Research Square

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Easyton ® transpalpebral versus Perkins applanation tonometry in different clinical populations

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Abstract

Objective

To compare intraocular pressure (IOP) measurements obtained using the new transpalpebral Easyton® tonometer and Perkins applanation tonometer (PAT) in three different clinical populations.

Methods

The participants of this prospective study were 84 subjects divided into the groups: 22 healthy children (G1), 42 healthy adults (G2), and 20 adult patients with primary open angle glaucoma (G3). The data recorded in 84 eyes of these subjects were age, sex, eye, central corneal thickness (CCT) and axial length (AL). In all eyes, IOP was determined in the same examination room by the same experienced examiner using Easyton® and PAT in random order.

Results

Mean differences in IOP readings between Easyton® and PAT were 0.45 ± 1.97 ($p = 0.295$), -0.15 ± 2.13 ($p = 0.654$), -1.65 ± 3.22 ($p = 0.033$), and − 0.018 ± 2.500 mmHg ($p = 0.500$) in the groups G1, G2, G3 and whole sample (G4), respectively. Correlations between Easyton® and PAT IOP values were 0.668 ($p = 0.001$) for G1, 0.463 ($p = 0.002$) for G2, 0.680 ($p < 0.001$) for G3 and 0.605 ($p < 0.001$) for G4. Moderate to good agreement between the two tonometers was found in all groups according to intraclass correlation coefficients, which were 0.794 ($p < 0.001$) for G1, 0.632 ($p < 0.001$) for G2, 0.809 ($p < 0.001$) for G3, and 0.740 ($p < 0.001$) for G4. The lower and upper limits of agreement between the devices were − 5.1 and 4.7 mmHg, respectively. No correlation was noted between CCT or AL and the Easyton® IOP measurements.

Conclusion

IOP measurements obtained with Easyton® and PAT show an acceptable level of agreement both in healthy individuals and in patients with glaucoma.

Introduction

Glaucoma is a leading cause of blindness worldwide and thus a significant public health concern [1]. While its origin is multifactorial, elevated intraocular pressure (IOP) has been identified as the main risk factor and has been also related to glaucoma progression. Accordingly, both before and after a diagnosis of glaucoma, this factor is a major therapeutic target.

There are several devices available to measure IOP. Many studies examining devices based on different principals including rebound, transpalpebral and non-contact air pump tonometers [2], among others, have compared the reproducibility and precision of their measurements [3–10]. Besides these parameters, each device offers its own benefits for use in specific populations or situations. Transpalpebral tonometry has the main advantage that corneal contact is avoided, which might be necessary when this is not possible [11] or not advisable due to a compromised corneal surface [7, 12, 13]. Today, Goldmann applanation tonometry (GAT) is considered the gold standard so most studies have focused on confirming the clinical interchangeability of GAT with each different device [4–10]. The Perkins applanation tonometer (PAT) is a handheld device that offers IOP measurements that are closely comparable with GAT [14].

The recently introduced TVGD-02 Easyton® (Yelatma Instrument Making Enterprise, JSC, Yelatma, Russia) is a transpalpebral tonometer that measures IOP through the upper eyelid using a hydraulic system. In the examination room, the subject is instructed to tilt the head backwards and the glance line is oriented at an angle of around 45º to the horizontal. The examiner stands behind the subject and presses the instrument against the upper eyelid approximately 1 mm away from the limbus and the measurement is automatically recorded. As with other transpalpebral tonometers, the reading is not influenced by corneal thickness [15] or the presence of corneal disease or any corneal irregularity [7, 12, 13] as occurs with GAT measurements.

To the best of our knowledge, however, no study has compared IOP measurements made with this transpalpebral tonometer and PAT. The aim of the present study was therefore to compare pressure readings offered by Easyton® and PAT in three clinical settings: healthy children, and adults with and without glaucoma

Methods

Participants

The subjects recruited for this comparative prospective study were 22 healthy children, 42 healthy adults, and 20 adults with primary open angle glaucoma (POAG). All measurements were made in the same examination room at the Hospital Clínico San Carlos, Madrid, Spain. The study protocol adhered to the principles of the Declaration of Helsinki and was approved by the clinical review board of this hospital.

