An Agreement of Two Tonometers: Goldmann Applanation and Non-Contact Scheimflug Technology in Healthy, Ocular Hypertension and Open-angle Glaucoma Patients

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ABSTRACT

Objective: The primary objective was to find an agreement of intraocular pressure (IOP) assessed by Goldmann applanation tonometry (GAT) and Corvis in healthy, ocular hypertension (OHT) and primary open-angle glaucoma (POAG). The secondary objective was to find a reliability of intra-examiner and inter-examiner IOP measurement by GAT and Corvis.

Methods: Fifty three eyes from 53 participants were included and were divided into healthy (N=20), OHT (N=13) and POAG group (N=20). Only right eyes were selected for further statistical analysis except one patient with only left eye eligible. The eyes with corneal pathologies, greater than 2.5 diopters astigmatism, or recent ocular surgery were excluded. Randomized examining sequence between GAT and Corvis was applied. To minimize an after measurement IOP fluctuation, five minutes and two minutes gap between measurements were strictly applied for Corvis and GAT respectively. The first ten patients had 3 measurements per measurer and two measurers were assigned per machine to evaluate intra-examiner and inter-examiner reliability. Intraclass correlation coefficient was used to analyze the reliability of the IOP measuring machine. Bland & Altman plot was used to analyze an agreement between the machines.

Results: High ICCs were found in both measurers using GAT (ICC of measurer 1 = 0.954, measurer 2 = 0.977) and Corvis (ICC of measurer 1 = 0.920, measurer 2 = 0.927) which indicated excellent intra-examiner reliability. High ICCs were found when comparing IOP between 2 measurers who used the same machine (GAT ICC = 0.928, Corvis ICC = 0.915) which indicated excellent inter-examiner reliability. GAT tends to yield higher IOP reading. The mean IOP were 13.93±3.849 by GAT and 12.15±4.030 by Corvis. The mean IOP differences were 1.8, 1.7, 1.4 and 2.2 mmHg in total, healthy, OHT and POAG group respectively. POAG had highest mean difference and widest standard deviation which might result from poor agreement between 2 machines. According to Bland & Altman plot the values were scattered and no trend was found indicating higher or lower average IOP would result in higher or lower difference between the two machines. From the clinical point of view, 71.7% and 47.2% fall into IOP difference range of ±3 and ±2 mmHg respectively.

Conclusion: Corvis-IOP is a good parameter with excellent intra-examiner and inter-examiner reliability. In clinical practice, the usefulness of Corvis-IOP is limited especially in POAG patients according to the poor agreement with gold standard GAT-IOP.

Keywords: Corvis; comparison; tonometry; tonometer; intraocular pressure measurement; repeatability (Siriraj Med J 2019;71: 201-206)

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INTRODUCTION

Introcular pressure (IOP) measurement is crucial for glaucoma diagnosis and management. Gold standard instrument is Goldmann applanation tonometer. Unfortunately, there were some drawbacks using this machine such as well-trained user is required to take measurement, required anesthetic and fluorescein eye drops, need to calculate central corneal thickness (CCT)-corrected IOP, CCT and corneal biomechanical properties should be taken separately by different machine. Corvis ST (Corneal visualization scheimflug technology, Oculus, Wetzlar, Germany) is an IOP measurement machine approved by FDA in the year 2013. IOP and CCT from Corvis demonstrated excellent repeatability from previous studies.[1-3] They do not need eye drops or well-trained user. Corvis is an interesting new machine that should be considered. Moreover, plenty of data such as CCT, corneal biomechanical properties and IOP are retrieved at same time. There are insufficient clinical studies to conclude that these two machines showed acceptable agreement. There is controversy since some studies showed good agreement,[1,2,4] but some did not.[5] The primary aim of the study was to assess the usefulness of Corvis by evaluating an agreement with gold standard GAT in healthy, ocular hypertension (OHT) and primary open-angle glaucoma (POAG).

MATERIALS AND METHODS

The study was a cross-sectional study approved by the Ethics Committee (Si 622/2014) of our institution which followed the tenets of the Declaration of Helsinki and signed inform consent were obtained.

