

Comparison of Intraocular Pressure Measurements with Icare® Rebound Tonometer and Goldmann Applanation Tonometer in Normal Pediatric Population

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Abstract

Original Research Article

Accurate measurement of intraocular pressure (IOP) is vital in screening, diagnosis and management of paediatric glaucoma. This study compares the agreement in IOP taken with GAT (Goldman applanation) and ICare in a normal paediatric cohort. **Methods:** This was an observational, prospective, cross-sectional study conducted on children of age group 7-14 years presenting to ophthalmology clinics in a tertiary care hospital. The subject underwent IOP measurement by two ophthalmologists blinded to the results of the other. Differences in IOP means between the tonometers were calculated and analysed. **Results:** 60 eyes of 30 subjects were enrolled in this study. The mean difference between the Icare and GAT was 2.31 mmHg, with a standard deviation (SD) of ± 3.17 mmHg which was statistically significant ($p < 0.001$) using Mann-Whitney U test, showing that Icare tonometer significantly overestimates IOP values when compared to GAT by around 2.3 mmHg. There was only a weak positive correlation between the IOP values obtained with GAT and ICT as indicated by Pearson's correlation coefficient $r=0.258$; $p<0.05$. The results also show poor inter-observer reliability with an intraclass correlation coefficient of 0.286 (95% CI -0.111, 0.554) Agreement between tonometers was evaluated using the Bland-Altman method. **Conclusion:** Our study found poor correlation and agreement between ICT and GAT. Based on our study results and previous publications, we can recommend that when normal readings are obtained by Icare tonometer, the IOP is most likely to be within the normal range. When higher readings are obtained, confirmation may be required by more accurate methods.

Keywords: Intra ocular pressure, Icare tonometer, paediatric.

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INTRODUCTION

Accurate measurement of intraocular pressure (IOP) is a vital component in the screening, diagnosis and management of paediatric glaucoma. Goldmann applanation tonometry (GAT) has been the gold standard method for IOP measurement in adults, but many new alternative methods and devices have been developed in the last few years [1]. Newer methods for IOP measurement are necessitated by certain limitations of GAT, which include its invasiveness, need for topical anaesthesia, slit-lamp mounting with sitting posture, and disinfection of tonometer head after each use, requirement of an experienced technician, variability of readings depending on corneal material properties,

curvature and thickness, and inaccuracy in post-refractive surgery eyes [2].

The invasiveness of GAT is a major limiting factor in the pediatric population, especially in younger children, who do not cooperate and resist eye examination [3]. A tonometer that produces less sensations on eye contact may be more acceptable to children, who are usually anxious and uncooperative when touched in their eyes by GAT.

The Icare tonometer® is a rebound tonometer (RBT) that operates on the principle of measuring the motion parameters of a probe that bounces back after making contact with the eye, with higher IOPs resulting in faster rebounds [4, 5]. The impact of the sensor

against central cornea is minimal and six readings are obtained in rapid succession without eliciting the blink reflex [6]. Icare is a portable device, doesn't require topical anesthesia, can be hand-held few millimetres away from the eye, all of which may be less frightening to children [7, 8]. The probe in icare tonometer has a disposable tip that obviates need for disinfection, but can also be potentially reused after disinfection with less chances of crossinfection [9]. In addition, icare can be handled effectively even by less experienced tonometrists [10].

Previous studies in adults have shown that IOP values measured with Icare tonometry (ICT) have a positive bias compared to values of GAT, but ICT can be a reliable method due to its good correlation with GAT, both in healthy and glaucomatous eyes [6, 10-13].

In the pediatric age group, ICT is a comfortable, accurate and reproducible method with high rates of successful IOP measurement and has been observed to reduce the need for anesthesia [7, 8, 14, 15]. ICT has been reported to be one of the preferred methods for IOP measurement in children less than ten-years in real life clinical settings [16]. The purpose of this study was to compare the agreement in IOP readings taken with Goldmann applanation tonometer and ICare® rebound tonometer in a normal paediatric cohort.