Exclusion criteria were the presence of any corneal, eyelid or scleral pathology that could hinder measurements. Candidates were also excluded if they were non-cooperative. If both eyes did not meet any of the exclusion criteria, the eye to be examined was selected randomly using a web application (www.randomization.com).

Inclusion criteria for the glaucoma group were a clinical diagnosis of POAG (open angle detected on gonioscopy, IOP over 21 mm Hg on at least 3 different days, typical changes at the optic nerve head and visual field defects consistent with POAG). The healthy adult group included subjects with an IOP of 21 mm Hg or lower, no visual field defects, no other ocular diseases and no family history of glaucoma.

These subjects were consecutively recruited among the hospital staff including nurses, relatives of patients, and persons visiting our clinic for a routine visual acuity examination.

Clinical measures

A comprehensive ophthalmologic examination was performed in all subjects including visual acuity testing, slit lamp biomicroscopy, fundus evaluation, central corneal thickness (CCT), axial length (AL) and IOP. CCT was measured by ultrasound pachymetry (Dicon P55; Paradigm Medical Industries Inc., Salt Lake City, UT) and AL was measured using an optical biometer (IOL Master 700, Carl Zeiss Meditec, Jena, Germany). For each participant, data were recorded including age, gender and the eye randomly selected for the study. For the patients with POAG, additional data compiled were their hypotensive treatment regimen (number of intraocular pressure-lowering drugs taken) and their latest visual field data square root of loss variance (sLV) and mean deviation (MD).

The same examiner performed all IOP measurements consecutively in a single session using the PAT (Perkins®; Clement-Clarke, Columbus, OH, USA) and Easyton® tonometers. The order of use of both devices was randomized using a web application (www.randomization.com). For the applanation tonometry, we used topical fluorescein and anesthetic, Three measurements were taken with each device and the mean of these three measures entered in the statistical analysis.

Demographic and clinical data are provided in Table 1 for each participant group: group 1 (G1) including 22 eyes of 22 healthy children of mean age of 9.7 ± 2.5 years, group 2 (G2) including 42 eyes of 42 healthy adults of mean age of 77.6 ± 10.0 years, and group 3 (G3) including 20 eyes of 20 patients with POAG of mean age 73.3 ± 9.3 years. Data for the whole group of 84 participants (G4) are also provided.

Table 1
Demographic and clinical data in the different groups of patients evaluated in the current sample.

Mean (SD) **Range**	**Children (G1) (N = 22)**	**Adults (n = 62)**		**Total (G4) (n = 84)**	**P-value***
		Healthy subjects (G2) (n = 42)	**Glaucoma patients (G3)** **(n = 20)**		
Age (years)	9.69 (3.5) 5–13	77.6 (10.0) 61–95	73.3 (9.3) 61–86	56.1 (32.1) 5–95	< 0.001
Transpalpebral IOP (mm Hg)	14.6 (2.5) 9–18	15.5 (2.0) 8–21	15.6 (4.0) 10–31	15.3 (2.7) 9–30	0.231
PAT IOP (mm Hg)	14.13 (2.19) 9–17	15.36 (2.09) 8–23	17.25 (4.06) 13–28	15.49 (2.90) 9–28	0.002
AL (mm)	22.76 (1.11) 20.89–25.10	23.51 (1.50) 21.16–30.58	24.08 (1.89) 21.76–26.56	23.42 (1.56) 20.89–30.58	0.013
CCT (µm)	545.8 (39.4) 492–662	542.8 (38.9) 472–637	550.4 (38.1) 496–632	545.4 (39.0) 456–687	0.780
MD **(dB)**	-	-	6.7 (6.8) -1.5-22.9	-	
sLV **(dB)**	-	-	4.7 (2.1) 1.5–8.3	-	
Ocular medication **(drops)**	-	-	1.6 (1.4) 0–4	-	

Abbreviations: SD, standard deviation; IOP, intraocular pressure; CCT, central corneal thickness; AL, axial length; MD, mean deviation; sLV, square root of loss variance

*Result of the comparison between G1, G2 and G3.

