Comparisons of the Tono-Pen® and Goldmann Applanation Tonometer in the Measurement of Intraocular Pressure of Primary Open Angle Glaucoma Patients in a Hospital Population in Southwest Nigeria

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Key Words
Glaucoma · Intraocular pressure · Goldmann applanation tonometer · Tono-Pen® · Nigeria

Abstract
Objective: The aim of this study was to compare intraocular pressure (IOP) measured with the Tono-Pen® to that measured using the Goldmann applanation tonometer (GAT) in patients with primary open angle glaucoma attending a glaucoma clinic. Subjects and Methods: A comparative clinical observational study was conducted involving 75 patients (39 men and 36 women) attending a glaucoma clinic in Southwest Nigeria. A pretested structured questionnaire was used to collect sociodemographic data. The Tono-Pen and the GAT were used to measure the IOP in each patient. Central corneal thickness (CCT) was measured with an ultrasonic pachymeter, and the corrected GAT value was calculated for each patient. The Tono-Pen readings were compared with the uncorrected and corrected GAT readings. Descriptive and comparative analyses were performed. Values for p < 0.05 were considered statistically significant. Results: The mean age of the participants was 60.39 ± 16.71 years. The mean IOP using the Tono-Pen was 21.1 ± 6.8 mm Hg versus the mean uncorrected GAT value of 17.1 ± 6.9 mm Hg and the corrected GAT value of 18.9 ± 7.5 mm Hg. The mean CCT was 510.5 ± 29.6 μm. The mean differences between the Tono-Pen reading and uncorrected and corrected GAT readings were 3.9 ± 2.6 and 2.1 ± 3.5 mm Hg, respectively. Gender (Tono-Pen vs. GAT; p = 0.981 vs. 0.437) and corneal thickness (p = 0.057) did not significantly affect the IOP value. Of the 75 patients, 68 (90.7%) preferred the Tono-Pen to the GAT. Conclusion: In this study, the Tono-Pen gave a higher value for IOP than the uncorrected and corrected GAT values. Gender and corneal thickness did not significantly affect the measurements. Most patients found the Tono-Pen more acceptable than the GAT.

Introduction
The term ‘glaucoma’ includes a group of diseases characterized by optic neuropathy and visual field defect, with elevated intraocular pressure (IOP) believed to be the major risk factor for both structural change and functional...
deficit [1]. Glaucoma, a treatable condition, is the second most common cause of blindness in the world, surpassed only by cataract [2]. Worldwide, over 3 million people are bilaterally blind as a result of primary open angle glaucoma (POAG), which develops in more than 2 million people each year [3]. Glaucoma in West Africa is predominantly POAG [4], which begins at an earlier age in Africans than in Europeans, and the disease typically advances rapidly [5].

Applanation tonometry is a method for measuring IOP, with the pressure being estimated from the force required to flatten the corneal apex. The Goldmann applanation tonometer (GAT) is regarded as the ‘gold standard.’ However, there are other instruments, such as the Tono-Pen® (Reichert Technologies, Depew, N.Y., USA), the ocular blood flow tonograph, and the noncontact tonometers, which offer certain benefits over the GAT in special circumstances [6]. Presently, the GAT is the instrument most commonly used for the measurement of IOP but, since it is usually mounted on a slit lamp, it is unwieldy and can be difficult to use in many situations, such as to measure IOP in infants under anesthesia, in field surveys, and in primary care centers [6]. A major issue with the other computerized tonometers is their poor accuracy, which affects the standardization of glaucoma control and monitoring. However, several authors have shown good agreement between IOP measurements with the Tono-Pen and the GAT [6–9]. Besides, among the computerized tonometers, the Tono-Pen has been found to be the most convenient for glaucoma screening and for measuring IOP in infants, unconscious or paraplegic patients, and in seriously ill patients; it also reportedly causes minimal discomfort to the patient [8]. It is easy to handle, being portable and operable in any position, and its use can be learnt quickly [8]. Furthermore, as Azuara-Blanco et al. [9], Rootman et al. [10] and Ménage et al. [11] have demonstrated, the Tono-Pen can be used for IOP measurement in patients with corneal ulcers, penetrating keratoplasty, or cornea irregularity due to other causes.