We included subjects who were 18 years old or older in the study. Participant with corneal pathologies, for example corneal edema or keratoconus was excluded. Participant who had more than 2.5 diopters astigmatism, recently underwent corneal or glaucoma surgery within 3 months, nystagmus and uncooperative were excluded.

In this study, we classified all participants into 3 groups which were healthy, ocular hypertension (OHT) and primary open-angle glaucoma (POAG). Healthy participant was defined as participant who had no evidence of glaucoma or ocular hypertension from medical record and complete eye examination by ophthalmologist. Ocular hypertension was defined as participant who had intraocular pressure (IOP) of 21 mmHg or more with no evidence of glaucoma. Primary open angle glaucoma was defined as participants who were diagnosed with POAG.

Subject allocation was done in each participant group by randomizing into 2 different examining sequences as displayed in the diagram 1, in order to minimize the effect of machine sequence on IOP measurement. The sequence was created using http://www.randomization.com.

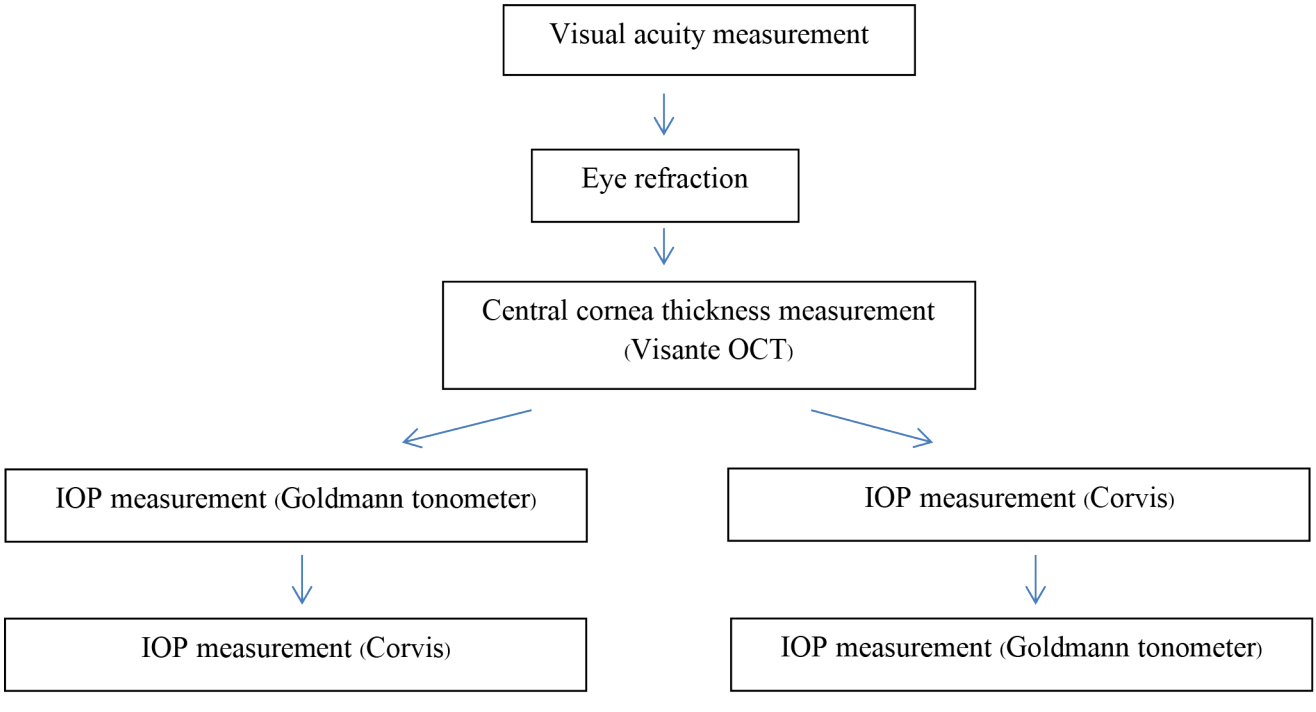

Diagram 1. Examining sequence

Two experience opticians (Measurer 1 and 2) who worked in special equipment room and trained for using Corvis machine were responsible for Corvis measurement. Meanwhile, GAT was done by two ophthalmologists (S.P. as measurer 1 and S.K. as measurer 2) during an eye examination. Visual acuity, eye refraction and central corneal thickness (CCT) by using Visante OCT were done by one experienced optician.

