

Original article

A comparative study of intraocular pressure measurement by three tonometers in normal subjects

Prabhakar SK, Mahesh BS, Shanthamallappa M
JSS Medical College & Hospital
MG Road, Mysore-570004, Karnataka, India

Abstract

Introduction: Contact Goldmann applanation tonometry (GAT) is gold standard for measuring intraocular pressure; however its routine use is limited by its non-portability and the need for a Slit Lamp Microscope. The Portable Perkins tonometer is also considered gold standard because it is based on the same principles as the GAT. The iCare is a newly introduced, portable, non-contact tonometer (NCT) that measures intraocular pressure (IOP) using a thin metallic probe. **Objective:** To evaluate reliability and accuracy of IOP measurements using iCare and Keeler Pulsair tonometers against Perkins tonometer. **Subjects and methods:** A comparative, randomized, prospective clinical study conducted on 166 eyes of 83 (n=83) subjects in the age group 14 to 71 years. The pressures were first recorded by iCare and Pulsair and then by Perkins. The SPSS 11.00 version was used for analysis. **Results:** Mean pressures and standard deviation (+/-SD) for iCare, Pulsair and Perkins were 14.62(+/-2.47), 14.53(+/-3.36) and 13.06(+/-2.69) and the Standard Error of the Mean (SEM) was 0.27, 0.36 and 0.30 respectively. There was a good correlation between iCare and Perkins with statistically significant difference ($r=0.610$, $p<0.05$). Regression analysis was performed. Using the Bland-Altman analysis 95% Limits of Agreement (LoA) for iCare and Pulsair were determined as -6.1 to 2.9 and -4.5 to 7.5 respectively. **Conclusion:** Although both tonometers overestimated the Perkins values, Pulsair showed a better agreement with Perkins tonometer than iCare tonometer.

Keywords: iCare tonometer, Keeler Pulsair tonometer, Goldmann applanation tonometer, Perkins tonometer, Intraocular pressure

Introduction

The only recognizable and treatable risk factor for progression of glaucoma is elevated IOP. The Goldmann tonometer estimates the pressure by measuring the force required to appanate a fixed area of the cornea based on the Imber-Fick Principle. However, it requires a slit lamp

microscope and topical anesthetic agents, which have a slight decreasing effect on IOP and can record pressures only in sitting posture (Almubrad TM, 2007). Pressure measurements by GAT depend on corneal biomechanics, curvature and thickness and are widely proved to be inaccurate in post-refractive surgical eyes. Perkins has slightly (1-1.5 mm Hg) lowered values than Goldmann. Nevertheless, it can be safely be used in the post operative period and during the retinal detachment surgery (Vernon SA, 1989; Chiqnell AH, 1971).

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Address for correspondence: Dr SK Prabhakar, 57, 8th cross, 4th main, Vinayaka Nagara, Mysore-570012, Karnataka, India.

Tel: +919880074529, Residence: 08212410360

Office: 08212524999

Email: svp_pbk1947@yahoo.co.in

The Perkins tonometer is portable, simple and capable of measuring IOP in all positions. Its disadvantage is in the initial slow learning phase, or else it could be considered a reliable alternative to Goldmann (Wallace J, 1968).

Keeler Pulsair is a NCT which does not require a topical anaesthetic based on the principle that the IOP is determined from the time taken for the air jet to appanate the cornea, which in turn is proportional to the power of the air sprayed from the instrument. The instrument has a console consisting of a central air plenum flanked on either side by an infrared light emitter and detector. It has a handle consisting of two buttons one for recording IOP below 30 mm Hg and another above 30 mm Hg (subflux button). Through the eyepiece when a focused and centered target image is seen 8 mm to 16 mm from the corneal apex, that indicated the correct positioning of the hand piece for automatic activation. Jet air is released with click sound and the pressures recorded directly in numerical values on the display screen.