Despite these various advantages, however, the Tono-Pen is not widely used in Nigeria. This may be due in part to the uncertainty regarding the accuracy of IOP measurement, as some studies have reported a poor correlation with GAT [12]. The accuracy of tonometry – which is affected by patient age, central corneal thickness (CCT), corneal curvature, and the level of IOP [13] – is important as it determines the correct classification of a POAG patient into high tension, normal tension, and ocular hypertension, each of which requires a specific management approach. The Tono-Pen has disposable tips, which is advantageous when dealing with patients in the immediate postoperative period or those with infections such as HIV. Furthermore, due to its short learning curve, ophthalmologists can easily use the Tono-Pen for measuring IOP, which should help increase the rate of early diagnosis and referral for specialist care [13]. An easily accessible instrument that gives reliable and accurate measurements is needed, and the Tono-Pen meets these requirements. However, there is no published data comparing the Tono-Pen and GAT in a Nigerian population. Hence, the objectives of this study were to determine the agreement between the Tono-Pen and the GAT for IOP measurement in glaucoma patients and the effect, if any, of age, gender and CCT on IOP measurement. We also aimed to determine the acceptability of the Tono-Pen among patients.

### Subjects and Methods

#### Study Design and Participants

This comparative clinic-based observational study was conducted at the Deseret Community Vision Institute (DCVI) located in rural Ijebu-Mushin, Ogun State, Southwest Nigeria. The DCVI is a tertiary eye care facility that serves as the community branch of the Eye Foundation Hospital, Lagos, Nigeria. It serves as a low-cost referral center for various ophthalmic disorders for patients from Ogun State and its environs. On average, 600 new glaucoma patients are managed at the DCVI annually. Patients can avail investigatory and therapeutic services, including optical, medical, laser, and surgical treatment. The Ijebu-Mushin community is predominantly of the Yoruba ethnic group, the dominant tribe in Nigeria’s southwest geopolitical zone, with farming and trading as their major occupations.

The minimum sample size was estimated using the formula for comparative studies [14]. A power analysis with a 95% confidence level showed that 68 participants were required, and a total of 75 participants were enrolled into the study.

Newly diagnosed glaucoma patients between 30 and 90 years of age, presenting consecutively to the glaucoma clinic of DCVI, were included in the study until the estimated sample size was achieved. The 75 newly diagnosed glaucoma patients included 39

<table>
<thead>
<tr>
<th>Table 1. IOP measurements</th>
<th>Right eyes</th>
<th>Left eyes</th>
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<tbody>
<tr>
<td></td>
<td>mean ± SD</td>
<td>range</td>
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<tr>
<td>GAT IOP, mm Hg</td>
<td>17.1 ± 6.9</td>
<td>8.2–47.2</td>
</tr>
<tr>
<td>Tono-Pen IOP, mm Hg</td>
<td>21.1 ± 6.8</td>
<td>13.3–52.1</td>
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<tr>
<td>Pachymetry, μm</td>
<td>510.5 ± 29.6</td>
<td>455–587</td>
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<tr>
<td>Corrected GAT, mm Hg</td>
<td>18.9 ± 7.5</td>
<td>11.1–51.0</td>
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DOI: 10.1159/000448953
males and 36 females; 66 were married, 25 had secondary school education, and 64 were of Yoruba ethnicity.

The Health and Medical Research Ethics Committee of Lagos University Teaching Hospital, Lagos, Nigeria, approved this study, which was compliant with the 1964 Helsinki Declaration (last revised in 2008). Written informed consent was obtained from each participant prior to the examination.

Study Procedure

The study was conducted on 75 participants between January 1, 2013, and April 30, 2013. A pretested structured questionnaire was used to obtain demographic data and the clinical history of each patient. The ophthalmological examination, conducted by the primary investigator (C.O.), included a best corrected visual acuity evaluation, slit lamp, and IOP measurement using both the Tono-Pen AVIA (Reichert Technologies) and GAT. The Tono-Pen was calibrated weekly and the GAT was calibrated monthly by our biomedical technician. The GAT was used first and then, after 10 min (to allow recovery of the cornea), the Tono-Pen measurement was performed. All the measurements were made by the same examiner (C.O.) and in all patients the IOP measurements were made during the same period of the day (i.e. between 09.00 and 12.00 h). Two readings were taken with each instrument and the average of each was recorded. After the measurements the subject was asked which of the instruments they found more acceptable. The CCT was measured with an ultrasonic pachymeter (OcuScan RxP; Alcon Laboratories, Fort Worth, Tex., USA). Visual field defects were assessed using a visual field perimeter (Humphrey Matrix FDT; Carl Zeiss Meditec AG, Jena, Germany). Gonioscopy and slit lamp biomicroscopy of the fundus after papillary dilatation were performed subsequently.