CCT is the main parameter that could affect IOP measurement. There is no best CCT-corrected equation for GAT when comparing with Dynamic contour tonometer (DCT).[6] To minimize the effect of central corneal thickness (CCT), corrected GAT IOP was calculated from GAT IOP and CCT (Visante OCT) by using Doughty & Zaman equation. This equation came from meta-analysis and big database. Meanwhile, corrected Corvis IOPs were automatically generated and collected. The study selected only corrected IOPs from both devices for statistical analysis.

For the first 10 eyes, we took three different IOP measurements by using each machine to assess intra-examiner reliability and all measurements were repeated by another examiner to assess inter-examiner reliability. The intra-examiner and inter-examiner ICCs were excellent in both GAT and Corvis group, as showed in Table 1. For the rest of participants, GAT and Corvis measurements were done by only measurer 1.

Two minute and 5 minute gaps between each measurement were applied for GAT and Corvis respectively, to minimize the effect on IOP from previous measurement. Only the data from right eye was analyzed, except one patients who had only left eye eligible for the study so the data from left eye was used.

Sample size and statistic

Intraclass correlation coefficients (ICC) is used to assess interrater and intrarater reliability. In order to compare an agreement of two measurement devices, Bland and Altman plot was applied. All the statistical analyses were performed using SPSS version 18.0 software.

Aiming for excellent correlation between Goldmann applanation tonometer (GAT) and Corvis, we used the following statistical formula to calculate sample size for intraclass correlations coefficients of 0.75. At a confident level 95%, SD 0.15 resulted in sample size of 131.

$$n = 8z^2\alpha/2\ \{(1-\rho I)^2(1+(k-1)\rho I)^2\}/\{k(k-1)w^2\}+1$$

RESULTS

The study ended up with 53 eyes from 53 participants (female = 36) which included 3 groups healthy (N=20), OHT (N=13) and POAG (N=20). Mean age of participants was 62.40±10.132 years old. Mean IOP from three different measurements by 2 measurers were shown in Table 1. Intraclass correlation coefficients were calculated from first ten participants for both intra-examiner and inter-examiner as shown in Table 2. The excellent reliability was found according to ICC level ≥ 0.75 in all parameters.

As shown in Table 3, mean IOP was lowest in POAG group. This result was from a treatment that aimed for low target IOP in this group. OHT group had highest mean IOP which was consistent with a key feature of the disease and treatment was not aimed for as low as the IOP in POAG. GAT tended to yield higher IOP reading than Corvis in total participants and in each group. ICC in total participants reflected fair to excellent correlation between GAT and Corvis. However, in each group, POAG group had poor correlation as ICC level < 0.4 and ICC in OHT and healthy group were <0.4 as well if consider a lower bound of 95%CI.

Mean IOP difference result from GAT IOP was minus Corvis IOP which positive value means that GAT tends to give higher IOP than Corvis. Mean IOP differences were 1.8, 1.7, 1.4 and 2.2 mmHg in total, healthy, OHT and POAG respectively. POAG had highest mean difference and widest standard deviation which

TABLE 1. Mean IOP of GAT and Corvis by two measurers of first ten participants.

	GAT IOP (mmHg)		Corvis IOP (mmHg)	
	Measurer 1 mean ± SD	Measurer 2 mean ± SD	Measurer 1 mean ± SD	Measurer 2 mean ± SD
First time	14.81± 3.823	15.10± 4.795	12.41± 4.307	12.05± 4.995
Second time	14.63± 3.856	15.30± 4.218	11.99± 4.033	12.30± 5.321
Third time	14.40± 3.831	15.10± 4.067	11.93± 4.071	11.53± 4.309

TABLE 2. Intra-examiner and inter-examiner Intraclass correlation coefficients.

