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Agreement of Intraocular Pressure Measurement of Icare ic200 with Goldmann Applanation Tonometer in Adult Eyes with Normal Cornea

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Purpose: To study the agreement between the Icare ic200 (ICare Finland Oy, Helsinki, Finland) and the Goldmann Applanation Tonometer (GAT) in the measurement of intraocular pressure (IOP) in adult eyes.

Design: Noninterventional, cross-sectional study.

Participants: A total of 156 eyes of 156 adult participants with clear corneas were included.

Methods: The IOP measurements were obtained with the Icare ic200 by 1 observer followed by GAT readings by a second masked observer. The central corneal thickness (CCT) and biometry of all subjects were recorded.

Main Outcome Measures: The agreement between Icare ic200 and GAT was measured using the Bland–Altman plot.

Results: The mean age ± standard deviation of subjects was 55.3 ± 13.7 years. The GAT IOP ranged from 6 to 50 mmHg with a mean IOP of 19.5 ± 8.8 mmHg. The Icare ic200 IOP ranged from 7.4 to 50 mmHg with a mean IOP of 20.8 ± 9.3 mmHg. The mean difference between the IOP measurement of GAT and Icare ic200 was −1.27 mmHg with the 95% limits of agreement (LoA) ranging from −3.4 to 0.9 mmHg for all ranges of IOP. The mean difference (95% LoA) between the IOP measurement of GAT and Icare ic200 was −1 mmHg (−3 to 1 mmHg) and −1.8 mmHg (−4 to 0.2 mmHg) for a GAT IOP ≤21 mmHg and >21 mmHg, respectively. The CCT, axial length, age, and gender did not significantly affect the difference in measurement of IOP between the 2 tonometers. However, for every 1-mmHg increase in GAT IOP, the difference between the 2 tonometers increased by 0.04 mmHg ($P < 0.001$).

Conclusions: In our study, the Icare ic200 overestimated the IOP. The overestimation increased as the baseline IOP increased. The agreement between the IOP measurement by GAT and Icare ic200 was <2 mmHg at all ranges of IOP. The narrow LoA between the tonometers for an IOP <21 mmHg makes it a useful alternative to GAT in this pressure range. *Ophthalmology Glaucoma 2020;■:1–5 © 2020 by the American Academy of Ophthalmology*

The Goldmann Applanation Tonometer (GAT) is the most commonly used tonometer for the measurement of intraocular pressure (IOP), which is the only modifiable risk factor for glaucoma. The need for topical anesthesia, fluorescein dye, and skilled personnel for the measurement of IOP with GAT limit its utility, and variations in corneal thickness and biomechanical characteristics can affect its accuracy.[1]

The rebound tonometers—the Icare TA01i (Tiolat, Oy, Helsinki, Finland), the Icare PRO (Icare PRO; Icare Finland Oy, Helsinki, Finland), and the Icare ic200 (Icare ic200; Icare Finland Oy)—are rapid, easy to use handheld tonometers that do not require topical anesthesia and can be used in children.[2,3] These tonometers use an impact bound technique. A small probe measuring 1.8 mm in diameter is accelerated against the cornea, and the rebound acceleration is measured and translated into the IOP. The time and area of contact with the corneal surface are minimal. The inability to measure the IOP in the supine position limits the use of Icare (TA01i), for example, in infants. The Icare PRO tonometer is an improvised version of the Icare (TA01i) tonometer, which can measure the IOP in both sitting and supine positions. However, the small probe length compared with Icare (TA01i) necessitates placement of the device closer to the patient's eye, which can be intimidating for children.[4]

The Icare ic200 Tonometer[5] can measure IOP when the patient is sitting, standing, half-sitting, or in the supine or lateral recumbent position due to its free angle measurement addition. A longer probe length means a larger working distance, increasing the comfort of testing and its use in children. The indication of the correct position by a green color ring at the base of the probe minimizes the

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position-related error, which is an issue with the Icare and Icare PRO. The provision of saving and retrieving individual readings from its memory makes it useful when repeated measurements are taken or while recording in children. The measurements can be retrieved and shared on Bluetooth.[6]

The literature lacks studies comparing the Icare ic200 tonometer with GAT. This study aims to study the agreement of Icare ic200 with GAT in adult eyes with normal cornea and a wide IOP range.

