Comparison of the ICare© Rebound Tonometer with Goldmann Applanation Tonometer in Healthy Adults

ICare Rebound Tonometresinin Goldmann Applanasyon Tonometresi ile Sağlıklı Yetişkin Bireylerde Karşılaştırılması*

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ABSTRACT

Purpose: To compare intraocular pressure (IOP) measurements provided by the Goldmann Applanation Tonometer (GAT) and the iCare© rebound tonometer (RBT) in healthy adults and to assess the influence of central corneal thickness (CCT) on these measurements.

Materials and Methods: This prospective, randomized study includes 131 right eyes of 131 adult volunteers (63 females, 68 males) with no ocular pathology. All subjects' IOP readings were taken using the iCare RBT before they received topical anesthetic, and using the GAT after receiving topical proparacaine, with a 15-minute interval between readings.

Results: For the measurements taken with the iCare RBT and GAT, the mean corrected IOP values were 18.19±4.42 mmHg and 18.56±4.42 mmHg, respectively. The differences between corresponding measures (iCare RBT value vs. GAT value) had a mean of -0..37±2.89 mmHg, and a 95% confidence interval of -5.3 to 6.0 mmHg ($p<0.001$) according to the Bland-Altman scatter-plot. The iCare RBT has a sensitivity of 58.1% and a specificity of 84.1%. According to linear regression analysis, every change of 10µm in CCT level caused a 0.98 mmHg change in IOP measurements with the iCare RBT.

Conclusion: There is a reasonable level of correlation between the iCare RBT and GAT in healthy individuals. Because of the clinically reasonable correlation, sensitivity and higher specificity detected for the iCare RBT compared to the GAT, the iCare RBT is an adequate screening tool for healthy individuals. However, it should be considered that iCare RBT measurements are influenced by CCT, so its use should be combined with pacymetric evaluation.

Key Words: Glaucoma, iCare rebound tonometer, intraocular pressure, Goldmann applanation tonometry.

ÖZ

Amaç: ICare rebound tonometre (RBT) ve Goldmann applanasyon tonometresi (GAT) ile sağlıklı yetişkin bireylerde elde edilen göz içi basınç (GİB) değerlerinin karşılaştırılması ve merkezi kornea kalınlığının (MKK) ölçümler üzerine etkisinin belirlenmesi.

Gereç ve Yöntemler: Bu prospektif ve randomize çalışmaya herhangi bir oküler patolojisi bulunmayan sağlıklı 131 gönüllünün (63 kadın, 68 erkek) 131 sağ gözü alındı. Tüm bireylerin topikal anestezi öncesi iCare RBT ve topikal anestezi sonrası GAT ile 15 dakika arayla GİB ölçümleri gerçekleştirildi.

Bulgular: ICare RBT ve GAT ile elde edilen ortalama GİB değerleri sırasıyla 18.19±4.42 mmHg ve 18.56±4.42 mmHg idi. Ortalama iCare RBT ve GAT değerleri arasındaki fark (iCare RBT- GAT değeri) -0.37±2.89 mmHg, %95 güven aralığı -5.3 mmHg to 6.0 mmHg ($p<0.001$) tespit edildi. ICare RBT'nin sensitivitesi %58.1 ve spesifitesi %84.1 tespit edildi. Lineer regresyon analizine göre, MKK'daki her 10 µm'luk değişim, iCare RBTölçümlerinde 0.98 mmHg değişime neden olmaktaydı.

Sonuç: Sağlıklı yetişkin bireylerde iCare RBT ve GAT arasında makul bir korelasyon saptanmıştır. Bu iki yöntem arasındaki klinik olarak kabul edilebilir düzeydeki korelasyon, sensitivite ve spesifite sayesinde, iCare RBT'nin sağlıklı bireylerin taramasında kullanılabiliceğini düşünmekteyiz. Ancak iCare RBT MKK'dan etkilendiği akılda tutulmalı, pakimetrik ölçümler ile kombine edilmesi gerektiğini düşünmekteyiz.

Anahtar Kelimeler: Glokom, iCare rebound tonometre, göz içi basıncı, Goldmann applanasyon tonometre.

