

Intra-Ocular Pressure Measurements by Canon TX-F Pulsair Tonometer and Goldmann Applanation Tonometer

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Abstract

Background: To analyze the limits of agreement for the intra- and inter-session measurements of intra-ocular pressure as measured by the Goldmann applanation tonometer and the Canon TX-F non-contact pulsair tonometer

Methods: For this cross sectional study, 138 eyes of 138 cases of age > 16 years with no evidence of glaucomatous changes were recruited. Cases with astigmatism $\geq \pm 3.0$ Diopters, corneal refractive surgery and scars, ocular inflammations, anterior chamber dysgenesis were excluded. Intra-ocular pressure was measured with the Goldmann Applanation Tonometer proceeded by Canon TX-F non-contact tonometer on day 1 and day 7. Bland-Altman plots were created for method comparison, with correlation and repeated measures ANOVA analysis using MedCalc Version 13.0.6.0

Results: On day 1 the intra-ocular pressures were 16.29 (± 3.10) mmHg and 16.56 (± 3.09) mmHg and on day 7, 16.26 (± 3.09) and 16.56 (± 3.09) mmHg respectively from Goldmann Tonometer and Canon TX-F. Independent t-test & Repeated measures ANOVA showed no statistically significant differences in repeated IOP measurements on days 1 and 7 between and across the instrument measurements. Method-comparison showed strong limits of agreements.

Conclusion: The Canon TX-F offers precision and accuracy that allows its results to be interchanged with those of the Goldmann Applanation Tonometer.

Key Words: Intra ocular pressure, Goldmann Applanation Tonometer, Non-contact Tonometer, Pulsair Tonometer

Introduction

Air-puff tonometers are widely used as screening tools for glaucoma. With advances in their design together with the advantage of no-contact with the patient's eye, they are now competing with the Applanation

tonometer. Intra-ocular pressure remains an important etiologic risk factor and a strong prognostic indicator for the treatment of open angle glaucoma.¹ Goldmann applanation tonometer is considered to be the gold standard for its measurement.² Pulsair non-contact tonometer flattens the cornea by a puff of air generated by a pneumatic system and calculates the intra-ocular pressure by measuring the force required to appanate the corneal surface that produces maximal reflection of light.³ This is in contrast to the Goldmann applanation tonometer which flattens the cornea by physical contact.

Non-contact tonometers have been employed as a screening tool for open angle glaucoma⁴. The non-contact tonometers avoid touching the corneal surface thus negating transmission of disease from the applanating head of the Goldmann tonometer. The intimidating factor, for the patient, of the tonometer head approaching the patient's eye is also avoided. Also serial readings taken with a non contact tonometer do not show a progressive decrement in the measured values, as opposed to the Goldman applanation tonometer.⁵

Method comparison studies provide high quality evidence with regards to the determination of the accuracy of two methods of measuring the same variable. They are therefore used in clinical investigations to compare measurements against an established standard.⁶ Method-comparison studies, conducted largely on Caucasian populations, between Goldmann applanation tonometer and noncontact tonometers have shown strong agreement for a broad range of Intra-ocular pressure measurements^{7,8}. However pressure measurements from Goldman applanation as well as non-contact tonometers are influenced by race and ethnic backgrounds.^{9, 10} Asians have a higher reported intra-ocular pressure as compared to Americans and Europeans.¹¹ Evidence for comparative data, between Goldmann Applanation Tonometer and Non-Contact Pulsair Tonometer, for our population is limited to correlation studies without method-comparison analysis.¹²⁻¹³ Canon TX-F is an

evolution of the Canon TX series non-contact Pulsair tonometer with built-in visual confirmation of errors and range based intra-ocular pressure measurement warnings.