Methods

This cross-sectional study included consecutive patients who attended the glaucoma service at the L V Prasad Eye Institute, a tertiary eye care institute in India. The study was conducted between February 2019 and April 2019. Informed consent was obtained from all participants, and the Ethics Committee of L V Prasad Eye Institute approved the study (LEC No. 01-19-201). The study protocol adhered to the tenets of the Declaration of Helsinki for research involving human subjects.

All types of glaucoma were included in the study along with normal eyes. Eyes with corneal pathology, history of corneal or glaucoma surgery, history of cataract surgery in the last 2 months, corneal astigmatism of >3 diopters (D), central corneal thickness (CCT) of <400 μm or >700 μm, or nystagmus; pregnant women; and patients who were uncooperative or refused to consent were excluded. All participants underwent a comprehensive ocular examination that included a detailed medical history, refraction, ocular examination with the slit-lamp, IOP measurements with Icare ic200 and GAT, dilated fundus examination with indirect ophthalmoscopy, and A-scan for CCT, axial length (AL), and keratometry.

The handheld Icare ic200 tonometer was placed at a distance of 5 to 8 mm from the central cornea to obtain the measurement. The average IOP displayed (the highest and the lowest values of the 6 readings taken in each eye is discarded by the software) was noted. The Icare ic200 readings were obtained on the consecutive measurement mode by 1 clinician using a new probe for each patient. Only reliable readings indicated by the green color were recorded. Another clinician, masked to the Icare ic200 readings, measured the IOP with GAT (GAT AT900, Haag Streit, Koniz, Switzerland) within 5 minutes of the Icare ic200 measurement. The measurements were carried out with the subject seated, by the same 2 clinicians for all eyes. The clinicians were well experienced with the technique of IOP measurement using both tonometers. The Icare ic200 was used first to eliminate any change in the IOP caused by corneal applanation by GAT.[7] The GAT was regularly calibrated as per the recommendations by Choudhari et al.[8]

A-scan by IOLMaster 700 (Carl Zeiss Meditec AG, Jena, Germany) was performed to obtain the CCT, AL, and keratometry. The CCT and AL values were considered if the standard deviation (SD) was less than 10 and 0.1, respectively.

Statistical Analysis

The sample size of 156 eyes was calculated to detect a difference of 0.5 mmHg in the mean IOP measurements between GAT and Icare ic200 at an SD of IOP of 9 mmHg with both instruments, at an alpha level of 5% and power of 80%.

The limits of agreement (LoA) of IOP measurement between Icare ic200 and GAT was assessed using the Bland–Altman plot. Proportional bias was formally evaluated by regressing the difference between the measurements with 2 devices on the average of the measurements with 2 devices. Factors associated with the agreement between the 2 tonometers were evaluated by assessing the relationship between the difference in the IOP between the 2 tonometers and GAT IOP, age, gender, CCT, and AL of the eyes. The relationship was initially evaluated using univariable regression models and the factors associated with the difference at $P < 0.10$ in univariable models were evaluated in multivariable regression models.

Statistical analysis was performed using Stata version 13.1 (StataCorp LP, College Station, TX) statistical software. A P value of ≤ 0.05 was considered statistically significant.

Results

There were 156 eyes of 156 patients. Only 1 eye of each patient was included. There were 78 right eyes and 78 left eyes. There were 51 female and 105 male patients. There were 60 normal eyes and 96 glaucomatous eyes (primary open-angle glaucoma, 47; angle-closure disease, 38; pseudoexfoliation glaucoma, 7; glaucoma in pseudophakia, 3; neovascular glaucoma, 1). Table 1 shows the characteristic features of the study participants. The IOP measured on GAT ranged between 6 and 50 mmHg, and that measured by Icare ic200 ranged between 7.4 and 50 mmHg. The distribution of IOP in the study subjects is given in Fig 1.