	Intra-examiner				Inter-examiner	
	GAT		Corvis		GAT	Corvis
	Measurer 1	Measurer 2	Measurer 1	Measurer 2		
ICC	0.954	0.977	0.920	0.927	0.928	0.915
95%CI	0.929-0.972	0.937-0.994	0.877-0.950	0.835-0.982	0.728-0.982	0.665-0.979

TABLE 3. The correlation between GAT and Corvis in IOP measurements.

Group	GAT (mmHg) Mean±SD	Corvis (mmHg) Mean±SD	GAT-Corvis (mmHg) Mean±SD	ICC(95%CI)
Total	13.93±3.849	12.15±4.030	1.78±2.944	0.793(0.520-0.899)
Healthy	12.91±3.393	11.22±3.191	1.69±2.371	0.797(0.353-0.927)
OHT	17.90±2.611	16.45±3.559	1.45±2.860	0.701(0.107-0.906)
POAG	12.11±2.984	9.96 ± 2.620	2.15±3.675	0.207(-0.648-0.674)

Abbreviations: OHT=Ocular hypertension, POAG=Primary open angle glaucoma

may result from poor agreement between 2 machines. The value was scattered with no trend for which higher or lower average IOP will result in higher or lower difference between the two machines. From clinical point of view, 71.7% and 47.2% fall into IOP difference range of ±3 and ±2 mmHg respectively.

DISCUSSION

From the study, both Corvis and GAT demonstrated excellent repeatability and reproducibility by different examiners for IOP measurement. This is consistent with previous studies that IOP from Corvis is a parameter that showed excellent intra-examiner and inter-examiner reliability both in healthy and glaucoma eyes.[1-3]

Interestingly, there was no difference or tendency of IOP from the first to the third measurement (Table 1). That means repeated measurement with 5 minutes and 2 minutes gap for Corvis and GAT respectively was sufficient to lessen the IOP effect from previous measurements. There was no study about how long should the gap be, but air-puff technology as Corvis should take longer than an applanation for the effect of prior measurement to be vanished. The gap could be smaller, so a well-designed study will answer this question.

According to the results, IOP acquired from GAT tends to be higher than Corvis in all groups of participants. Hong et al.,[1] who enrolled healthy volunteers and glaucoma patients in their study to investigate an agreement between GAT and Corvis found the same bias, approximately 1.3 mmHg higher when acquiring IOP from GAT. From the study of Tejwani et al., GAT showed overestimated IOP from GAT when compared to other machines including Corvis.[7] However, there were some studies which reported higher IOP readings from Corvis when compared to GAT.[5,8] It is to be noted that this study, Hong et al. and Tejwani et al. studies had randomized an examination sequence. In contrast, Smedowski et al., use fixed examination sequence which could result in a bias from after-IOP measurement fluctuation.

Although, ±3 mmHg IOP difference seems to be acceptable, but for precise decision making in the clinic ±2 mmHg range is more reasonable. From Bland and Altman, only 47.2% of all participants fall in to ±2 mmHg range of IOP difference which indicated that Corvis and GAT could not be used interchangeably in the clinic. It is to be highlighted that POAG group demonstrated highest mean IOP difference and widest standard deviation. Keep in mind that this study used CCT-corrected IOP, assuming