The iCare tonometer (iCare; Tiolat Oy, Helsinki, Finland) is hand-held and has been used for non-invasive measurements of the IOP in animals. It is now being recommended for use in humans. The instrument uses a metallic probe of length 24 mm and weight 11 mg with a diameter of 1 mm plastic cover at its tip to minimize corneal damage. It is held in the nozzle by an electromagnetic field, which moves back and forth when the button is pressed gently. The microprocessor analyses the deceleration of the probe that seems to correlate with the IOP (Dawn EC Roberts, 2005; Martinez-de-la-casa JM et al, 2005).

This study was conducted to establish the validity of the iCare and Pulsair tonometer with Perkins and also to evaluate the repeatability (reliability) of the tonometers in question and whether they could be interchangeable (agreement) or the new iCare could replace the Perkins tonometer. To our knowledge this would be one of few studies available in the literature on the comparison between the iCare and Pulsair with the Perkins tonometer.

Subjects and methods

The Subjects: A total of 83 visually normal individuals were randomly recruited in this study who attended the outpatient department of Ophthalmology between November 2007 and May 2008 with permission granted from Institutional Ethical Committee. Significant refractive errors, diabetes mellitus, hypertension and other anterior segment problems were excluded as would be expected to interfere with the acquisition of pressure levels. Informed consent was obtained from all the subjects regarding the tonometers and the procedures involved. A baseline examination of the anterior segment that included a recording of the best corrected visual acuity, autorefractometry and detailed dilated funduscopy. Pressure measurements recorded by a single surgeon to reduce the inter-observers' bias and conventionally the right eye pressures were always recorded before obtaining the left eye measurements.

The procedure: iCare tonometry was done prior to the Pulsair and Perkins procedures to prevent bias due to a reduction in the measured IOP caused by ocular massage effect or by the administering of a local anaesthetic (Ogbuehi KC et al, 2006).

1. The forehead rest of the iCare tonometer was adjusted after loading the electromagnetic probe into its nozzle so as to position the probe at a distance of 4-8 mm from the corneal apex. The smooth movement of the probe was demonstrated to the patients just before commencing the recording. The device was vertically held and the button was gently pressed to obtain six consecutive readings automatically. The final reading was the average which was displayed on the screen as P without a hyphen. The measurements were repeated when P was blinking or accompanied by a hyphen in the upper or lower case according to manufacturer's catalogue given the pressures taken likewise would be erroneous.
2. During Pulsair tonometry a gap of 8-10 seconds was kept in between measurements as the readings taken continuously could be inaccurate.



The 'click' sound of the Pulsair tonometer was demonstrated to the subjects to avoid any scared jerks during the procedure and an average of three readings were obtained (Rao BS et al, 1984).

- IOP was recorded by Perkins tonometer after instilling 4% lignocaine hydrochloride eye drops and staining the tear film with a fluorescein strip. The forehead rest was adjusted and the gearwheel slightly rotated so that the doubling prism could be released and centered on the corneal apex. The stained tear film was lit in a brilliant green by two cobalt blue bulbs incorporated below the prism, which appeared as mirror-imaged hemispherical mires. The pressures were directly measured by gently rotating the gearwheel further until the inner sides of the two hemispherical mires coincided. This was taken as the endpoint of the IOP measurement. Each small graduation on the rotating wheel equaled 0.2 multiplied by Ten would give the correct pressure levels.

Results

This paper studied a total of 166 eyes of 83 individuals. The data was analyzed using SPSS 11.00 version. The study population consisted of 48 (57.8%) males and 35 (42.2%) females in the age group 14 to 71 years (mean age 42.53 +/- 13.55). The mean age for males and females were 43.7 (+/-13.8%) and 40.9 (+/-13.2%), respectively. The Mean+/-SEM and SD was calculated for both the eyes with each tonometer as shown in Tables 1 and 2. There was no statistically significant difference between iCare and Keeler Pulsair compared to Perkins tonometer (Table 3). The right eye pressures were analyzed for the convenience of finding out the best estimates of the true value by plotting the difference on the Y axis against the mean on the X axis using the Bland-Altman analysis. The difference between the measurements by the two methods should lie within 95% limits of agreement computed as the mean bias +/-1.96 times SD (Srinivas Mantha, 2000; Bland JM, 2003). The bias and 95% LoA were calculated