PATIENTS AND METHODS

This was an observational, prospective, cross-sectional study conducted at the department of ophthalmology, Father Muller Medical College, Mangalore, India. The study was approved by the Institutional Ethics Committee and conducted in accordance with the principles outlined in the Declaration of Helsinki. The study procedure was explained to the subjects and the parents/guardians in their own language. The parents/guardians gave written informed consent and children were asked to give assent where relevant.

The study enrolled children in the age group between 7-14 years presenting for ophthalmology evaluations to the department clinic during the study period. The study included children who could cooperate with measurement of IOP by Goldmann applanation tonometry and Icare tonometer. The exclusion criteria included children with a history of glaucoma, ocular surface disorders like allergic conjunctivitis, infections, corneal scarring, eye trauma, and previous ocular surgeries. Uncooperative children and those who were squeezing the lids during the Icare readings were also excluded.

All the patients underwent a preliminary ophthalmic examination including visual acuity and slit lamp biomicroscopy to rule out the exclusion criteria and were recruited for the study prior to wet

retinoscopy. Both the eyes of the subjects were evaluated in the study. Two ophthalmologists (SB and MP) took the measurements required for this study, always in the same order (ICT then GAT) to prevent IOP reduction by appplanation. All Icare IOP measurements were performed first by the same ophthalmologist (MP) in both eyes of all enrolled patients. Measurements were taken as outlined in the instruction manual with the child seated comfortably, the probe held approximately 4-8 mm from central cornea in a perpendicular fashion and the best reliability value was recorded. Approximately 5 minutes later, GAT readings were obtained at slit lamp biomicroscopy following the standard procedure by the second ophthalmologist (SB), who was blinded to the readings of Icare tonometer. IOP data were recorded on two separate case report forms with patient ID and at the end of the study data was entered into a computerised database.

STATISTICAL METHODS

Data was summarized using frequencies and percentages for categorical data and with average values (mean, median), range, and standard deviation (SD) for continuous variables. The percentage of eyes with an IOP difference between tonometers within ± 1 , 2, 3 mmHg was assessed, with ± 3 mmHg considered as clinically acceptable difference.

Differences in IOP means between the tonometers were calculated using the Wilcoxon signed-rank and between-groups comparisons were done using Mann-Whitney U test.

The correlation between tonometers was calculated using the Pearson correlation coefficient. The inter-observer reliabilities were established by calculating the intraclass correlation coefficients. Agreement between tonometers was evaluated using the Bland-Altman method. We graphed a Bland-Altman plot of the differences between the two methods against the average of the two methods. The 95% limits of agreement between the two methods have been reported [17, 18]. In addition, we have used a modified Bland-Altman plot, where the IOP differences between the ICT and GAT were plotted against the GAT-measured IOP. The statistical analysis was performed using SPSS 20.0 (IBM Corp, Armonk, NY, USA). All statistical tests were 2-sided, and p value < 0.05 was considered as a significant difference.

RESULTS

Sixty eyes of 30 subjects were enrolled in this study. There were 17 male (56.66%) and 13 female (43.33%) participants in the age range of 7 to 14 years, with a mean (\pm SD) age of 10.5 (\pm 1.9) years. The descriptive statistics of IOP measurements obtained by Goldmann applanation tonometry (GAT) and ICare® tonometry (ICT) were as depicted in Table-1.

Table-1: Descriptive statistics for GAT and ICT measured IOP

	N	Mean IOP (mmHg)	Median IOP (mm Hg)	Standard deviation	Minimum IOP (mmHg)	Maximum IOP (mmHg)
Goldmann	60	12.70	12	1.93	10	18
ICare®	60	15.02	14	3.06	10	24

The mean difference between the Icare and the Goldmann tonometer readings was 2.31 mmHg, with a standard deviation (SD) of ± 3.17 mmHg, and 95% confidence interval (mean difference $\pm 2 \times SD$) of -0.86 to 5.47 mmHg. This positive bias of 2.31 mmHg in ICT measured IOP compared to GAT measured IOP was statistically significant ($p < 0.001$).

