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Effects of puff times on intraocular pressure agreement between non – contact and Goldmann applanation tonometers

Ibrahim Toprak[1], *Deniz Kilic*[2]

[1]Department of Ophthalmology, Servergazi State Hospital, Denizli 20070, Turkey
[2]Department of Ophthalmology, Faculty of Medicine, Zonguldak Bulent Ecevit University, Zonguldak 67000, Turkey
Correspondence to: Ibrahim Toprak. Department of Ophthalmology, Servergazi State Hospital, Bereketli Beldesi, Denizli 20070, Turkey. ibrahimt@ doctor. com
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非接触式和 Goldmann 压平眼压计测量结果的一致性分析

Ibrahim Toprak[1], Deniz Kilic[2]
(作者单位:[1]20070 土耳其德尼兹利, Servergazi 州立医院眼科;[2]67000 土耳其宗古尔达克,宗古尔达克埃杰维特大学医学院眼科系)
通讯作者:Ibrahim Toprak. ibrahimt@ doctor. com

摘要

目的:在原发性开角型青光眼(POAG)中应用佳能 TX-F 非接触式眼压计(NCT)和 Goldmann 压平眼压计(GAT)测量眼压(IOP),并比较测量值。

方法:55 例(55 右眼)确诊为 POAG 的患者接受详细的眼科检查,光学相干断层扫描成像和自动视野检查。使用 NCT1(一次喷气模式),NCT3(三次喷气模式)和 GAT 测量眼压,每隔 5 分钟一次。

结果:55 例(55 右眼)POAG 患者平均年龄为 64. 1±8. 1 岁。比较 NTC1,NTC3 测量的眼压值(14. 22±3. 42, 14. 28±3. 29mmHg)与 GAT 测量的眼压值(14. 66 ± 3. 49mmHg)无统计学差异(P=0. 291)。使用 Bland-Altman 方法比较 NCT1-GAT, NCT3-GAT 和 NCT1-NCT3 得出的 95% 一致性界限(LoA)分别为-4. 9 ~ +4. 4mmHg,-4. 1 ~ +3. 4mmHg 和 -3. 4 ~ +3. 3mmHg。

结论:虽然 NCT 与 GAT 测量的眼压值相似,但偏大的 LoA 范围限制了 NCT1,NCT3 和 GAT 在 POAG 患者中的互换应用。

关键词:Bland-Altman 方法;青光眼;眼压;一致性界限;非接触式眼压计

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Abstract

• AIM: To compare intraocular pressure (IOP) values obtained from two different puff modes of Canon TX-F non – contact tonometer (NCT) and Goldmann applanation tonometer (GAT) in patients with primary open angle glaucoma (POAG).

• METHODS: The study group comprised 55 right eyes of 55 patients with a confirmed diagnosis of POAG, which were under treatment. All patients underwent detailed ophthalmological examinations, optical coherence tomography imaging and automated perimetry. Intraocular pressure measurements were performed using 1 – puff mode of NCT (NCT1), 3 – puffs mode of NCT (NCT3) and GAT with 5 minutes intervals in order.

• RESULTS: Fifty – five eyes of 55 patients with POAG (mean age of 64. 1 ± 8. 1 years) were enrolled into the study. NCT1 and NCT3 gave similar IOP values when compared with GAT measurements (14. 22 ± 3. 42, 14. 28 ± 3. 29, 14. 66 ± 3. 49mmHg respectively, P = 0. 291). Intertonometer agreement was assessed using the Bland-Altman method. The 95 % limits of agreement (LoA) for NCT1 – GAT, NCT3 – GAT and NCT1 – NCT3 comparisons were -4. 9 to +4. 4mmHg, -4. 1 to +3. 4mmHg, and -3. 4 to +3. 3mmHg respectively.

• CONCLUSION: Although IOP measurements obtained from two puff modes of NCT and GAT showed similar values, wide range of LoA might restrict use of NCT1, NCT3 and GAT interchangeably in POAG patients.

