestimates IOP at high IOPs. Further studies to compare RBTs with other tonometers and taking into consideration corneal properties other than CCT will better elucidate their potential for use in our daily practice.

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