Patients and Methods

Approval for the study was taken from the institutional review board. The sample size was calculated using the mean difference function of Open Source Epidemiologic Statistics for Public Health using a confidence interval (CI) of 95%, power 80% and ratio of sample size in two groups as 1:1. The value of mean (\pm standard deviation) intra-ocular pressure values were taken from Prabhakar et al.¹⁴ A total of 138 right eyes of 138 cases were recruited from the Out Patient ophthalmology clinic of the Shifa Foundation Community Health Center, Islamabad Pakistan between May 2013 and December 2013. Inclusion criteria for cases in this study were an age greater than 16 years with an Intra-Ocular Pressure (IOP) of < 22 mmHg as measured by Goldmann applanation tonometer, gonioscopically open angles (Scheie Grade >2) an optic nerve head cup disk ratio of < 0.5 with no visible notching and an age matched normal 30-2 visual field performed on Humphrey automated perimeter. Cases with astigmatism of $\geq \pm 3.0$ Diopters, history of corneal refractive surgery, active ocular inflammations, corneal ectasias and scars, anterior chamber dysgenesis, pigment dispersion, pseudoexfoliation and sensitivity to Sodium Fluorescein dye were excluded from the study.

A full disclosure of the study was made to all the cases and informed consent was taken from them. Details of the measuring procedures were provided to all cases and all of their queries were answered to their satisfaction. All measurements, for both the instruments, were taken during morning hours (between 8am and 10am) to minimize time based variations in the intra ocular pressure (IOP). The calibration of all instruments was assured by the bio-medical engineering department prior to the beginning of and during the study. For all cases the Intra-ocular pressure was first measured by Canon TX-F pulsair non-contact tonometer (NCT) by a qualified technician who was blind to the study. A mean of three readings, labeled as NCT1, was taken after disregarding the first reading for calibration. After a 15 minute break the pressure was measured using a Goldmann Applanation Tonometer (GAT) by an Ophthalmologist who was blind to the study. A single reading was taken and labeled as GAT1. The same GAT was used throughout the study ensuring

sterilization of the instrument as recommended by the manufacturer. The IOP was measured again using the same protocol and procedure on day 7, (labeled as NCT2 and GAT2) to assess inter-session repeatability of IOP as measured by NCT and GAT. All statistical analysis was carried out using MedCalc Version 13.0.6.0. The IOP measurements from GAT were considered as the established standard. A p value of <0.05 was taken to be significant. Frequency distribution, taken as mean with standard deviation, was calculated for the age and the intra-ocular pressure measurements by GAT and NCT.

Pearson correlation co-efficient was used to observe the relationship between IOP measurements of GAT and NCT. Independent t-test was used to evaluate statistically insignificant differences in the measurement of IOP between GAT and NCT on day 1 (GAT1 and NCT1) and day 7 (GAT2 and NCT2). Repeated measures ANOVA was utilized to analyze the statistical differences in the inter-session measurements of the IOP by GAT (GAT1 and GAT2) and NCT (NCT1 and NCT2). Bias and precision statistics for method comparison were analyzed by creating modified Bland-Altman and repeated measure Bland-Altman plots. Pearson correlation was used to detect the systematic errors. The difference in measurements between GAT and NCT were analyzed for goodness of fit by D'Agostino-Pearson test.

Results

A total of 138 eyes of 138 cases (82 male, 56 female) were recruited for the study. The mean age of cases was 54.65 (± 11.62) years. On day 1 the IOP as measured by GAT (GAT1) and NCT (NCT1) were 16.29 (± 3.10 , range 10.00 - 21.00) mmHg and 16.56 (± 3.09 , range 10.00 - 21.40) mmHg respectively. Independent t-test showed this difference to be statistically insignificant ($p=0.47$). On day 7 the IOP as measured by GAT (GAT2) and NCT (NCT2) were 16.26 (± 3.09 , range 10.00 - 21.00) mmHg and 16.59 (± 3.09 , range 10.20 - 21.50) mmHg respectively. Independent t-test shows this difference to be statistically insignificant ($p=0.37$) (Table 1). Repeated measures ANOVA showed no statistically significant differences in repeated IOP measurements taken on days 1 and 7 by GAT ($p=0.90$) and by NCT ($p=0.92$). A highly significant relationship was seen between IOP readings of GAT1 and NCT1 ($r=0.99$, $p<0.0001$), GAT2 and NCT2 ($r=0.99$, $p<0.0001$) (Figure 1&2). Modified Bland-Altman plots with mean difference (bias) and 95% limits of agreement for GAT1 & NCT1 and GAT2 & NCT2 (Figure 1 & 2).

