Usefulness of the Non-Contact Tonometry in Out-Patient Screening

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Abstract
Purpose: Goldmann applanation tonometry (GAT) is considered the gold standard for Intraocular Pressure (IOP) measurement. It has the disadvantages of being a contact device, need for a slit-lamp, non-portability and need of a skilled examiner. Many hospitals are using a Non Contact Tonometry (NCT) as a screening device to save clinician time, however the usefulness is not proved in terms of reliability. This study was aimed to determine the usefulness of the Air-puff tonometer (TONOREF NIDEK II, NIDEK CO., LTD., JAPAN) over a GAT in a tertiary care center.
Design: Cross-sectional Study
Methods: This was a cross-sectional, non interventional observational study conducted on 224 eyes (right eye) from 224 patients. All patients underwent the IOP measurement with both methods and a central corneal thickness (CCT) measured. The data was analyzed using SPSS 20.0 software.
Results: The mean age of the patients was 40.3±11.29 years. There was a statistically significant difference (p<0.001) between the mean NCT and GAT readings which persisted even after correction for central corneal thickness. The correlation between NCT and GAT using Pearson’s correlation coefficient was strong irrespective of the corrections for their corneal thickness (r = 0.751 and 0.718 for uncorrected and corrected values respectively). The correlation of the individual clinicians for the readings varied from moderate to strong. The ROC curve showed the best sensitivity and specificity to occur at around 13 to 14 mmHg.
Conclusion: NCT seems to overestimate the IOP at low ranges as compared to the GAT and underestimate at higher ranges. The crossover of the values is seen between 12 to 13 mmHg. The clinician should do an individualized analysis of his/her GAT measurements to the readings of the NCT machine at the clinic to obtain clinician specific nomogram.

Keywords: Air Puff, Applanation, Corneal Thickness, Goldmann, Non Contact, Tonometry,

Introduction
Intra ocular pressure (IOP) refers to the pressure exerted by the intraocular contents on the coats of the eyeball. Normal range of IOP is maintained due to the equilibrium which exists between aqueous humor formation, its outflow and its episcleral venous pressure. IOP measurement is an integral part of eye examination especially in patients in the older age group and in patients with glaucoma or suspect glaucoma. Raised IOP is the only risk factor that can be modified in patients with glaucoma and a precise measurement is very important in its management. Measurement of IOP

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can be done using various methods which includes contact techniques (Goldmann applanation, Schiotz Indentation, Rebound and Dynamic contour tonometry) or the non contact techniques (Air puff and Pulsair tonometry).2-4

Goldmann applanation tonometry (GAT) is considered the gold standard 3 for recording intra-ocular pressure and is based on the principle of Imbert-Fick law5,6 which states that the pressure within an infinitely thin, dry, smooth-walled, flexible sphere is equal to the external force required to flatten the surface of the sphere divided by the area flattened. The IOP is recorded based on the amount of pressure applied to applanate the area.4,6

Non-contact tonometry (NCT) measures the IOP by firing an air puff at the cornea. This air puff flattens the cornea and the IOP is calculated based on the time taken for the increasing velocity of the air-puff to flatten the cornea.7,8 The main advantages of NCT are that it is a non-invasive procedure and does not require use of anaesthetic drops, does not require Fluorescein staining, easy to perform, comfortable procedure and has minimal risk of infection and it takes less time to perform the procedure with added advantage of its usefulness in children.1,7-9

Central corneal thickness (CCT) affects the IOP when measured by GAT with thick and thin corneas, measuring false high and low IOP respectively.10-14 A thinner cornea requires less force to applanate and might give us IOP values on a lower side, thicker corneas would need more force and may give us artificially high IOP reading.11-13 Also there is proven evidence for diurnal variation of the IOP.15-17 Goldmann himself discussed the influence of variations of central corneal thickness on IOP measured by applanation, he felt that significant variations in CCT occurred rarely and hence assumed a “normal” CCT of 520 µm for his instrument.6

Patients and Methods
This was a cross sectional non interventional observational study conducted at a tertiary care center in South India. Both the IOP measurement procedures were explained to the patients and were enrolled after informed consent. This study was approved by the Institutional Review Board (IRB Min No: 8673).