• KEYWORDS: Bland – Altman method; glaucoma; intraocular pressure; limits of agreement; non – contact tonometer
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INTRODUCTION

Glaucoma is an optic neuropathy characterized by progressive visual field loss[1]. Elevated intraocular pressure (IOP) is the major and only modifiable risk factor for development and progression of glaucoma[1,2]. Previous clinical trials demonstrated that ocular hypotensive treatment delays or prevents the onset of primary open angle glaucoma (POAG) in patients with ocular hypertension[1,2]. Therefore, measurement of reliable IOP plays a critical role for the diagnosis and management of glaucoma in clinical practice.

Goldmann applanation tonometry (GAT) is regarded as "gold standard" for measuring IOP and its working principle is

based on the equality of forces required for flattening of central cornea[3,4]. However, influence of corneal thickness, need for topical anesthesia with fluorescein staining and patient compliance are the limitations of this technique[3,4]. In routine clinical practice, non-contact (air-puff) tonometers (NCT) are widely used as a primary method for measuring IOP. This technique has advantage of a faster IOP measurement and minimizes the risk for cross infection among patients, whereas it has been suggested that NCT has tendency to overestimate or underestimate the IOP measurement when compared with GAT[4-7]. Thus, it is important to determine whether NCT provides accurate and precise IOP measurements in patients with POAG in routine practice.

In the current study, we assessed the agreement in IOP obtained from two different puff modes (1-puff and 3-puffs mode) of NCT (Canon TX-F Full Auto Non-Contact Tonometer, Canon Inc., Tokyo, Japan) and GAT under routine clinical conditions in patients with POAG.

SUBJECTS ANDMETHODS

Subjects Local ethics committee approved the study protocol and tenets of the Declaration of Helsinki were followed. Written informed consent was obtained from all participants. Fifty-five right eyes of 55 patients with a confirmed diagnosis of bilateral POAG (under medical treatment) were enrolled in the study.

Patients were included in the study according to the following criteria; age between 40-80 years, clinical diagnosis of bilateral POAG (glaucomatous optic nerve damage confirmed by optical coherence tomography and 30-2 Swedish interactive thresholding algorithm standard automated visual field testing), normal anterior segment and gonioscopic examination. Subjects with history of any other ocular pathology or glaucoma surgery and refractive error >5D of sphere or >3D of cylinder were excluded from the study.

All participants underwent a complete ophthalmic examination including visual acuity measurement (Snellen charts), slit-lamp biomicroscopy examination, gonioscopy, and dilated fundoscopic examination with non-contact +90D lens.

Methods

Intraocular pressure measurements Intraocular pressure measurements were performed using following methods in order; NCT1 (1-puff mode), NCT3 (3-puffs mode) and GAT with five minutes intervals between each measurement. Tonometers were calibrated at the beginning of the study.

Non-contact tonometry The device, Canon TX-F Full Auto Non-Contact Tonometer (Canon Inc., Tokyo, Japan), records IOP values automatically for one measurement (1-puff mode) or mean of three consecutive measurements (3-puffs mode) optionally. Patients were informed about the measurement and asked to press his/her face against the forehead and chin rests (from user's manual). Full automatic mode was used and IOP measurement was acquired for 1-puff and 3-puffs with 5 minutes interval for each eye by a single experienced technician (GC). No topical anesthesia was used.

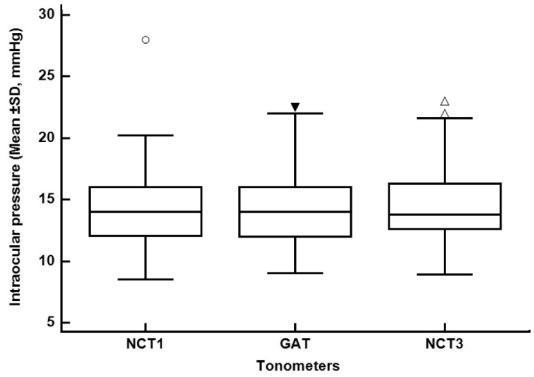

Figure 1 Box-and-whisker plots demonstrate comparison of mean intraocular pressure measurements obtained from NCT1 (1-puff), NCT3 (3-puffs) and Goldmann applanation tonometer. Triangles and circle indicate outliers. NCT= Non-contact tonometer.