Table 1. Intra-Ocular Pressure measurement on day 1 (GAT1 and NCT1) and day 7 (GAT2 and NCT2)

Measurement	Instrument-Measurement			
	GAT1	NCT1	GAT2	NCT2
Mean Intra-ocular pressure(±SD) in mmHg	16.29 (±3.10)	16.56 (±3.09)	16.26 (±3.09)	16.59 (±3.09)
Correlation	r=0.99, p<0.0001		r= 0.99, p<0.0001	
Independent t-test	p = 0.47		p = 0.37	
Repeated Measures ANOVA	GAT-1	GAT-2	NCT-1	NCT-2
	p = 0.904		p = 0.925	

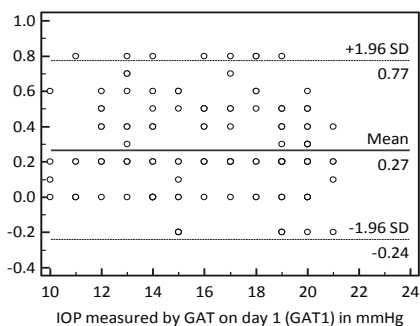


Figure 1. Bland-Altman Plot (Day 1). IOP measured by Goldman Applanation Tonometer (GAT1) versus the difference in IOP between GAT1 and Non-Contact Tonometer (NCT1).

Repeated measures Bland-Altman plot for GAT and NCT (measurements on days 1 and 7) reveals on day 1 that the mean IOP reading from GAT was 16.29 (±3.10) mmHg, bias of NCT method was 0.27 (95% CI = 0.2 to 0.31), SD = ±0.25 (95% limits of agreement: lower limit = -0.23 (95% CI = -0.31 to -0.16), upper limit = 0.84 (95% CI = 0.76 to 0.92). For measurements on day 7 the mean IOP reading from GAT was 16.26 (±3.09) mmHg, bias of NCT method was 0.33 (95% CI = 0.28 to 0.37), SD = ±0.25 (95% limits of agreement: lower limit = -0.17 (95% CI = -0.25 to -0.10), upper limit = 0.83 (95% CI = 0.76 to 0.91)(Figure 3). For repeated measures plot the mean IOP reading from GAT was 16.27 (±3.09) mmHg, bias of NCT method was 0.30 (95% CI = 0.28 to 0.34), SD = ±0.26 (95% limits of agreement: lower limit = -0.21, upper limit = 0.8). Systematic error between GAT and NCT was detected using Pearson correlation co-efficient statistic. For GAT1 & NCT1 (r=-0.06, p=0.45), GAT2 & NCT2

(r=-0.04, p=0.60) and repeated method plot (r=-0.05, p=0.36) no significant correlation was seen. Histogram plots of differences in IOP on day 1 (NCT-1 & GAT-1) and day 7 (NCT-2 & GAT-2) (Figure 4). D'Agostino-Pearson test shows that the differences on day 1 (p=0.13) and on day 7 (p=0.08) are normally distributed.

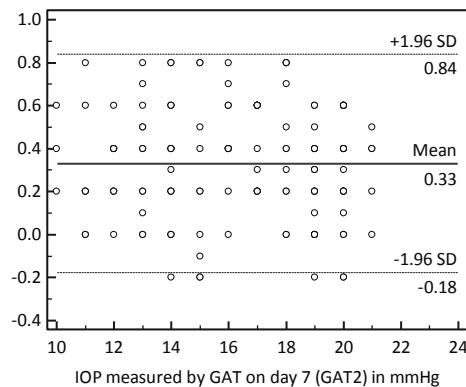


Figure 2. Bland-Altman Plot (Day 7). IOP measured by Goldman Applanation Tonometer (GAT2) versus the difference in IOP between GAT2 and Non-Contact Tonometer (NCT2).