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INTRODUCTION

Glaucoma is one of the major causes of blindness in the world. Increased intraocular pressure (IOP) is the main and the only controllable risk factor for glaucoma.[1] Although various alternatives have been developed for IOP measurement, Goldmann applanation tonometry (GAT) is still considered to be the gold standard.[2] The requirement of slit lamp biomicroscopy and topical anesthetic, a blepharospasm due to topical anesthetic, the possibility of allergic reactions, the possibility of central corneal thickness (CCT) affecting measurement results, local trauma on cornea and the risk of infection in IOP measurement using the GAT has encouraged physicians to search for the possibility of eliminating these disadvantages. ICare rebound tonometry (RBT) (iCare TA01; Tiolat, Helsinki, Finland), which is the newest version of RBTs, also known as impact or dynamic tonometry, was put into clinical use in 2003. The instrument contains two probes: a magnesite probe made of thin steel with a knob-shaped tip that contacts the cornea, and a solenoid probe that provides the movement for the magnesite probe. The return rate of the probe after it touches the cornea provides information about IOP. The iCare RBT, with its simple use, portability and most importantly, not requiring topical anesthetic, puts it into routine use, especially for children and bedridden patients in many clinics.[3]

The purpose of this study is to compare IOP measurements provided by the GAT and the iCare RBT in healthy adult subjects with no ocular pathology.

MATERIAL AND METHOD

This prospective study included 131 right eyes of 131 adult volunteers (63 females, 68 males), having a mean age of 47.0±16.4 years (range 18 to 65 years) and with no ocular pathology. The local medical ethics committee approved the study. Informed consent for participation, according to the Declaration of Helsinki, was obtained from each subject before the examination. All patients underwent a complete ophthalmologic examination, including best-corrected visual acuity (BCVA) evaluation, slit-lamp examination, gonioscopy, and biomicroscopy. Adult volunteers age 18 and over, with BCVA 1.0 according to the Snellen vision chart, and the absence of any anterior or posterior segment pathologies were included in the study.

Measurement Techniques: Both instruments were calibrated according to the manufacturer's guidelines. All measurements were made in the same time period (09:00-11:00 AM) in order to reduce the diurnal variations to a minimum. All subjects' IOP readings were taken using the iCare RBT before topical anesthetic was administered, and by the GAT (Haag-Streit AG, Bern, Switzerland) after topical proparacaine (Alcaine, Alcon, USA) administration, with a 15- minute interval between readings. All measurements were taken by two different physicians (iCare RBT-HHC; GAT-ME) in two different rooms and were masked to the other's readings. First, without topical anesthetic, 6 measurements were taken from the central cornea using the iCare RBT at a distance of 4-8 mm from the central cornea; the highest and the lowest readings were discarded and then the mean value was calculated. The probe was replaced for all measurements. After the iCare RBT readings, the second physician performed the IOP measurement using the GAT 3 times, using topical anesthetic and fluorescein. Subsequently, the average value was calculated. To obtain a corrected IOP value depending on the CCT, the Doughty and Zaman formula was used; this was also used in the Brusini et al. study.[4,5] The calculation was carried out using this formula:

Corrected GAT value=Measured GAT value-[(CCT-535)x(0.05)].

Corrected GAT values have been accepted as the gold standard. The iCare RBT readings and corrected GAT values were correlated using simple linear regression analysis; corrected iCare RBT values were calculated, taking account of the CCT changes. In addition, the correlation between IOP values and CCT was examined.

Statistical Analysis: SPSS 17.0 for Windows was used for statistical analysis. Continuous variables are shown as means, standard deviations, and minimum and maximum values. The Shapiro-Wilk test was used to test normality. IOP measurements taken by the iCare RBT were corrected according to CCT and were estimated using simple linear regression analysis. The bias and 95% confidence interval of the difference between IOP measurements taken by applanation tonometry and iCare RBT were calculated by using the Bland-Altman method. A p value of <0.05 was considered statistically significant.

RESULTS

The mean age of subjects was 47.0±16.4 (range 18 to 65) years. The mean IOP readings taken by the iCare RBT and GAT were 18.19±4.42 mmHg and 18.56±4.42 mmHg, respectively ($p<0.001$). The average CCT was 519±25 µm. The deviations of the iCare RBT values from the corrected GAT values were correlated with the CCT values according to simple linear regression analysis ($r=0.588$, $p=0.0001$), (Figure 1). The linear regression function was y=-51,796+0,098xCCT and the linear regression line intercepted the x-axis at the CCT value of 529 mm (Figure 1). The following correction formula for the iCare RBT readings was used:

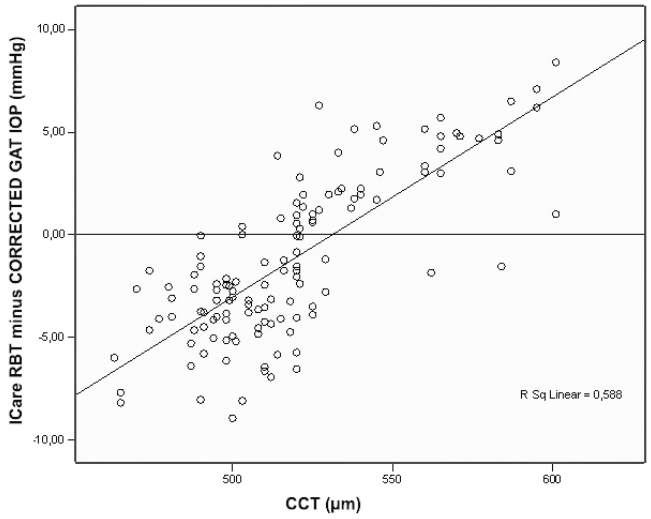

Figure 1: *Correlation between CCT and the deviation of the iCare RBT measurements from the corrected GAT values.*

Corrected iCare RBT IOP=measured iCare RBT IOP-(CCT-529)x0.098. According to this formula, every change of 10 µm in CCT level caused a 0.98 mmHg change in IOP measurements with the iCare RBT.

The Bland-Altman scatter-plot comparing the GAT and iCare RBT readings (Figure 2) showed reasonable correlation between the two methods. The differences between corresponding measurements (GAT value minus iCare RBT value) had a mean of 0.37±2.89 mmHg, and a 95% confidence interval of -5.3 to 6.0 mmHg (p<0.001).

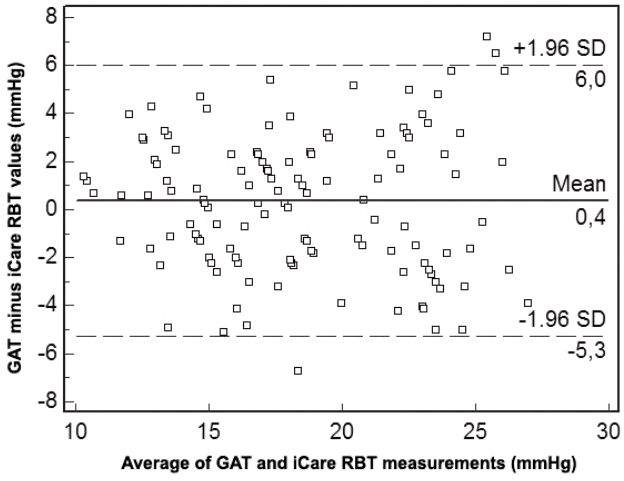

Figure 2: *Bland-Altman analysis showing the distribution of differences in IOP (GAT value minus iCare RBT values, mmHg) (y-axis) and the mean IOP value of the tonometers (x-axis) for each eye measured.*

According to the iCare RBT readings of IOP, 19.1% of subjects were within ±1 mmHg of IOP performed by GAT; 46.6% of subjects were within ±2 mmHg and 67.9% were within ±3 mmHg.

The iCare RBT identified an IOP 21 mmHg or above in 25 of 43 subjects with a GAT- identified IOP equal to or above 21 mmHg (iCare RBT has a sensitivity of 58.1%). The iCare RBT identified an IOP under 21 mmHg in 74 of 88 subjects having a GAT IOP under 21 mm Hg (iCare RBT has a specificity of 84.1%).

DISCUSSION

An accurate measurement of IOP is crucial for the diagnosis and management of glaucoma. Although various methods have been used to identify IOP in the past, the GAT is still considered to be the gold standard.[2] Due to the disadvantages mentioned before, clinical use requires instruments at least as precise as the GAT. The iCare RBT is the first commercial tonometer to use an induction-based rebound method. Being small, light, and portable, providing a comfortable measurement without requiring a biomicroscope or local anesthetics, and being suitable for environments convenient for patients, the iCare RBT makes rapid measurements possible with children and uneasy patients.[3] The aim of this study was to determine the reliability of the iCare RBT compared to the GAT in clinical use, by comparing both instruments' IOP measurements in healthy individuals.