The Icare ic200 overestimated the IOP in comparison with GAT measurement by a mean of 1.27 mmHg (95% LoA: −3.4 to 0.9 mmHg) (Fig 2A). The mean difference in IOP (95% LoA) between the tonometers was −1 mmHg (−3 to 1 mmHg) and −1.8 (−4 to 0.2 mmHg) when the GAT IOP was ≤21 mmHg (Fig 2B) and >21 mmHg (Fig 2C), respectively. The Bland–Altman plot also shows that as the baseline IOP increased, the overestimation also increased (coefficient −0.06, $P < 0.001$).

On univariable analysis, GAT IOP, age, and CCT were found to affect the difference in the IOP measured by the 2 tonometers. However, on multivariable analysis, we found that only the GAT IOP affected the difference in IOP measurement by GAT and Icare ic200

Table 1. Clinical and Demographic Parameters of the Study Participants (n=156)

Parameter	Mean ± SD	Range
Age (yrs)	55.3 ± 13.7	23–80
GAT IOP (mmHg)	19.5 ± 8.8	6–50
Icare ic200 (ICare Finland Oy, Helsinki, Finland) IOP (mmHg)	20.8 ± 9.3	7.4–50
CCT (μm)	517.6 ± 38.9	420–676
AL (mm)	23.3 ± 1.4	16.6–32.5

AL = axial length; CCT = central corneal thickness; GAT = Goldmann Applanation Tonometer; IOP = intraocular pressure; SD = standard deviation.

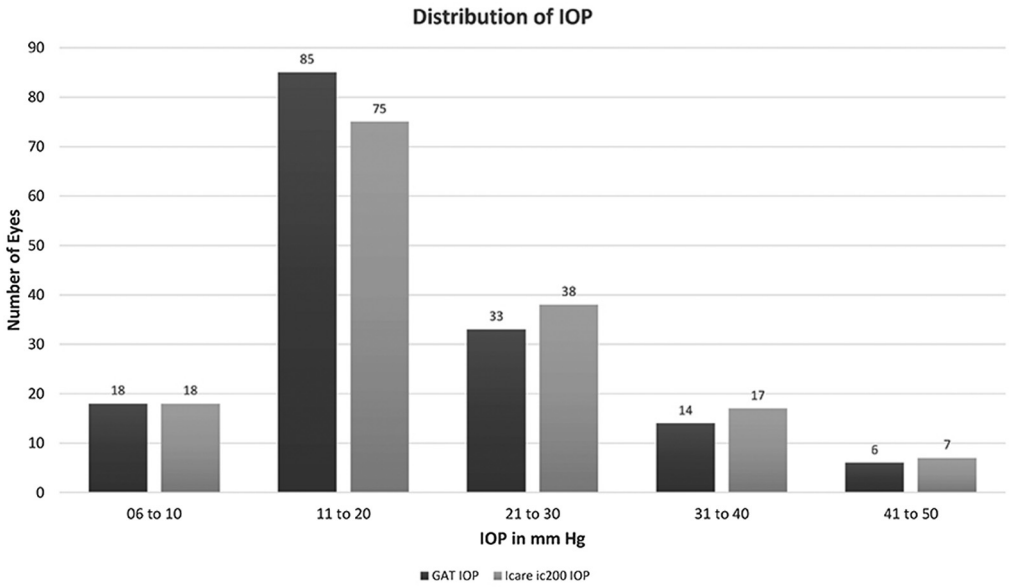

Figure 1. Distribution of the intraocular pressure (IOP) in the study subjects as measured by the ICare ic200 (ICare Finland Oy, Helsinki, Finland) and Goldmann Applanation Tonometer (GAT).