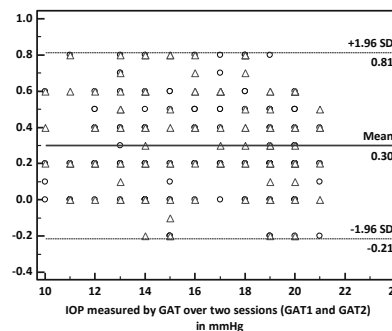


Figure 3. Repeated measure Bland-Altman Plot. IOP measured by Goldman Applanation Tonometer (GAT) versus the difference in IOP between GAT and Non-Contact Tonometer (NCT) over two measurement sessions (days 1 and 7). Circles represent measurement pair for day 1. Triangles represent measurement pair for day 7 for each case.

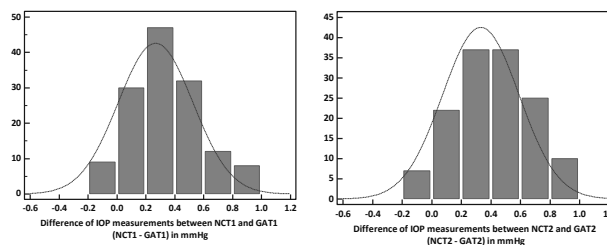


Figure 4. Frequency distribution histograms of differences in IOP between Goldmann Applanation Tonometer (GAT) and Non-Contact Tonometer (NCT) on day 1 (GAT1 - NCT1) and day 7 (GAT2 - NCT2). Normal distribution curves are superimposed on the histograms.

Discussion

Intra-ocular pressure (IOP), to date, remains a key indicator to monitor the effectiveness of Glaucoma treatment as well as clinical decision making.¹⁴⁻¹⁶ Despite advances in ocular diagnostics over the last several decades, the Goldmann Applanation tonometer remains the established 'Gold' standard for measuring IOP.¹⁷ Non-contact tonometry is a fast, effective and non-invasive technique to measure the intra-ocular pressure and can be performed by either Ophthalmologists or qualified technicians.¹⁸ While the working principle for all NCTs remains the same, manufacturers tend to distinguish their products by improving upon the design of the sensors and the software, leading to investigations into manufacture specific NCTs.^{19,20}

A strong correlation has been reported between the IOP measurements taken with GAT and NCT. The correlation between GAT and NCT in our study on day 1 ($r = 0.99$, $p < 0.0001$) and day 7 ($r=0.99$, $p < 0.0001$) follows a similar trend.^{12,13,18} However, correlation alone does not interpret the limits of agreement between GAT and NCT. Bland and Altman proposed a form of method-comparison analyses based on plots with bias and precision statistics to compare the results obtained from an established and an under-observation method of measurement.¹⁹ The South-East Asia Glaucoma Interest Group (SEAGIG) defines the tolerance for GAT intra-ocular pressure measurements.²⁰ The tolerance range is directly proportional to the IOP measured and widens as the measured IOP rises. At 20 mmHg the tolerance is ± 2 mmHg. This implies that on repeated measurements the IOP can vary by as much as ± 2 mmHg and still be within acceptable limits of measurement if the IOP being measured is ≤ 20 mmHg. The range widens to ± 4 mmHg at IOP measurements of ≤ 60 mmHg.

