ORIGINAL ARTICLE

Goldmann Applanation Tonometry: Comparison of Intraocular Pressure Values Obtained with Disposable Tip and Conventional Applanation Prism in the Population without Clinical Signs of Glaucoma

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Abstract

Aim: Comparing intraocular pressure (IOP) measurements using Goldmann applanation prism and TonoSafe® in the population without signs of glaucoma.

Material and methods: Patients with no ocular pathologies, except ametropia (until ± 4 D) or IOP of <30 mm Hg without signs of glaucoma by optic disc structural analysis by fundus biomicroscopy. The IOP was measured sequentially using the traditional cone and the TonoSafe®, according to a randomization list to determine which device would be used first. The measurements from the right and left eyes were compared separately. Since there was no statistical difference, both eyes were considered in this study.

Results: A total of 385 eyes of 194 patients with a mean age of 66.4 ± 11.2 years old were included. The mean IOP with conventional prism was 14.2 ± 3.6 and 14.3 ± 3.6 mm Hg with TonoSafe®. Differences were not statistically significant by the Wilcoxon test ($p = 0.3$). The median was 14.0 mm Hg for both groups. The mean difference between measurements was 0.04 mm Hg, with the median equal to zero. There was no statistical difference in IOP readings according to which device was the first measurement.

Conclusion: No statistical difference was found in IOP was measured with conventional prism or TonoSafe® in the population without signs of glaucoma.

Clinical significance: The data provided by our study support the efficacy and safety of the disposable tonometer compared to the Goldman tonometer in measuring IOP in patients without glaucoma.

Keywords: Cross-sectional studies, Disposable tip, Intraocular pressure, Tonometry.

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Introduction

The pandemic caused by the new coronavirus disease 2019 (COVID-19), decreed in March 2020 by the World Health Organization, has brought demands for readaptation in medical routines in the in-hospital, outpatient, and surgical settings. The routine of the doctor's office, which is responsible for much of the ophthalmologist's daily life, has been undergoing changes to ensure the protection of the patient and the doctor from severe acute respiratory syndrome coronavirus 2. In this sense, some situations, once routinely considered safe, are being reassessed since the ocular surface is a possible site of infection in virus transmission.[1]

Goldmann applanation tonometry is an indispensable part of the ocular examination, and because the tonometer is in contact with the ocular surface, it is pointed out as a possible source of transmission of infectious diseases.[2–5] Studies report the presence of pathogens in the tear from infected patients, and experimentally the viability of these agents was demonstrated in the tip of the tonometer cone.[6] The literature reports outbreaks of epidemic keratoconjunctivitis associated with nondisinfection of the tonometer.[7,8] Concerning COVID-19, the literature is still inconclusive on the role of the ocular surface in the transmission of this virus.[1] Despite this, the ocular surface is considered a possible site of infection, considering it is composed of mucous membranes.[1]

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In the majority of ophthalmology services, the most commonly used technique for cleaning the applanation cone is the use of gauze or paper wipes soaked in 70% ethyl or isopropyl alcohol.[9–12] However, according to some studies, this technique may not be efficient for the complete disinfection of the tonometer.[2,4,5,11,12] Another drawback associated with the use of alcohol is the possibility of damage to the material of the cone. The user manual of the major Goldmann tonometer manufacturer

(Haag-Streit, Switzerland) does not recommend the use of alcohol for cleaning the cone.[13,14] Some studies have reported a reduction of transparency, surface irregularity, and the reaction of the alcohol with the material used to glue the parts of the cone, especially when it is immersed for some time in the alcohol solution.[2,15–18]

As an alternative to chemical disinfection of the cone, sterile single-use applanation tips can be used.[11,19–26] The Haag-Streit offers the TonoSafe® internationally (Figs 1 and 2).[24] TonoSafe® is a disposable transparent acrylic tip with the same area as the traditional applanation cone that is fitted into a plastic holder which plugs into the tonometer, just like the traditional cone. Studies demonstrate a good correlation between the measurements obtained with the disposable cone and the traditional one.[19–22,25,27] In the national literature, to the present day, there are no series comparing IOP measurements with disposable and conventional tips.

The objective of this study was to compare IOP measurements obtained by applanation tonometry with the traditional and the disposable TonoSafe® cone.

Materials and Methods

The study was conducted at the Ophthalmology Department of the Health Sciences Institute of the Federal University of Triângulo Mineiro (UFTM) in Uberaba-MG. It was approved by the UFTM Research Ethics Committee via consubstantiated decision number 4.276.858.