Data Analysis

SPSS for Windows, version 16, 2007 (SPSS Inc., Chicago, Ill., USA) was used for statistical analysis. Quantitative data are expressed as means ± standard deviation (SD). Frequency tables and charts were used for qualitative variables. The paired t test was used to determine the significance of differences between the IOP measurements with the two instruments. One-way ANOVA was used to determine the effect of the age group on IOP. The independent t test was used to determine the effect of gender on IOP. A p value <0.05 was considered to be statistically significant.

Results

The age range of study participants was between 35 and 86 years with a mean age 60.39 ± 16.71 years. The majority of the patients (21, 27.8%) were within the age bracket of 60–69 years. The patterns of IOP and CCT in the 75 patients are shown in Table 1. In both eyes, the mean Tono-Pen reading was higher than the mean GAT reading in the right eye (Tono-Pen 21.0 ± 6.9 mm Hg, GAT 17.1 ± 6.9 mm Hg) and left eye (Tono-Pen 20.7 ± 7.8 mm Hg, GAT 17.0 ± 8.3 mm Hg).

In both eyes the Tono-Pen readings were significantly (p = 0.005) higher than the uncorrected GAT readings (Table 2). After correction of the GAT reading for CCT, the difference between the measurements with the two instruments was less, but still statistically significant (Table 3).

Comparison between Tono-Pen and GAT measurements among different age groups showed that IOP measured with the Tono-Pen was significantly higher in all of the age groups (p < 0.05; Table 4). The Tono-Pen readings remained higher than the GAT readings even after correction for CCT, but the difference was now statistically significant only in those above 50 years of age (Table 5). A strong positive correlation was seen between the Tono-Pen and GAT measurements, with a correlation coefficient (r) of 0.957 (p < 0.001; Fig 1). With both the Tono-Pen and GAT, IOP was generally higher in women (21.2 ± 9.0 mm Hg) than in men (16.4 ± 5.0 mm Hg; GAT: 17.9 ± 8.7 mm Hg in women vs. 16.4 ± 5.0 mm Hg in men; Tono-Pen: 21.2 ± 9.0 mm Hg in women vs. 21.1 ± 4.8 mm Hg in men). The mean corneal thickness was also less in women (501.6 ± 28.1 μm) than in men (516.6 ± 29.4 μm). However, the differences in IOP (p = 0.981, 0.437 and 0.788 for Tono-Pen, GAT and corrected GAT, respectively) and corneal thickness (p = 0.057) between genders were not statistically significant (p = 0.057). Of the 75 patients, 68 (90.7%) found the Tono-Pen more acceptable.
than the GAT. While the relative comfort of the Tono-Pen compared to GAT is implied, the actual reason for the preference was not elucidated in this study.

**Discussion**

The mean age of the patients in this study (60.4 ± 16.7 years) was similar to that of a previous study (62.4 ± 11.3 years) on tonometry in glaucoma patients [15]. The finding that mean IOP using GAT was lower than that using the Tono-Pen did not confirm the results of previous studies [6, 16]. This difference could be attributable to the use of a different model of the Tono-Pen and the larger sample sizes in those studies. While in the aforementioned studies the Tono-Pen XL model was used, this study used the AVIA model.

In our patients, the mean CCT of 510.5 ± 29.6 μm was comparable to the mean values reported from other studies in Nigeria (529.3 ± 35 μm) [17] and Sudan (530.15 ± 40 μm) [18].
58.10 μm) [18]. However, the mean CCT of our patients was far lower than the mean CCT’ of 565.2 ± 37.9 μm found in a large population study amongst Caucasians [19]. This is further evidence that indigenous black Nige-rians have lower mean CCTs than Caucasians.