The bias and confidence limits in present study show that the NCT over estimates the IOP by as much as a mean value (bias) of 0.33 mmHg with 95% of the results falling within the -0.18 to +0.84 mmHg of readings taken from GAT (figure 2). For repeated measurements, the NCT over estimates the IOP by a mean value of 0.31 mmHg with 95% of the measurements falling within -0.21 to +0.81 mmHg of IOP taken from GAT. Thus in our investigations both the accuracy (bias) and precision (confidence limits) measurements fall within the tolerance limits defined for GAT by SEAGIG. Visual analysis of Bland-Altman plots and Pearson Correlation shows that no systematic error exists between the measurements taken by GAT and NCT over the range of IOP

measurements on day 1 ($r=-0.06$, $p=0.45$) and day 7 ($r=-0.04$, $p=0.60$). There are no specific studies that compare the Canon TX-F NCT with GAT; investigations into agreement between GAT and other NCT instruments reveal varying results.^{6,20-26}

The results of our study match with those conducted on the Keeler 3000 NCT.⁶ The Keeler 3000 over estimated the IOP by a mean difference (bias) of 0.48 mmHg with the limits of agreement between -2.72 and 1.75 mmHg.²³ The Canon TX-F NCT under investigation in our study performed better than the Keeler 3000 (bias 0.32 mmHg, limits of agreement -0.18 to +0.84). The Topcon CT-80 NCT was tested against the GAT for intra- and inter-session accuracy and precision by Ogbuehi.¹⁸ A pioneer in inter-session comparison, this study showed that the CT-80 is an accurate and reliable method of assessing the IOP, with the measurements of NCT being interchangeable with those of GAT both for intra-session and inter-session observations. These findings are in agreement with our own intra- and inter-session observations. However not all evidence shows a strong level of agreement between the two tonometers. Comparing Canon TX-10 with GAT, Tonnu et al found only a moderate level of agreement between the IOP measurements.²² Studies on the South-Asian populations show a fair level of agreement between the readings taken with NCT and GAT.²⁵

The NCT employed by Hanneman (Keeler 3000), Ogbuehi (Topcon CT-80), Jorge (Reichert AT550), Tonnu (Canon TX-10) and Mohan (Keeler Easyeye) were all from different manufacturers and some variation of IOP measurements and limits of agreements between these instruments and GAT should be expected.^{6,20-26} However studies that employ the same tonometer have shown varying results.^{8,24-26} Race, ethnicity and associated variations in ocular morphology are likely to be responsible for the differences of IOP measurements and limits of agreement from the same instrument. Similar observations have been noted for the IOP measurements taken by the Goldmann applanation tonometer thus necessitating regional, race and ethnicity based investigations.¹⁵

To evaluate whether the differences in the IOP as measured by GAT and NCT were normally distributed, histograms (figure 5) of difference in IOP measurements for day 1 and day 7 were created and evaluated for goodness of fit by D'Agostino-Pearson test for normal distribution; this showed the data to be normally distributed. To our knowledge this is the only study evaluating the normalcy of distribution.

Our study focused on normotensive individuals and excluded all patients with glaucoma; either diagnosed or suspect. Comparisons between early, first generation NCTs and GAT reported that the NCT tends to over-estimate the GAT at high intra-ocular pressure and under-estimate the GAT at low IOP.²⁷ Evaluations of recent NCTs show that they can measure a wide range of IOPs, even in glaucomatous range, without statistically significant estimation errors at extremes of Intra-ocular pressure as compared to GAT.²⁹ We did not take into account central corneal thickness of the cases in our study which has been shown to impact IOP measurements by GAT and NCT, with an increase in central corneal thickness being directly proportional to the recorded IOP.^{26,27} The estimated increase is about 0.6mmHg for every 10 microns increase in central corneal thickness for NCT and 0.4 mmHg for GAT leading to a difference of ± 0.2 mmHg per ± 10 microns change in central corneal thickness between NCT and GAT.²⁸ This variation, in perspective of the reported central corneal thickness of our population, is within the tolerance limits.²⁹

Conclusion

1. The Canon TX-F Non-contact tonometer intra-ocular pressure measurements strongly agree with those of the applanation tonometer for normotensive cases.
2. It can be used as a reliable tool to monitor intra-ocular pressure for the normal range of intra-ocular pressure distribution and validating its results with those of the Goldmann applanation for higher measurements.

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