Statistical analysis

All statistical tests were performed using SPSS software version 12.0 for Windows (SPSS Inc., Chicago, IL, USA) and MedCalc 7.3. The Kolmogorov–Smirnov test was used to check the normality of the distribution of quantitative data. Normally distributed data were compared using the Student's t-test and Pearson's r coefficient of correlation and non-normally distributed data with the Mann Whitney nonparametric test and Spearman's r coefficient. Individual groups were compared through one-way analysis of variance (ANOVA) and the Kruskal-Wallis test for normally and non-normally distributed data variables respectively. Post-hoc Bonferroni adjustment was used to correct for the effect of multiple comparisons. To assess agreement between the two tonometers, we calculated intraclass correlation coefficients (ICC). The Bland-Altman method was used to graphically depict the level of agreement between the Easyton© and Perkins© IOP measurements for the whole sample. Significance was set at $p < 0.05$.

Results

The mean IOP values obtained through applanation and transpalpebral tonometry and the mean differences between the two devices may be seen in Table 2. No significant differences were found between transpalpebral and PAT measurements in the participant groups G1, G2 and G4. Mean IOP differences were 0.45 ± 1.97 ($p = 0.295$) for G1, -0.15 ± 2.13 ($p = 0.654$) for G2 and − 0.02 ± 2.50 ($p = 0.500$) for G4. In G3, PAT readings were significantly higher than those obtained with the transpalpebral tonometer with a mean difference of -1.65 ± 3.22 ($p = 0.033$). Positive significant correlation was found between the PAT and Easyton® IOP measurements in all groups (G1: $r = 0.668$, G2: $r = 0.463$, G3: $r = 0.680$, G4: $r = 0.605$, all $p < 0.002$) (Table 3). Strongest correlation was found for G3 ($r = 0.680$, $p < 0.001$) (Table 3).

Table 2
Tonometric data in the different groups of patients evaluated in the current sample.

Mean (SD)	Mean IOP		Mean difference (Transpalpebral - PAT)	
	Transpalpebral (mm Hg)	PAT (mm Hg)	mm Hg	p-value
G1	14.62 (2.54)	14.13 (2.19)	0.45 (1.97)	0.295
G2	15.36 (2.09)	15.51 (2.02)	-0.15 (2.13)	0.654
G3	15.6 (3.97)	17.24 (4.08)	-1.65 (3.22)	0.033
G4	15.31 (2.73)	15.49 (2.90)	-0.02 (2.50)	0.500

Abbreviations: SD, standard deviation; IOP, intraocular pressure.

Table 3
Correlation coefficients and intraclass correlation coefficient (ICC) in the different groups of patients evaluated in the current sample.

	Agreement				
	Correlation coefficient (r)	p-value	ICC		
			Mean value	IC 95%	p-value
G1	0.668	0.001	0.794	0.504–0.915	< 0.001
G2	0.463	0.002	0.632	0.316–0.802	< 0.001
G3	0.680	< 0.001	0.809	0.519–0.925	< 0.001
G4	0.605	< 0.001	0.740	0.569–0.843	< 0.001

Moderate to good agreement was found between the IOP measurements made with both devices in all groups (Table 3); ICC values were always over 0.6 (mean ICC's G1 = 0.794, G2 = 0.632, G3 = 0.809, G4 = 0.740). According to the Bland-Altman plot in Fig. 1, there was agreement between the PAT and Easyton® measurements in the whole sample (n = 84). As shown, the mean difference between the tonometers was − 0.2 mm Hg (p = 0.500), and the lower and upper limits of agreement were − 5.1 and 4.7 mm Hg, respectively. In the plot, only two readings were above and another two below the limits of agreement (5.9% of the readings), whereas the rest of the readings (79/84) were within such limits.

Finally, we also looked for correlations between CCT or AL and the IOP readings obtained with both tonometers in all groups (Table 4). No significant correlations emerged between both measurements (CCT or AL) and Easyton® IOP in any of the four groups (G1: IOP-CCT: r=-0.23 (p = 0.913), IOP-AL: r=-0.137 (p = 0.505); G2: IOP-CCT: r = 0.342 (p = 0.059), IOP-AL: r=-0.308 (p = 0.057); G3: IOP-CCT: r=-0.093 (p = 0.696), IOP-AL: r=-0.008 (p = 0.972); G4: IOP-CCT: r = 0.086 (p = 0.424), IOP-AL: r=-0.081 (p = 0.456). As expected, PAT IOP measurements showed significant correlation with CCT (r = 0.314; p = 0.013).