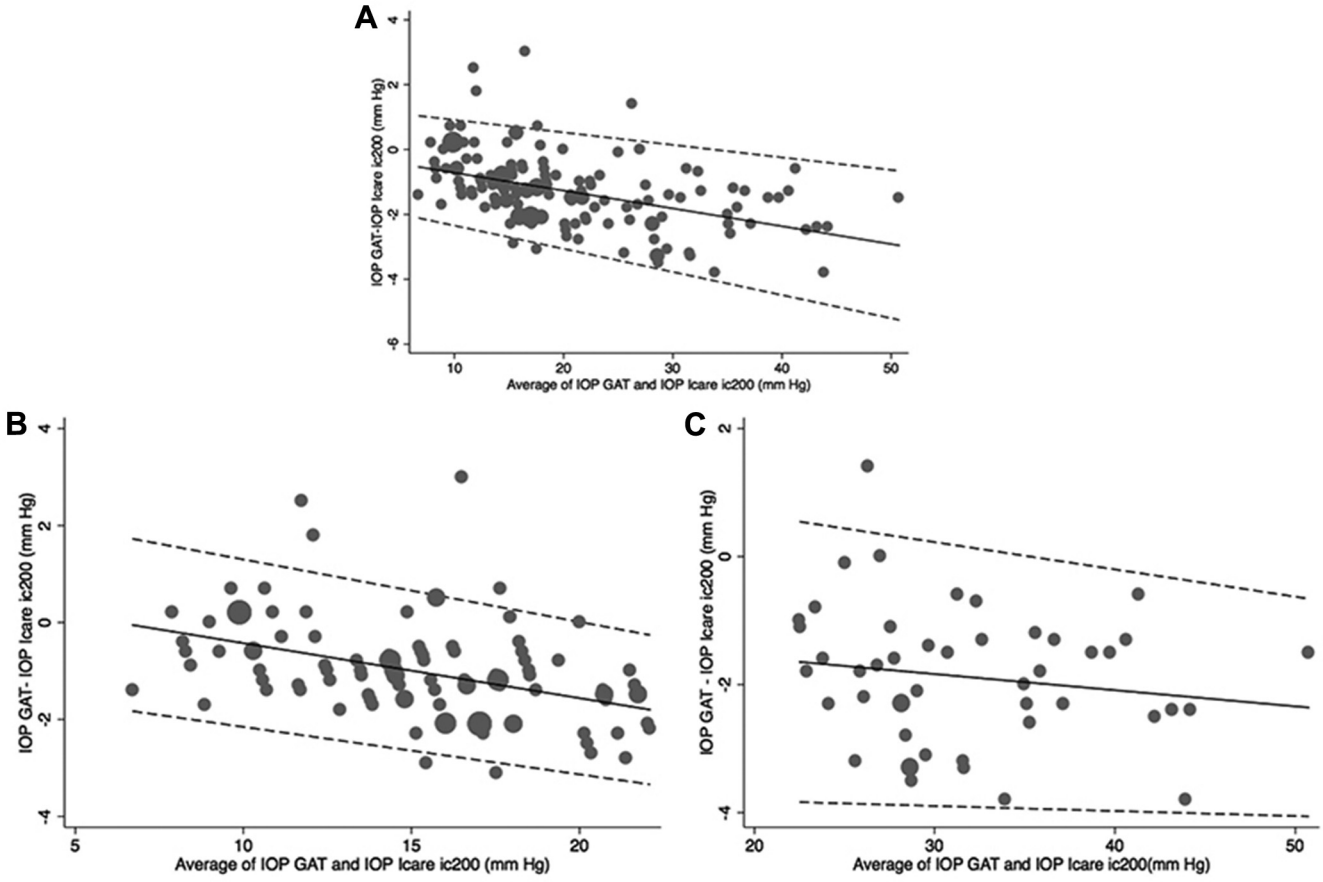

Figure 2. Bland–Altman plot showing the agreement between Goldmann Applanation Tonometer (GAT) and Icare ic200 in the entire cohort at all ranges of intraocular pressure (IOP) **(A)**, at IOP ≤21 mmHg **(B)**, at IOP >21 mmHg **(C)**.

Table 2. Factors Affecting the Difference in Intraocular Pressure Measured by Goldmann Applanation Tonometer and Icare ic200 (GAT IOP − Icare ic200 IOP)

	Univariable Analysis		Multivariable Analysis	
Factors	*Coefficient (95% CI)*	*P Value*	*Coefficient (95% CI)*	*P Value*
GAT IOP	−0.05 (−0.06 to −0.03)	<0.001	−0.05 (−0.07 to −0.03)	<0.001
Age	0.01 (−0.001 to 0.02)	0.07	0.01(−0.01 to 0.02)	0.39
Gender	0.05 (−0.31 to 0.43)	0.75		
CCT	−0.005 (−0.01 to 0)	0.04	−0.003 (−0.01 to 0.001)	0.12
AL	−0.19 (−0.14 to 0.10)	0.75		

AL = axial length; CI = confidence interval; CCT = central corneal thickness; GAT = Goldmann Applanation Tonometer; IOP = intraocular pressure.