Goldmann applanation tonometry After NCT measurements, a single measurement was performed for each eye after topical anesthetic (proparacaine hydrochloride 0.5%) instillation and fluorescein staining (standard fluorescein strip) by same physician (IT) who was unaware of NCT measurements.

Statistical Analysis Statistical analysis was performed with the MedCalc software version 12.6.1.0 (MedCalc Software bvba, Ostend, Belgium). Right eyes of all subjects were used for statistical analysis. The values were expressed as the mean ± standard deviation (SD). The repeated measures ANOVA test was used to compare mean IOP values among three methods. The Bland-Altman method was used to evaluate agreement between two tonometers[8]. This method plots the mean difference between IOP measurements obtained from two tonometers (bias) against the averages, and 95% limits of agreement (LoA, bias±1.96SD) are calculated[8]. A P value less than 0.05 was considered statistically significant at 95% confidence interval.

RESULTS

Fifty-five eyes of 55 patients with a confirmed diagnosis of POAG were included in the study. The study group consisted of 15 (27.3%) male and 40 (72.7%) female. The mean age was 64.1±8.1 years. All patients were under topical ocular hypotensive treatment.

The mean IOP values were 14.22±3.42, 14.28±3.29, 14.66±3.49mmHg for NCT1, NCT3 and GAT respectively (P=0.291). Figure 1 represents mean IOP values for three tonometers.

The Bland-Altman method was used to assess intertonometer agreement. The 95% LoA (bias±1.96 SD of the differences) for NCT1-GAT comparison was -4.9 to +4.4mmHg, and LoA ranged from -4.1 to +3.4mmHg for NCT3-GAT comparison. However, LoA was -3.4 to +3.3mmHg for NCT1-NCT3 comparison. Figure 2, Figure 3 and Figure 4 demonstrate the Bland-Altman plots for NCT1-GAT, NCT3-GAT and NCT1-NCT3 comparisons respectively.

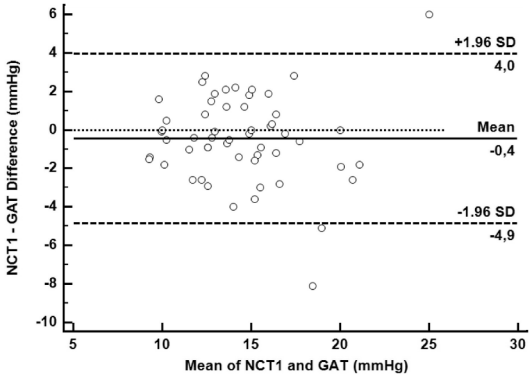

Figure 2 The Bland-Altman analysis (differences are plotted against the averages) shows intraocular pressure agreement between NCT1 (1 - puff) and Goldmann applanation tonometer. The 95 % limits of agreement and mean difference are presented. NCT = Non-contact tonometer.

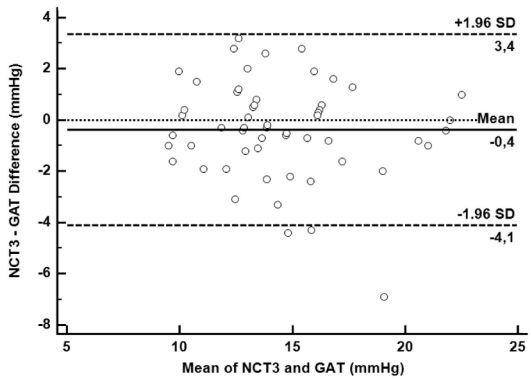

Figure 3 Intraocular pressure agreement between NCT3 (3-puffs) and Goldmann applanation tonometer is demonstrated with the Bland - Altman plots (the differences against the averages). NCT = Non-contact tonometer.