as shown in Figures 1 and 2. The regression analysis was performed for iCare and Keeler Pulsair against Perkins tonometer to determine the linear relationship between them. The slope and intercept with their determination of coefficient (r^2) were shown in Figure 3 and 4. The upper and lower limits of predictable intervals for slope and intercept were compared with 95% of LoA of Bland-Altman plots (Table 4). The slope was not equal to zero in either case thereby rejecting the null hypothesis.

Table 1: Descriptive statistics of the three tonometers for the right eyes (n=83)

Tonometer	Mean+/-SEM	SD	Minimum IOP mmHg	Maximum IOP mmHg
iCare	14.62+/-0.27	2.47	10	23
pulsair	14.53+/-0.36	3.36	7.33	25.67
Perkins	13.06+/-0.30	2.69	8	20

Table 2. Descriptive statistics of the three tonometers for the left eyes (n=83)

Tonometer	Mean+/-SEM	SD	Minimum IOP	Maximum IOP
iCare	14.51+/-0.35	3.15	9	25
pulsair	14.46+/-0.33	3.06	9.67	26.67
Perkins	13.21+/-0.29	2.68	8	22

Table 3. Paired t test

Tonometers	r	Right eyes (n=83)	MD	r	Left eyes (n=83)	MD
		Exact p			Exact p	
iCare+Perkins	0.610	0.0001	1.57	0.627	0.004	1.30
Pulsair+Perkins	0.510	0.002	-1.47	0.648	0.006	-1.25
iCare+Pulsair	0.545	0.84	0.10	0.510	0.91	0.05

r: Pearson correlation coefficient, p: level of significance, MD: mean difference

Table 4. Regression and Bland-Altman analysis for right eyes (n=83)

Tonometers	r^2	Slope (x)	Predication interval (intercept y)	95% LoA
Perkins vs. iCare	0.371	0.39 to 0.72	5.17 to 9.46	-6.1 to 2.9
Perkins vs. Pulsair	0.260	0.40 to 0.87	3.02 to 9.36	-4.5 to 7.5

r^2 : coefficient of determination

Discussion

The Schiotz indentation tonometry has limitations in terms of acquiring the exact pressures and is insufficient for diagnosis and essentially for follow-

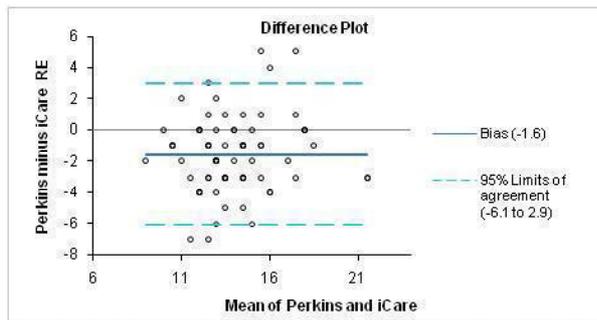


Figure 1. Bland-Altman plots of difference vs. mean of IOP value. Thick solid line indicates mean difference of the two methods.

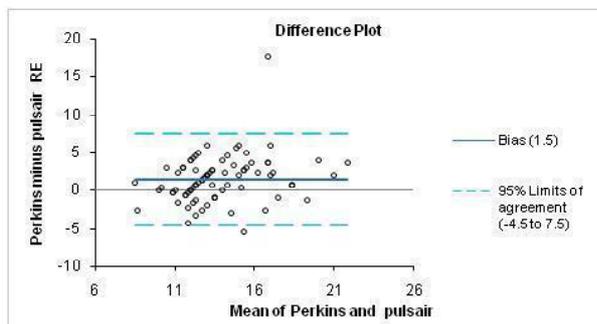


Figure 2. Bland-Altman plots of difference vs. mean of IOP value. Thick solid line indicates mean difference of the two methods.