We selected patients who were referred to the UFTM ophthalmology service for routine ophthalmological visits and who, on examination, had no ocular pathologies, except for ametropia between −4.00 D and +4.00 D, and with IOP of <30 mm Hg with no sign of glaucomatous neuropathy evaluated by optic disc structural analysis at fundus biomicroscopy. For the purpose of this study, statistical analyses of the IOP measurements obtained by the traditional cone and the TonoSafe® (Figs 1 and 2) were done separately for the right eyes and the left eyes. Because there was no statistically significant difference in the analysis of the measurements obtained by the tonometers in each eye separately, both eyes were considered for the comparison between traditional and TonoSafe® cones.

Fig. 1: Applanation cones. Above the traditional one supplied with the Goldmann tonometer and below the TonoSafe® cone. (Image by coauthor JAPJ).

Three different examiners were responsible for all measurements, with each patient's measurements being taken by the same examiner, using a calibrated model R 900 tonometer (checked before the study started), coupled to the slit lamp with the traditional applanation cone and the TonoSafe® (Haag-Streit Inc. ANVISA 80102511455). A previously compiled randomization list was followed to choose the first applanation cone to be used. The measurements were always acquired in the same routine: obtained before pupil dilation and after the instillation of eye drops containing topical anesthetic agent (proximetacaine hydrochloride 0.5%) and fluorescein 1%. After tonometry with the two cones, the central corneal pachymetry was measured with a Tomey IM 10 ultrasonic pachymeter.

The data were tabulated and statistically analyzed using GraphPad Instat software (GraphPad Software Inc. La Jolla, California, United States of America). The descriptive statistics were calculated and tabulated. The measures were tested for normality by the D'Agostinho and Pearson test. In the case of a normal sample, the Student's *t*-test for paired samples was chosen, and in the case of a negative sample, the IOP measurements with the two cones were compared by the Wilcoxon test for paired samples. The correlation of the IOP measurement with each cone and the pachymetry was analyzed by Spearmann's test. The Bland-Altman differentiation method was applied.

Results

A total of 385 eyes from 194 patients with a mean age of 66.4 ± 11.2 years were included (Table 1). The mean IOP measured with the traditional applanation cone was 14.2 ± 3.6 mm Hg (6–28 mm Hg), and that obtained with TonoSafe® was 14.2 ± 3.6 mm Hg (6–29 mm Hg) (Table 1). The samples did not present normal distribution ($p < 0.0001$). The Wilcoxon test showed no statistically significant difference between the two measures ($p = 0.3$) (Fig. 3). The median IOP measurement was 14.0 mm Hg in both groups. The mean difference between the measurements was 0.04 mm Hg with a median of 0 mm Hg. The measurements were equal in 197 eyes. The largest difference was 2 mm Hg, which occurred in 33 eyes. The traditional cone showed smaller measurements than TonoSafe® in 101 eyes, of which 83 had a difference of 1 mm Hg. The measurement was higher with the traditional cone in 87 eyes, of which 72 had a difference of 1 mm Hg. There was no statistical difference between the order of IOP measurement, that is, if the traditional cone was used in the first or second measurement. A total of 17 patients had IOP equal to or higher than 22 mm Hg (22–29 mm Hg). The Bland-Altman differentiation method indicated a bias of −0.04 with a standard deviation of the bias = 0.86. Figure 4 presents the obtained IOP means in the 95% confidence interval. In all cases, the results were in the confidence interval.

The mean central corneal thickness was 525.3 ± 36.1 µm (Table 1), with a median of 526 µm, a 25% percentile of 501.5 µm, and a 75% percentile of 551.5 µm. Both measurement devices showed an *"r"* correlation index = 0.1 with the central corneal thickness values.

Discussion

In this study, it was observed that the IOP values measured with the traditional applanation cone did not differ statistically from the values obtained with the TonoSafe®. This is in accordance with an internationally published series.[19,21,25,28] Salvi et al.[18] reported a difference between measurements of 0.1 mm Hg, very similar to that obtained in this study (0.04 mm Hg), which is also in

Figs 2A to C: (A) Above, uncoupled TonoSafe® system; (B) Each acrylic tip is packaged in a single-use blister pack; (C) The acrylic tip is snapped into the plastic holder to be positioned on the tonometer for the exam (images by coauthor JAPJ)