(Table 2). For every 1-mmHg increase in IOP GAT, the difference between the 2 tonometers increases by 0.04 mmHg (Fig 3).

Discussion

In our study comparing the Icare ic200 and GAT tonometers in adult eyes with normal cornea, the Icare ic200 tonometer overestimated the GAT IOP by 1.2 mmHg with the 95% LoA ranging between −3.4 mmHg and 0.9 mmHg in all ranges of IOP. At a baseline IOP ≤21 mmHg and >21 mmHg, the mean difference between the 2 tonometers was −1 mmHg (95% LoA: −3 to 1 mmHg) and −1.8 mmHg (95% LoA: −4 to 0.2 mmHg), respectively. The GAT IOP significantly affected the difference in IOP measurement between the 2 tonometers, with a 0.04 mmHg increase in the difference for every 1-mmHg increase in GAT IOP.

Studies comparing Icare ic200 with GAT are lacking in the literature. However, the agreement between GAT and the previous generation rebound tonometers, the Icare PRO and Icare TA01i have been extensively studied.

Munkwitz et al[9] compared the Icare TA01i with GAT in IOP ranges of 7 to 15 mmHg, 16 to 22 mmHg, and 23 to 60 mmHg, and found that the Icare overestimated the GAT by a mean of 0.79 ± 4.73 mmHg (95% LoA: −8.67 to 10.25 mmHg). They also found that the Icare tonometer agreed better with GAT in IOP ranges of 7 to 15 mmHg (mean ± SD: 2.6 ± 3.25 mmHg [95% LoA −3.9 to 9.1 mmHg]) and 23 to 60 mmHg (mean ± SD: 0.04 ± 3.96 mmHg [95% LoA −7.34 to 7.42 mmHg]) compared with IOP range of 16 to 22 mmHg (mean ± SD: −0.28 ± 6.13 mmHg [95% LoA −12.56 to 11.98 mmHg]). In a study by Brusini et al[10] comparing the Icare TA01i IOP and GAT IOP measurements, the mean difference between the 2 tonometers was −1.0 ± 3.5 mmHg with the 95% LoA ranging between −7 and 6.6 mmHg.

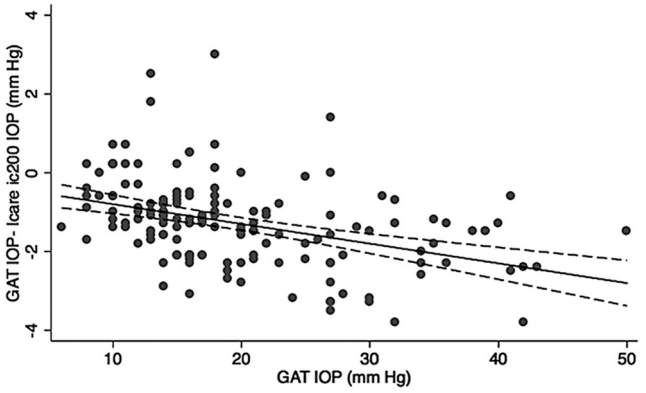

Figure 3. Scatterplot showing the relationship between the Goldmann Applanation Tonometer (GAT) intraocular pressure (IOP) and the difference between the GAT and Icare ic200 IOP.