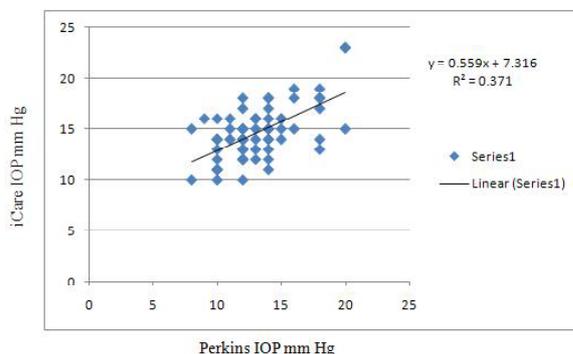


Figure 3. Regression analysis of Perkins and iCare IOP

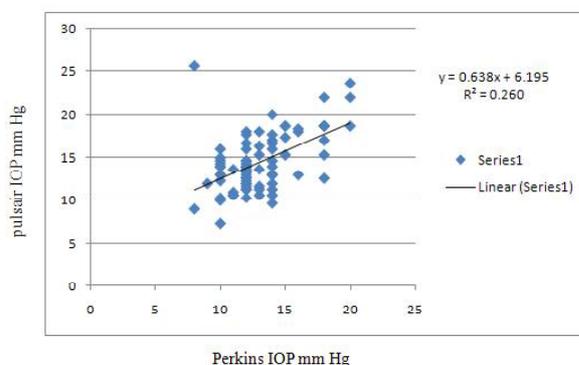


Figure 4. Regression analysis of Perkins and pulsair IOP

up of glaucoma patients (Schiotz H, 1935). The mean \pm -SD of age in this study was 42.53 \pm 13.55 that included older subjects who were prone for glaucoma in contrast to the previous study which reported mean IOP \pm -SD of 13.6 \pm -2.3 mm Hg and 13.4 \pm -2.3 mm Hg measured with GAT and Topcon CT80 NCT in the younger age group 20 to 27 years (22.6 \pm -1.6) and found no statistically significant difference between the tonometers (Ogbuehi KC et al, 2006). Garcia-Resua C et al (2006) measured the IOP with iCare and Perkins in the younger age group 19 to 21 years and found a mean pressure \pm -SEM and SD of 17.94 \pm -0.48 and 3.88 mm Hg compared to the lowered readings of 14.62 \pm -0.27 and 2.47 mm Hg in the present study, but the pressure values obtained by Perkins tonometry in the present study were very well correlated indicating the accuracy and precision of Perkins. The low Perkins pressure values could be attributable to the local anesthetic and ocular massage effect due to repeated IOP measurements facilitating the aqueous humor drainage. Although a good correlation was seen between the iCare and Perkins ($r=0.610$, $p<0.0001$) and Pulsair and Perkins ($r=0.510$, $p<0.002$) tonometries in our study, we found statistically significant difference between the two tonometers similar to the results ($r=0.82$, $p<0.0001$) of the study reproducibility and clinical evaluation of the Rebound tonometer (Martinez-de-la-casa JM, 2005). Kontiola A (2004) found a mean difference (MD) \pm -SD of 0.31 \pm -2.45 and 0.36 \pm -2.17 for the right and left eyes with $r=0.84$ and $r=0.80$. These findings were closely comparable to the values 0.10 \pm -3.36 and 0.05 \pm - 3.06 for the respective eyes in the present study.