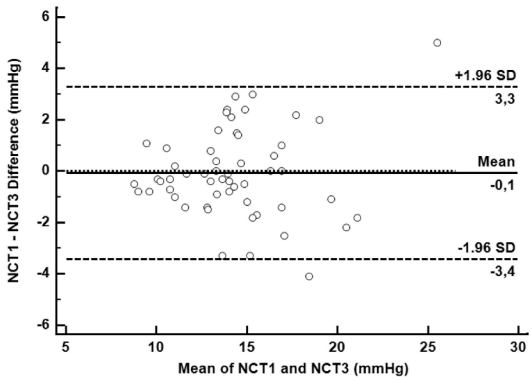

Figure 4 The Bland-Altman analysis (differences are plotted against the averages) demonstrates comparison of NCT1 (1-puff) and NCT3 (3-puffs). The 95 % limits of agreement are presented. NCT = Non-contact tonometer.

DISCUSSION

Previous clinical studies demonstrated that lowering IOP reduces the incidence and progression of POAG[1,2]. Hence, measurement of accurate and precise IOP is crucial in clinical practice. Current literature comprises comparisons of different tonometers with GAT, which is accepted as "gold standard" for measuring IOP[9-15]. In clinical practice, NCT provides a rapid IOP measurement, whereas reliability of this method in glaucoma patients is not completely determined.

Previous studies presented conflicting results of NCT - GAT comparisons. Non-contact tonometers were reported as a part of screening protocol for glaucoma and IOP values measured with NCT were found to be overestimated or underestimated when compared with those obtained from GAT[4,6,7]. On the contrary, some NCT devices were found to be clinically comparable with GAT for measuring IOP[16-20].

To best of our knowledge, the NCT device in our study and the effect of puff times on IOP readings were not compared with GAT previously. In the current study, we compared two different puff modes (1-puff and 3- puffs) of NCT with GAT to establish the reliability of Canon TX - F NCT in patients with POAG under routine clinical conditions.

In published studies, correlation analysis was widely used to assess agreement between two tonometers, whereas Bland and Altman emphasized that statistical techniques such as correlation coefficients and regression analysis, which are expected to be high are not appropriate for comparing two measurement methods[8]. They suggested that it is important to answer the question how much the new method is more likely differ from the other. In the Bland - Altman method, differences between the two methods are plotted against the averages and 95% limits of agreement (mean difference ± 1.96SD of the differences) are calculated[8]. Two methods can be used interchangeably if the differences are within the clinically acceptable LoA.

The main objective of our study was to demonstrate IOP agreement between two puff modes of NCT and GAT under routine practice in POAG patients. In the present study, NCT1 and NCT3 provided similar IOP values when compared with GAT measurements (underestimation of 0.44 and 0.38 mmHg in IOP respectively). This result might suggest that both 1-puff or 3-puffs modes of NCT are clinically reliable and rapid for measuring IOP in POAG patients based on GAT measurements. However, ranges of LoAs (9.3mmHg for NCT1-GAT, 7.5mmHg for NCT3-GAT and 6.7mmHg for NCT1 - NCT3 comparisons) seem to be unacceptable for glaucoma management. While it can be critical to reduce IOP even 1mmHg to preserve visual field in some glaucoma patients. From another perspective, further studies might be conducted to compare visual field changes in POAG patients who are followed using different tonometers.

In conclusion, although IOP values obtained from NCT1 and NCT3 appear to be similar with GAT measurements, wide range of LoA might limit the use of this NCT (both 1-puff and 3-puffs) and GAT interchangeably in POAG patients.

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