When compared to the reference readings of GAT, the ICT measurements differed in the range of -4 mmHg to $+12$ mmHg over the 60 eyes measured. IOP measured by ICT were higher in 66.7% eyes, same in 23.3% eyes and less in 10% eyes, when compared to GAT-measured values. Measurements between the two tonometers differed by ± 1 mm Hg in 36.7% eyes, by ± 2 mm Hg in 56.7% eyes, and within the clinically acceptable ± 3 mm Hg in 68.3% eyes (Figure-1).

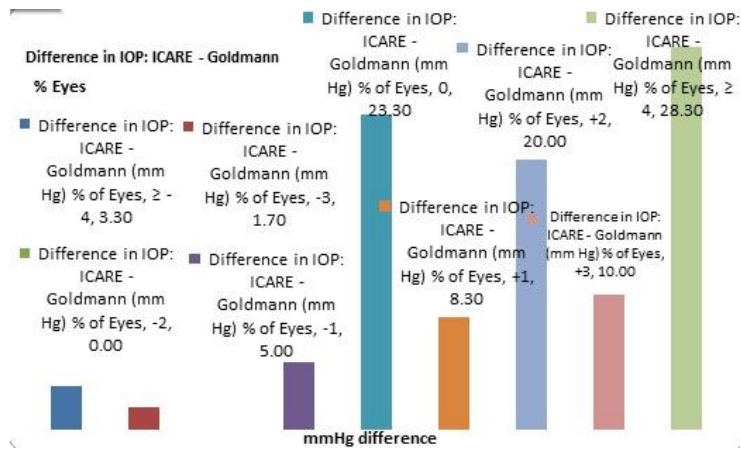


Fig-1: Differences in ICT and GAT measured IOP (in mmHg)

There was only a weak positive correlation between the IOP values obtained with GAT and ICT as indicated by Pearson’s correlation coefficient $r=0.258$; $p < 0.05$ (high correlation $r = 0.7$ to 0.99 ; moderate correlation $r = 0.4$ to 0.69 ; and weak correlation $r < 0.4$). The results also show poor inter-observer reliability with an intraclass correlation coefficient of 0.286 (95% CI $-0.111, 0.554$).

Bland-Altman plot (Figure-2). The centre line is the bias, and the peripheral two lines represent the 95% limits of agreement. The 95% limits of agreement between the two tonometers were 3.89 mmHg (upper limit) and -8.52 mmHg (lower limit). This implies that 95% of the ICT values will be spread within this wide margin from the GAT IOP, which indicates poor agreement between the methods and less clinical acceptability of ICT.

The agreement between IOP measured by ICT and GAT were graphically analyzed by charting a

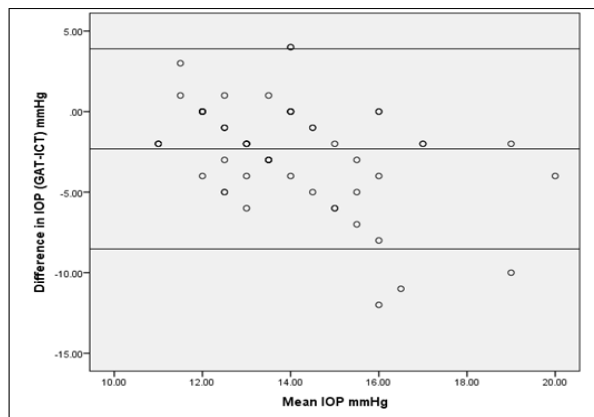


Fig-2: Bland-Altman plot of the average versus the difference between GAT and ICT IOPs