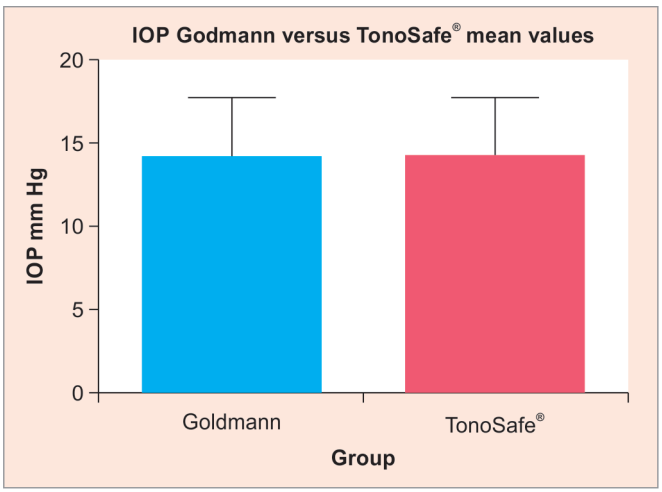

Fig. 3: Mean and standard deviation of the measurements with the traditional Goldmann applanation tip and with the disposable tip

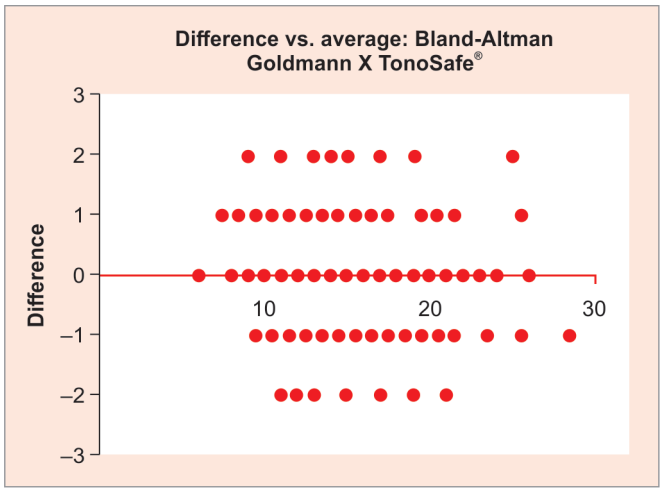

Fig. 4: Bland-Altman differencing analysis. The interval between the dotted lines is the 95% confidence interval. The bias obtained was –0.04

Table 1: Age, pachymetry, and IOP; Goldmann and TonoSafe®

	Goldmann	*TonoSafe®*
Age (years)	66.4 ± 11.2	66.4 ± 11.2
Pachymetry (µm)	525.3 ± 36.1	525.3 ± 36.1
IOP (mm Hg)*	14.2 ± 3.6	14.2 ± 3.6

*Differences were not statistically significant by Wilcoxon's test ($p = 0.3$)

concordance with Ajtony et al.,[29] who described mean differences <0.5 mm Hg. Tsai et al.,[30] also, when comparing the traditional cone with TonoSafe®, reported bias agreement of Bland-Altman = 0.2, a value similar to that described in this series. Although Maino et al.[22] suggested that TonoSafe® should be avoided for IOP measurements higher than 25 mm Hg due to the bias found in their study, there were only nine eyes with pressures higher than this value in this study, which precludes statistical analysis to corroborate or contradict the cited author's conclusion.

Despite the advantage in effectively eliminating the chance of infectious agent transmission, the cost of using TonoSafe® is much more expensive than using a conventional applanation cone, even when considering the cost of antisepsis required between examinations.[25] Using the disposable tonometer increases the costs of care, which certainly may not be absorbed by all eye care services. These additional costs were not calculated in this study, and future studies are necessary to evaluate them.

On the other hand, the possibility of infectious disease transmission must be considered since the antisepsis techniques usually employed frequently have no support in the literature about their effectiveness.[2,4,5,11,12] However, several authors and systematic reviews point out that the risk involved in the usual practice of tonometry has not yet been effectively evidenced, weakening the argument for using disposable tips.[2,4]

As a limitation of this study, there was no evaluation in patients with different ocular surface situations or with IOP higher than 30 mm Hg. Differences in measurements could perhaps be detected at higher IOP values, although this is not very likely.

In any case, it should be noted that the use of TonoSafe® is easy and provides better observation of the tonometer readings since a new tip, which is extremely transparent, is always used, providing more precise and clearer readings.

Conclusion

There was no statistically significant difference between IOP measurement in applanation tonometry with the conventional cone and the disposable TonoSafe® cone in eyes without clinical signs of glaucoma.

Clinical Significance

The data provided by our study support the efficacy and safety of the disposable tonometer compared to the Goldman tonometer in measuring IOP in patients without glaucoma.

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