Table 4
Correlation between the intraocular pressure (IOP) measurements obtained with applanation tonometry using the Perkins device and with the transpalpebral tonometer Easyton© and the different clinical characteristics evaluated.

	Transpalpebral IOP-CCT		Transpalpebral IOP-AL		PAT IOP-CCT		PAT IOP-AL	
	r	**p-value**	**r**	**p-value**	**r**	**p-value**	**r**	**p-value**
G1	-0.23	0.913	-0.137	0.505	-	-	-	-
G2	0.342	0.059	-0.308	0.057	-	-	-	-
G3	-0.093	0.696	-0.008	0.972	-	-	-	-
G4	0.086	0.424	-0.081	0.456	0.314	0.013	0.151	0.243

Abbreviations: SD, standard deviation; IOP, intraocular pressure; CCT, central corneal thickness; AL, axial length.

Discussion

This study sought to assess IOP readings made with the new transpalpebral Easyton® tonometer using the Perkins applanation tonometer as reference in healthy children and adults and in adult patients with glaucoma. Our results indicate no significant differences between IOP measurements made using the two devices except in the group of glaucoma patients (-1.65 ± 3.22, p = 0.033). In this group, Easyton® readings were usually slightly lower than those recorded using PAT.

Other authors have also reported lower transpalpebral tonometry measurements in glaucoma patients [8, 16]. Schlote and Landerberger [16] found that the transpalpebral tonometer TGDc-01"PRA" significantly underestimated IOP compared to GAT in eyes with elevated IOP. Using the same transpalpebral tonometer, Troost et al [8] noted increasing underestimation of IOP with increasing IOP levels when compared to GAT. Our finding of this underestimation by Easyton® in our glaucoma group compared to the groups of healthy individuals is in line with previous reports. Further investigation is warrented to devise a correction factor for Easyton® when used in subjects with elevated intraocular pressures.

Despite the lower Easyton® IOP values obtained in our G3 compared to PAT, agreement between the devices was moderate to good in all groups and ICC's were over 0.60 [17]. Further, the ICC of 0.74 recorded for the whole sample (G4) may be considered as good according to the criteria defined by Koo and Li [17].

To examine the clinical interchangeability of the two devices we included data for the whole population of both healthy individuals and glaucoma patients. The mean difference detected between the Easyton® and PAT readings was − 0.018 ± 2.5 mm Hg and lacked significance (p = 0.500). Although most of the differences detected were small, the Bland-Altman plot revealed wide 95% limits of agreement, ranging from 4.7 to 5.1 mmHg. While this suggests a moderate level of interchangeability between devices, this range of agreement was narrower than those reported in studies that have compared other transpalpebral tonometers with GAT: lower and upper limits of agreement, respectively, of + 4.4 mmHg and − 11.8 mmHg reported by Lösch et al [9] for TGDc-01, + 8.4 mm Hg and − 9.6 mm Hg by Doherty et al [4] for the transpalpebral tonometer Diaton® and − 6 mmHg and + 6 mmHg by Sandner et al [18] also for TGDc-01, the latter being closer to our results.

Finally, we also examined correlations between IOP values obtained with both devices and CCT or AL as older models of transpalpebral tonometers are affected by corneal thickness, especially in subjects with thin corneas [19]. Here, no correlation was detected between CCT or AL and IOP measurements in any of our study groups. This independence from CCT is useful as it is one of the main limitations of GAT [20]. This means that an eye's AL and CCT are not confounding factors for Easyton® IOP measurements.

As limitations of our study, we should mention that IOP readings were taken consecutively with no pauses and we did not examine lid biomechanics, corneal biomechanics, or the impacts of lid thickness on measurements. Further, a subgroup analysis of different IOP ranges was not performed.

In conclusion, our findings indicate an acceptable level of agreement between the transpalpebral tonometer Easyton© and the Perkin's applanation tonometer in healthy individuals and glaucoma patients. The transpalpebral device, however, tended to underestimate IOP in the glaucoma patients. The readings obtained with this new tonometer were also highly independent from corneal thickness. As this device avoids direct contact with the eye, there is no need for topical fluorescein and it can be easily used in subjects with corneal infection or corneal irregularities, non-cooperative subjects or those with reduced mobility [3–9]. If our findings are confirmed in further work, these benefits make this transpalpebral tonometer especially useful for IOP screening and for use in children and individuals with corneal disease.