Whitty HP et al (1969) showed a very strong correlation of 0.962 and 0.978 for the right and left eyes between Perkins and Goldmann with MD of 1-1.5 mm Hg. The high correlation coefficient is misleading and shows only the degree of association between the two methods of measurements. But it does not imply anything about the reliability and agreement or accuracy between the two tonometers. The paired t test is definitely not appropriate for showing the agreement between the

two quantitative measurements. Therefore, we went further in order to calculate the 95% LoA by plotting the mean versus the difference between the iCare and the Keeler Pulsair against the Perkins tonometer. The data points for both tonometers were distributed above and below the zero bias line suggesting that there was no consistent bias of one method over the other. iCare measured the IOP less by -6.1 mm Hg and more by 2.9 mm Hg compared to Perkins tonometer. Although the mean negative bias for iCare was -1.6, and it was found that only 90.36% of data points were lying within 95% LoA. About 9.64% (8 points) were outside the limits that raised the question of good agreement between iCare and Perkins tonometers (Figure 1). This was in contrast with the previous study that showed a MD of -3.35 mm Hg (+/-2.28) with 95% LoA between the iCare and Perkins with the difference plots lying between -7.81 and 1.12. But it did not show the proportion of points lying outside the 95% limits (Garcia-Resua C, 2006). Similarly, Davies LN et al (2006) reported LoA differently for iCare as +/-5.11 mm Hg and for GAT as +/-3.15 mm Hg with $p < 0.05$.

Keeler Pulsair measured IOP less by -4.5 or more by 7.5 mm Hg with a positive bias of 1.5 mm Hg compared to Perkins tonometer with 97.59% of points lying between the 95% acceptable limits and only 2.41% (2 points) lying outside the LoA thereby, proving a very good agreement with the Perkins tonometer shown in figure 2. Parker VA et al, (2001) reported that 95% of the Pulsair 3000 results fell between 1.75 and -2.72 mm Hg with a mean value of 0.48 mm Hg compared with GAT. When the range of pressure values was considered both the iCare and the Keeler Pulsair tonometers overestimated the Perkins pressure values. To confirm that one method was overestimating the high values or underestimating the low values all the data points should lie above or below the zero bias line respectively which was not observed in our study.

There was a slight difference of the slope and intercept in the regression analysis equation for both the tonometers since for every unit change in the

Perkins value, iCare and Pulsair tonometric pressures were increased by 0.56 to 0.64 mm Hg. From coefficient determination (r^2), the proportion of variance between iCare and Pulsair was found to be 37% and 26% respectively. The regression line for Pulsair and Perkins was closely approximated the data points showing goodness of curve fitting compared to iCare and Perkins tonometer. One outlier was observed for both the iCare and Pulsair tonometers in the regression graph as a result of high IOP recordings. To find out the tonometer which is closer to Perkins, we analysed the 95% LoA and prediction interval of slope and the intercept of iCare and Pulsair. It was observed that the width of the intervals and the range of 95% limits were not in an acceptable range signifying that both the tonometers could not replace Perkins tonometer. iCare picked up pressures more than 21 mm Hg in five eyes, Pulsair in seven eyes and Perkins in one eye. There was a trend towards measuring lower IOP values for the left eyes which was not consistently found in the present study.

The iCare tonometer can be employed as a home tonometer, useful on scarred corneas and to find out the peripheral IOP in post Keratoplasty and post surgical corneas (Cervino A, 2006). It can easily be handled by technical personnel with a few minutes of training. It is advantageous in eliminating the chances of cross-infection and contamination. It is useful in patients with cervical spine problems, patients in wheelchairs, in children, obese and bed-ridden who have difficulties in positioning the chin on the Slit Lamp Microscope. (Choi WJ, 1990; Amin SZ, 2003; Tonnu PA, 2005).

The limitation of this study was smaller sample size and IOP was measured without the inclusion of central corneal thickness which has an impact on the pressures recorded especially with Goldmann and Perkins Tonometers.

Conclusion

The two tonometers in question could be used interchangeably if the limits of agreement is not clinically important but upto the upper limit of IOP of 21 mm Hg. A confirmation of pressures is obtained by Goldmann or Perkins Tonometer

whenever iCare or Pulsair measures high IOP values. Both iCare and Pulsair tonometers recorded pressures reliably without topical anaesthesia and therefore may be employed for mass screening, diagnosis and follow up of glaucoma cases.

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