Previously different results have been reported in various clinical studies comparing the iCare RBT and GAT. Usually, iCare RBT IOP levels were found to be a little higher than GAT levels (Table).[5, 6-17] Kim et al.,[13] performed the only experimental study on this subject, GAT IOP readings were found to be higher than iCare RBT readings.[18] Furthermore, Salvetat et al. showed in their study that iCare RBT measurements were reliable but lower than GAT measurements in steep corneal curvatures and higher than GAT measurements in normal corneal curvatures; they pointed out the effects of corneal biomechanic factors on results in their iCare RBT-GAT comparison. Pakrou et al.,[15] showed that in low IOP levels, iCare RBT readings were higher than GAT readings and in high IOP levels, iCare RBT readings were lower than GAT readings.

Various degrees of correlation have been reported between iCare RBT and GAT readings in previous clinical studies. According to Munkwitz et al.,[11] the tolerable interval of difference between iCare and GAT was accepted as ±3 mmHg and 60-64% of measurements were in this interval. Iliev et al.,[12] identified 84.1% of measurements in the same interval and in addition to that, 67.3% of the measurements in the interval of ±2 mmHg. However the deficiency of these two studies is that the correction for CCT was not performed for IOP measurements. According to the first comparison study without this deficiency, Brusini et al.,[5] 38.8% of iCare RBT IOP readings were within ±1mmHg of GAT IOP readings, 57.3% within

Table: *ICare RBT-GAT Comparing Studies*

ICARE-GAT Compressive Studies	ICARE-GAT difference Mean (mmHg)	ICARE-GAT difference 95% Confidence Interval (mmHg)
Van der Jagt et al.[6]	N/A	-6-+7
Abraham et al.[7]	0.5	-6-+5
	0.2	4.0-+4.4
Fernandes et al.[8]	1.34	±3.98
Martinez-de-la-Casa et al.[9]	1.8	±2.8
Salim et al.[10]	2.45	-1.79-+6.69
Munkwitz et al.[11]	0.79	-8.67-+10.25
Iliev et al.[12]	0.71-1.28	-3.2-+5.2
Salvetat et al.[13]	1.4	-5- +9
Brusini et al.[5]	1	-7.0-+6.6
Dahlmann-Noor et al.[14]	3.34	<21 mm Hg (-8.60, 3.90) ≥21 mm Hg (-21.08, 10.04)
Pakrou et al.[15]	0.4 (Sağ)	-5.5-+6.3
	0.8 (Sol)	-4.7-+6.2
Yamashita et al.[16]	2.8	-7.6- +3.5
Sahin et al.[17]	0.43	N/A
Kim et al.[18]	-5	-5.3- +7.8
Our Study	0.37	-5.3- +6.0

±2 mmHg and 74.1% within ±3 mmHg. In the same study, the sensitivity of the iCare RBT compared to the GAT was 67.4% and specificity was 88.9%. In a study by Şahin et al. 80% of the subjects' results were within 2.3 mmHg.[17] These percentages identified in earlier studies were found to be lower in our study, at 19.1%, 46.6%, and 67.9% respectively. In our study, similar to Brusini et al., the sensitivity of the iCare RBT was identified as 58.1% and the specificity was identified as 84.1%[5] Therefore according to our study, the iCare RBT seems to be sufficient for a glaucoma screening test and gives reliable results on follow-up of IOP.

According to the linear regression analyses reported in previous studies, CCT has an effect on IOP measurements using the iCare RBT in various degrees.[5,10,13,15,17,19,20] Poostchi et al.,[19] identified that for every 10% change in CCT, there was a change of 9.9% in iCare RBT IOP. While this ratio was 0.7 mmHg in IOP for every 10 µm change in CCT according to Brusini at al.,[13] it was 0.5 mmHg for every 10 µm change in the Salvetat et al.,[15] study, 0.1 mmHg for every 10 µm change in the Pakrou et al.,[17] study, 0.8 mmHg for every 10 µm change in adult patients and 0.37 mmHg for every 10µm change in pediatric patients in the Şahin et al.,[20] research; there was a 0.41 mmHg increase in iCare RBT IOP for every 10 µm increase in CCT. In our study every change of 10 µm in CCT level caused a 0.98 mmHg change in IOP.

In conclusion, in this study we obtained a reasonable correlation between iCare RBT and GAT readings in healthy inviduals, and we suggest that the iCare RBT is an adequate screening tool for healthy individuals. Although there was a clinically reasonable correlation, sensitivity and specificity detected between the iCare RBT and the GAT, it should be considered that iCare RBT measurements are influenced by CCT, so its use should be combined with pacymetric evaluation.

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