Declarations

Conflict of interest

The authors declare no conflict of interest

Funding statement

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Figures

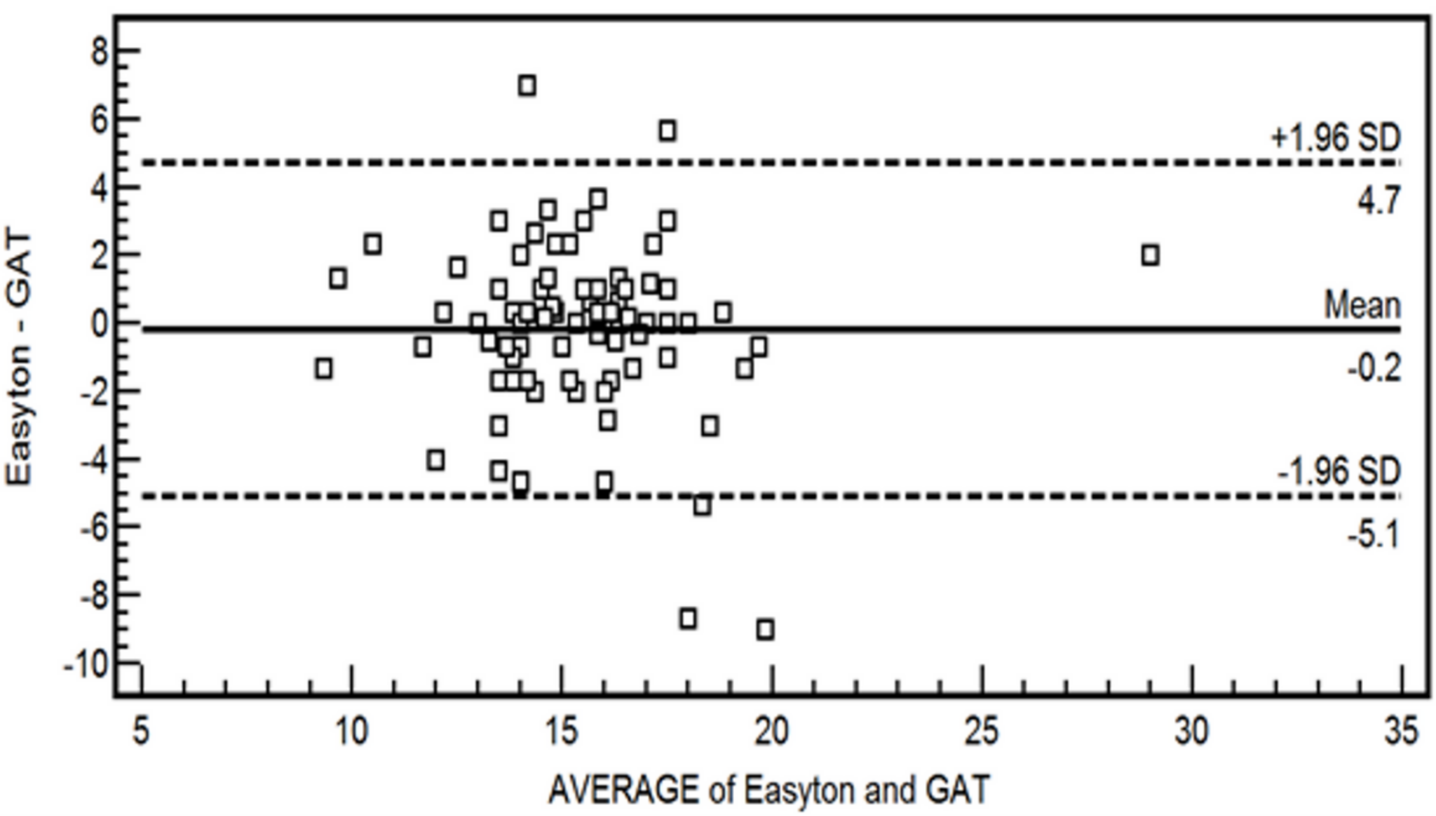

Figure 1

Bland-Altman plot showing the agreement between IOP measurements obtained with Goldmann applanation tonometry (GAT) and the transpalpebral tonometer Easyton© in mmHg.