Data of 50 patients fitting the inclusion and exclusion criteria, on whom NCT was measured by the primary investigator (CESJ) on patients of the two clinicians were collected, which was then used for the sample size calculation. A sample of minimum 109 subjects for each clinician were needed to be studied, to detect a mean difference of 1.21 mmHg between the two measurement of IOP with a 5% error and 80% power.

All patients registered for an out-patient visit to see two selected clinicians aged between 20 to 60 years were enrolled after informed consent. In patients with both eyes fitting the inclusion criteria, the right eye was chosen as the study eye. Patients with corneal pathology, shallow anterior chamber as assessed by torchlight and slit-lamp examination, intraocular surgeries in the past 6 months, ocular surface infections, one eyed patients and astigmatism of more than 3D were excluded from the study. Patients with systemic conditions who could not sit at the slit lamp for the recording of IOP were also excluded. The data from our study was further
sub-categorized and analyzed based on the GAT readings as group 1 (≤13 mmHg), group 2 (14-21 mmHg) and group 3 (≥ 22mmHg) respectively.

Methodology
The participants had their NCT readings taken using Nidek Tonoref (TONOREF NIDEK II, NIDEK CO., LTD., JAPAN) by the primary investigator (CESJ). The participants were seated comfortably with their chin on the chin-rest and asked to fix at the target shown and the IOP readings were taken. The machine displayed the average of three IOP measurements taken, which was considered as the NCT reading. CCT was measured with TOPCON (SP 3000P, Non Contact Specular Microscope) according to the instruction manual. The machine displays an average of 3 readings. NCT and the CCT were not given to the clinicians to avoid bias.

After the NCT and CCT measurements patients underwent refraction and torch-light examination by experienced optometrists. A drop of Tropicamide (0.8%) with Phenylephrine (5.0 %) was instilled in each eye and patient sent to the clinician. The clinicians examined the patients and a GAT (Haag Streit AT 900®), performed on the dilated eye. The GAT was calibrated every morning by standard protocol. The patients were explained about the procedure and a proparacaine drop (0.5%) and the tear film stained with Fluorescein strips 1% (Fluorescein Sodium Ophthalmic Strips USP, Fluro Strips). Goldmann applanation prism was positioned and IOP measurement of the right eye was taken by asking the patient to look ahead with the left eye. The readings were noted in the medical record, the patient was sent back to the primary investigator (CESJ) where they underwent a post dilated NCT and CCT measurements as before.

To avoid a diurnal variation affecting the readings, all the IOP measurements for a participant were completed within 90 minutes. Patients in whom the IOP readings were not done within the time zone as defined in the study were excluded. The data regarding the GAT values were extracted from the medical records by the primary investigator (CESJ) after the completion of the study for analysis.

Data entry was transcribed into a Microsoft Excel 2010 document and analyzed with SPSS software (Version 20.0). Pearson’s correlation coefficient and the Paired t test were done to compare the different set of readings by the two methods. Descriptive statistics was calculated using mean difference and Bland-Altman Plots. The categorical variables were analyzed using frequency and percentages.

Results
A total of 235 patients participated in the study, of which 11 patients were excluded (10 in whom all the IOP measurements could not be completed in 90 minutes and 1 patient who did not stay through the study protocol) from the study. 224 patients (right eye, n = 224) remained for the final analysis. The sample included 119 (53.1%) males and 105 (46.9%) females. The mean age of the patients was 40.3 ± 11.29 years (range 20 to 60 years). Table 1 shows the mean values and the standard deviation of the various IOP and the CCT measurements. The mean IOPs between the clinicians
in the different subsets were not statistically significant.

The pre dilatation (Pr D) and the post dilatation (Ps D) readings were analyzed for the agreement. There was a statistically significant difference (p<0.001) between the mean NCT (Ps D) and GAT which persisted even after correction for corneal thickness. The correlation between NCT (Ps D) and GAT using Pearson’s correlation coefficient was strong (0.751, p<0.001). The same values corrected for corneal thickness also had a strong correlation (0.718 p<0.001). The correlation was moderate if only the GAT values were corrected for corneal thickness (Table 2). However the correlation of the individual clinicians for the readings varied from moderate to strong (Table 3). When looking for correlation for various IOP levels measured with GAT, there was a strong correlation only in the group above 22 mmHg. Below 13 mmHg the correlation was very poor (Table 4).