We split the data, based on the IOP measured by GAT into two groups: One with GAT IOP ≤ 12 mmHg (N=38) and the other with GAT IOP > 12 (N=22) (see Table-2). The differences in IOP readings between ICT and GAT were more pronounced at lower

GAT IOP levels (mean difference 3.05 mmHg, $p < 0.001$) compared to the higher GAT IOP levels (mean difference 1.05 mmHg, $p = \text{non-significant}$). This difference between ICT and GAT IOPs between the two groups were statistically significant ($p = 0.12$)

Table-2: ICT compared to GAT based on two GAT IOP groups

Group*	N	GAT Mean (SD) mmHg	GAT Range	ICT Mean (SD) mmHg	ICT Range	Mean difference GAT-ICT mmHg	SD of mean diff	P diff between ICT & GAT
≤ 12 mmHg	38	11.50 (0.83)	10-12	14.55 (2.79)	11-22	-3.05	3.01	< 0.001
> 12 mmHg	22	14.77 (1.47)	13-18	15.82 (3.40)	10-24	-1.05	3.10	0.139

*based on GAT IOP values
Difference between the two groups $p = 0.12$

A modified Bland-Altman plot was graphed with IOP differences against and GAT-measured IOP (Figure-3). The differences in the IOP measured by the two methods decreased as the GAT-measured IOP

value increased ($r^2 = 0.129$, $p = 0.005$). The linear regression formula was $Y = 0.591X - 9.818$ (IOP Difference GAT-ICT = $0.591 * \text{GAT IOP} - 9.818$).

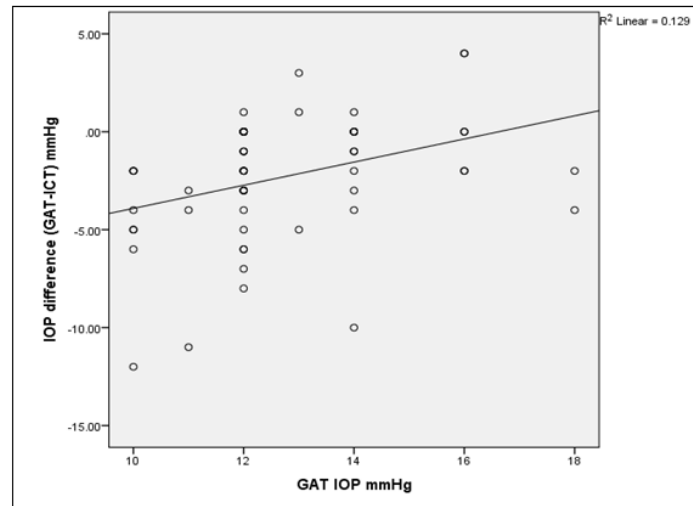


Fig-3: Modified Bland–Altman plot of IOP differences (GAT-ICT) against GAT-measured IOP

DISCUSSION

In the current prospective study, we found that Icare tonometer significantly overestimates IOP values when compared to Goldmann applanation tonometer by around 2.3 mmHg on an average. ICT measured IOP values were more than GAT in around two-thirds (66.7%) of the eyes in our study. Previous studies comparing ICT to GAT in normal and glaucomatous adult population have reported that ICT measured IOP values are higher than GAT either by smaller magnitudes of less than 1 mmHg [6, 10, 13, 19, 20, 21] or by a larger margins ranging from 1.34 to 3.36 mmHg [11, 12, 22-24].

The differences between the two tonometers in our study were more prominent and significantly different in the lower ranges of GAT measured IOP (≤ 12 mmHg) with ICT averaging around 3 mm more than GAT, when compared to the higher range of GAT measured IOP (> 12 mmHg) where ICT averaged only around 1 mm more than GAT. In the study by Pakrou et

al, the mean differences in IOP between the two tonometers in the lower range (< 21 mmHg) of GAT measured IOP were significantly higher than those in the higher range (≥ 21 mmHg) of GAT measured IOP (0.9 compared to 0.5 mmHg, $p = 0.008$) [6]. Kim and colleagues, also observed in their study that the IOP differences between the two tonometers significantly reduced as GAT-measured IOP increased [11].