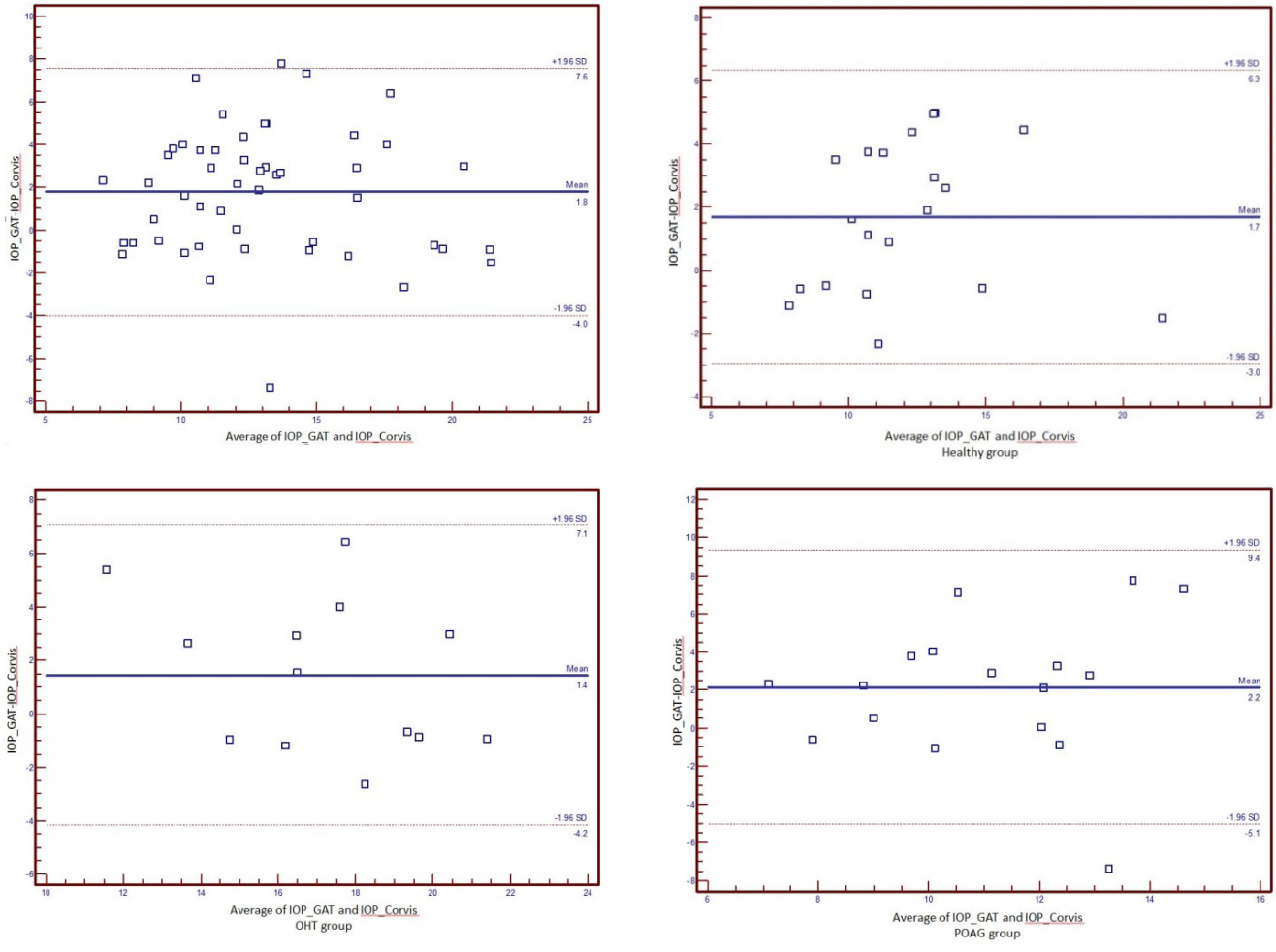

Fig 1. Bland-Altman plot, an agreement of IOP measurement between GAT and Corvis.

CCT effect should be minimal. Biomechanical corneal properties might be the reason, as POAG patients still using topical anti-glaucoma medications. Several studies showed that topical prostaglandin cause an effect on corneal biomechanical properties by increasing corneal hysteresis.[9-12] It could affect accuracy of IOP measurement including IOP fluctuation which finally resulted in more variation of IOP. Unfortunately, there is no study about the direct effect of long term usage of topical prostaglandin analogues on IOP measurement at this time.

The limitation of this study was a small sample size and corneal biomechanical properties were not taken into account. By the way this study's primary aim was to assess the clinical usefulness of the new machine, Corvis by comparing with GAT rather than to analyze factors that could affect IOP measurement.

In conclusion, Corvis-IOP is a good parameter with excellent level of reliability. In the clinic, the usefulness of Corvis-IOP is limited especially in POAG patients according to the poor agreement with gold standard GAT-IOP.

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Conflict of Interests: All authors declare no conflict of interests.

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