The mean GAT, corrected GAT, and Tono-Pen read-ings were generally higher in women than in men, which is consistent with the findings of Jeelani and Taklikar [20]. Equally important is the finding that women had a lower CCT than men, which was similar to the findings of another Nigerian study [17]. This may be due to the observed anatomical variations in overall corneal thick-ness between males and females. A multiracial study in-involved Caucasians, Asians, Hispanics, and African Americans reported that male subjects had thicker corneas than their female counterparts [21].

The finding by paired t test that the mean IOP was sig-nificantly higher with the Tono-Pen than with the GAT is also consistent with the observations of Hsu et al. [22]. The difference was less when Tono-Pen measurements were compared with corrected GAT measurements, but was still statistically significant. This suggests that Tono-Pen measurements are less affected by differences in the CCT. As reported by Mok et al. [23], this is because the Tono-Pen, unlike GAT, applanates a smaller area of the cornea. This finding is similar to that of Tonnu et al. [6] and Shah et al. [24], who compared manometric IOP against Tono-Pen readings. However, Salvetat and Zep-pieri [15] reported that the Tono-Pen overestimated IOP in thick corneas and underestimated it in thin corneas.

IOP was noticed to increase with age, but no statisti-cally significant difference was found in the pattern of increase with the use of either Tono-Pen or GAT. This finding is in agreement with another study on a similar population [6]. However, Salvetat et al. [15] noticed a statistically significant tendency for Tono-Pen to overesti-mate IOP in very old patients. The cornea is believed to stiffer with age as a result of ultrastructural changes in the collagen fibrils of the cornea stroma [25]. The finding of a relatively higher value of IOP seen with both instru-ments with increasing age may be explained by a stiffer cornea in older subjects.

The positive correlation noted between the GAT IOP measurement and CCT indicates that GAT measurements increase as CCT increases, which is consistent with the knowledge that GAT overestimates IOP in thicker corneas [19]. The statistically significant inverse relationship between CCT and corrected GAT readings is consistent with the knowledge that eyes with thinner corneas tend to have higher IOP values after GAT readings are corrected for CCT [19]. A linear relationship would indicate that there is a predictable change in one variable when the other changes. This is in agreement with studies by Bandypadhyay and Raychaudhuri [7] and Frenkel et al. [26]. Overall, the clinical implication is that failure to adjust IOP for CCT variation could lead to the inappropriate tar-geting of IOP, making it very high for patients with thinner corneas and very low for those with thicker corneas.

We found a strong positive correlation between Tono-Pen measurements and GAT measurements. Several in-vestigators in the past have determined the agreement be-tween different tonometers. Minckler et al. [27] reported similar IOP readings in adults with the first generation Tono-Pen (Tono-Pen-1) and GAT. Frenkel et al. [26] also compared Tono-Pen and GAT in adults and concluded that the Tono-Pen measures IOP in a manner that corre-sponds well to the GAT in the 11- to 20-mm Hg range, and fairly well in the 4- to 10- and 21- to 30-mm Hg ranges. A more recent survey reported that the between-instrument average measurement difference was small, and there was no tendency for the difference to vary with the level of the IOP [6]. The implication for practice is that IOP measure-ments are comparable with both instruments.

Our study participants, both male and female, found the Tono-Pen more acceptable than the GAT, which corre-sponds to the findings of other studies [7]. The prefer-ence for the Tono-Pen was highest in the age groups of 30–39 and 50–59 years, but this was not statistically sig-nificant. Male patients were also more likely to prefer the Tono-Pen than female patients. The preference for the Tono-Pen in a large number of patients may be due to the minimal discomfort associated with its use. The implication for practice is that the eye care provider should ask the patient which instrument he or she prefers. In a Nige-rian survey [28], up to 34.3% of surgeons did not rou-tinely discuss management options with patients or their families.

Conclusion

Tono-Pen AVIA IOP readings were higher than GAT readings with a lower mean difference when compared with corrected GAT readings. Patients found the Tono-Pen more acceptable than the GAT. While the Tono-Pen cannot replace the gold standard GAT, it will definitely be useful as a screening tool in the field. Large population studies and meta-analyses are necessary to validate the difference between the two instruments to enable standardization of the Tono-Pen.
Acknowledgement

Many thanks go to Mr. Charles Otoo, hospital biomedical technician, for his technical support.

Disclosure Statement

The authors have no conflicts of interest to disclose.

References