When a ± 3 mm Hg difference from GAT is taken as clinically acceptable, approximately two-thirds (68.3%) of the ICT measurements fell within this range in this study. However, the differences were widely spread ranging from -4 to +12 mmHg. Other published comparisons of ICT and GAT have reported IOP differences were within ± 3 mm Hg in the range of 60% to 91% of the eyes examined [10, 12, 19, 20, 21, 24].

In our study, we found that correlation, inter-observer reliability and agreement between the ICT and GAT were poor. Some of the previous comparative studies have reported that there is good to excellent

correlation between ICT and GAT [11, 13, 21, 25, 26]. In one of the studies, a high intra-class correlation (>0.9) was demonstrated in both the eyes indicating high inter-observer reliability between the two tonometers [6].

The 95% limits of agreement (GAT-ICT) in this study were 3.89 mmHg (upper limit) and -8.52 mmHg (lower limit). Previous publications have also reported similar 95% agreement limits (Lower limit, upper limit), such as Pakrou *et al.*, (right eyes -5.5, 6.3 mmHg; left eyes -4.7 mmHg, 6.2 mmHg) [6], Abraham *et al.*, (-4 mmHg, 4 mmHg) [10], Kim *et al.*, (-4.52mmHg, 8.37 mmHg) [11], Iliev *et al.*, (-3.2 mmHg, 5.2 mmHg) [20], Rampersad *et al.*, (-4.9 mmHg, 8.6 mmHg) [24], Fernandes *et al.*, (+/-3.98 mmHg) [12].

There have been previous studies of Icare in the pediatric age group, including couple of studies comparing it with Goldmann applanation tonometer [7, 8, 27-29]. To our knowledge, this is the first study comparing ICT with GAT in children without glaucoma. Flemmons *et al.*, compared ICT and GAT in children with confirmed or suspected glaucoma and reported that the Icare measured GAT was high by an average of 2.3 (\pm SD 3.7 mm Hg, $p < 0.0001$). Around 63% of the Icare measured IOP readings were within \pm 3 mm Hg of GAT in their study. As noted in this study, they also reported that the differences between ICT and GAT were greater in the lower GAT measured IOP range (GAT <10mmHg, ICT-GAT = 3.4mmHg) compared to the higher GAT measured IOP range (GAT 10-21mmHg, ICT-GAT=1.9 mmHg).

Dahlmann-Noor *et al.*, reported that ICT systematically overestimates IOP by 3.3mmHg when compared to GAT ($p < 0.001$) in glaucomatous children, sometimes overestimating to the tune of 10 mmHg. The 95% limits of agreement for IOP readings less than 21 mm Hg was (-8.6, 3.9) in their study, which is very similar to that noted in our study.

In conclusion, our study found poor correlation and agreement between ICT and GAT in children without glaucoma. However, it has to also be noted that in two thirds of the subjects, the measurements made by ICT were within \pm 3mmHg of GAT. Icare tonometer has been reported to be very agreeable to children in other studies [7, 8, 27, 29]. At the lower range of GAT-measured IOP, the mean difference between ICT and GAT (ICT-GAT) was about 3 mmHg in our study; but this difference in values at these levels may not have any impact on clinical management decisions. At the higher range (12-21mmHg), the mean difference (ICT-GAT) was about 1 mmHg, which may again not have significant implications on management decisions except in values bordering 21mmHg. Our study did not include children with glaucoma. Based on our study results and previous publications, we can

recommend that when normal readings are obtained by Icare tonometer, the IOP is most likely to be within the normal range. Only when high readings are obtained, confirmation may be required by more accurate methods such as GAT. Using this approach may help reduce the use of more invasive methods and decrease the need for examination under anaesthesia in children.

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