The graph in Figure 1 shows that from 13 mmHg, the NCT values were lower than the GAT values and vice versa below 13 mmHg. The ROC curve drawn also showed the best sensitivity and specificity of around 70% occurred at around 13 to 14 mmHg (Fig 2). Figure 3 shows the distribution of GAT and NCT (Ps D) readings with the Bland Altman Plot.

*NCT (Ps D) - Non contact tonometry (Post dilatation), †GAT - Goldmann Applanation Tonometry

Fig 1. Mean NCT (Ps D)* readings at each GAT†value
Fig 2. ROC curve of GAT (Ps D)* vs NCT (Ps D)†

Fig 3. Bland-Altman Plot of GAT (Ps D)* vs NCT (Ps D)† showing distribution of patients
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Discussion
Quick accurate measurements of IOP in the clinic setting will hasten patient throughput and is something most clinicians are looking for. GAT is the gold standard tonometer for IOP measurements but this takes time and has associated problems of the need for a skilled examiner, staining with fluorescein and the chance of spread of infection.\textsuperscript{5} NCT measurement is quick and easy and circumvents the above problems.

This study was initiated to look for the correlation and agreement of the IOP readings taken by NCT and GAT in a clinical setup and on patients from the Indian subcontinent. If NCT is found useful then it can be substituted for GAT in evaluation of patients in an eye clinic. Though various studies have been published in the literature, there are always variations that can occur with the different machines in measuring the NCT.

In this study we chose two clinician’s measurement to make it more relevant in a multi-clinician set up. Since there are clinical work flows where patients are seen after dilatation by the clinician we decided to do GAT only after dilatation. However, to see the change in NCT with dilatation, we took the post dilated readings too (Table 2 and 3). To evaluate the possible error due to instillation of eye-drops for dilatation which could change corneal hydration and give a false reading, the CCT readings were taken before and after the dilatation and the differences were found not to be statistically significant (Table 1).

The IOP measured by the GAT as we know is affected by CCT.\textsuperscript{10-14} Comparison between the mean differences between the NCT (Pr D) vs GAT (0.067±2.958) and the NCT (Pr D) vs cGAT (0.749±4.27) showed an increase in the latter. The fact that the mean cGAT moves away from the mean NCT, compared to uncorrected GAT values suggest that NCT is also affected by CCT in a similar fashion. Though the CCT influences the measured NCT values as studied by Tonnu et al\textsuperscript{13}, the correction factor is not well established. Since no correction nomogram were available to correct the NCT for the measured CCT, we applied the same correction formula as described by Ehlers et al\textsuperscript{14} for GAT, to compute the corrected IOP as measured by the NCT. The fact that the differences became smaller when the NCT was corrected with the same correction formula, suggested NCT too is affected in a similar manner as that of GAT (Table 1).

Though the correlation between the NCT and the GAT above 13 mmHg was moderate to good, the Bland Altman plot shows a wide variation. The Bland-Altman plot which gives the bird’s eye view of the entire data set shows great variations are possible from patient to patient in terms of the agreement between values at different IOP levels (Fig 1 and 3).

If the pattern shown in figure 1 was reversed and the NCT over estimated the IOP measured with GAT at higher values the chances of missing higher IOPs would have been less making it more useful in the clinical setting. The ROC curve showed that the NCT had a poor sensitivity and specificity (around 70%) even at 13 to 14 mmHg making it a poor test to measure IOP. To make it more useful each clinician should probably study their own correlation pattern of NCT vs GAT readings (Table 3).
To the best of our knowledge this is the first study that looked at two clinicians doing the comparisons simultaneously. This makes comparisons difficult and complicated.

In conclusion, there is only a moderate correlation between NCT and the GAT readings. Measurement by NCT seems to overestimate at low ranges and underestimate at higher ranges and the crossover of the values is seen between 12 to 13 mmHg. The correlation between NCT and GAT reading is best when both the readings are corrected for corneal thickness. The clinician should do an individualized analysis of the readings got from their clinic NCT machine and his/her GAT measurements so that a clinician specific nomogram is derived.

NCT in our study is still far from the ideal tool to be the only measuring device for IOPs in the clinic. The good correlation at higher IOP ranges makes it more useful to screen for patients with high tension glaucoma and patients with high IOP in the immediate post operative settings.

References
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