Chen et al[11] compared the Icare PRO with GAT in various ranges of IOP and found that the agreement was better in the lower IOP ranges of <10 mmHg and 10 to 21 mmHg with a mean of 1.3 ± 1 mmHg (95% LoA: 0.7−1.8 mmHg) and 1.3 ± 1.2 mmHg (95% LoA: 1.1−1.5 mmHg), respectively. The higher IOP ranges of 22 to 30 mmHg and >30 mmHg showed a mean difference between the tonometers of 2.3 ± 1.9 mmHg (95% LoA: 1.7−3 mmHg) and 2.1 ± 1.9 mmHg (95% LoA: 1.4−2.7 mmHg), respectively. They concluded that IOP measurement with the Icare PRO was highly consistent with GAT. Tamçelik et al[12] showed that the mean difference between GAT and Icare PRO was 0.864 ± 3.87 mmHg with the 95% LoA between −6.884 and 8.612 mmHg. They found that in the normal IOP range (9−22 mmHg), the agreement between GAT and Icare PRO was ±2 mmHg in 60.7% of the measurements. However, in the low IOP range (<9 mmHg), only 14.3% of the measurements were within ±2 mmHg. In the higher IOP ranges of 23 to 29 mmHg and >30 mmHg, 34.7% and 13.6% of the measurements, respectively, had an agreement of ±2 mmHg.

In this study, comparing the Icare ic200 with GAT, we found that for a GAT IOP of ≤21 mmHg, the mean difference between the 2 tonometers was −1 mmHg the 95% LoA ranged between −3 and 1 mmHg. For a GAT IOP >21 mmHg, the mean difference between the IOP measurements of GAT and Icare ic200 was −1.8 mmHg and the 95% LoA ranged between −4 and 0.2 mmHg.

In our study, the GAT IOP significantly affected the difference between the IOP measurement of the 2 tonometers. It was noted that as the GAT IOP increased, the mean difference between the tonometers became more negative. There was a 0.04-mmHg increase in the mean difference between the IOP measurement of the 2 tonometers for every 1-mmHg increase in GAT.

Other factors such as age, gender, CCT, and AL showed no significant association with the IOP measurement by Icare ic200 or with the difference in IOP measurement between GAT and Icare ic200.

Although there are no major technical differences between the previous version of Icare and the current Icare ic200,[6] we found a better agreement between Icare ic200 and GAT. We think that the software modification that detects errors in positioning of the device has possibly helped to reduce the measurement errors related to positioning.

The cost−benefit aspect is another implication determining the use of these tonometers. Although the initial cost is higher for the GAT and it needs a slit-lamp for its use, the GAT probe can be disinfected and reused. The initial cost of Icare ic200 is less, but a disposable probe is needed for each patient. The use of Icare ic200 would be promising in community screening, and it may also hold value in teleophthalmology, home visits, and optometry clinics.

Study Limitations and Strengths

The strengths of our study include a large cohort of the population with a wide range of IOP. Two independent masked observers recorded IOP by the GAT and Icare ic200 tonometers, thereby eliminating observer bias in assessing the agreement between the tonometers. The limitation in our study is that the subjects were all adults, and this result needs to be extrapolated to the pediatric population with caution. Also, the eyes included had normal corneas. The effect of corneal edema, corneal scar, and keratoplasty needs to be studied. Eyes with astigmatism >3 D were excluded, and thus the effect of cylindrical refractive error on the agreement is not known.

In conclusion, the Icare ic200 overestimated the IOP compared with GAT. The LoA for measurement of IOP between tonometers increased with increasing IOP by GAT. The mean difference between the 2 tonometers was <2 mmHg in all ranges of IOP. The LoA between the tonometers was acceptable when the GAT IOP was ≤21 mmHg. The Icare ic200 can be used as an alternative to GAT in normal ranges of IOP (<21 mmHg).

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Footnotes and Financial Disclosures

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No animal subjects were used in this study.

Author Contributions:

Conception and design: Badakere, Chary, Choudhari, Rao, Garudadri, Senthil

Data collection: Badakere, Chary

Analysis and interpretation: Badakere, Choudhari, Rao, Garudadri, Senthil

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Overall responsibility: Badakere, Choudhari, Rao, Garudadri, Senthil

Abbreviations and Acronyms:
AL = axial length; **CCT** = central corneal thickness; **D** = diopters; **GAT** = Goldmann Applanation Tonometer; **IOP** = intraocular pressure; **LoA** = limits of agreement; **SD** = standard deviation.

Keywords:
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