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Title

Evaluation of a new rebound tonometer for self-measurement of intraocular pressure

Sub-title

Self-measurement using Icare Home showed good agreement with Goldmann applanation tonometry. Icare Home self-measurement was well accepted and reliable results obtained by 3 in 4 subjects, suggesting potential use for home measurement of intraocular pressure.

Keywords

Self-tonometry, Rebound tonometry, Glaucoma, Intraocular pressure, Methods comparison study

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ABSTRACT

Background/ aims: To compare the accuracy of self-, partner-, and trainer-obtained measurements using the handheld Icare Home rebound tonometer with Goldmann applanation tonometry (GAT), and to evaluate the acceptability to subjects of Icare Home measurement.

Methods: 76 subjects were trained to use Icare Home for self-measurement using a standardised protocol. A pre-specified checklist was used to assess the ability of a subject to perform self-tonometry. Accuracy of Icare Home self-measurement was compared with GAT using one eye per subject, randomly selected. Bland-Altman difference analysis was used to compare Icare Home and GAT intraocular pressure (IOP) estimates. Acceptability of self-tonometry was evaluated using a questionnaire.

Results: 56 subjects (74%, 95%CI 64-84) were able to correctly perform self-tonometry. Mean bias (95% limits of agreement) was 0.3mmHg (-4.6 to 5.2), 1.1mmHg (-3.2 to 5.3), and 1.2mmHg (-3.9 to 6.3) for self-, partner-, and trainer-assessment respectively, suggesting underestimation of IOP by Icare Home tonometry. Differences between GAT and Icare Home IOP were greater for CCT below 500 μ m and above 600 μ m than data points within this range. Acceptability questionnaire responses showed high agreement that the self-pressure device was easy to use (84%), the reading was quick to obtain (88%) and the measurement was comfortable (95%).

Conclusion: Icare Home tonometry can be used for self-measurement by a majority of trained subjects. IOP measurements obtained using Icare Home tonometry by self- and third party-assessment showed slight underestimation compared with GAT.

INTRODUCTION

The measurement of intraocular pressure (IOP) is essential in management of the glaucomas. Elevated and fluctuating IOP are risk factors for the development and progression of primary open angle glaucoma (OAG).[1-4] IOP remains the principal risk factor modified in the treatment of OAG.

IOP assessment is subject to variability, and measurement error may contribute considerably to misclassification. Using data from the Blue Mountains Eye Study, it was shown that 34% of individuals with ocular hypertension (OHT) would be missed using a tonometer that underestimated IOP by 1mmHg. Conversely, 58% false positive screening tests would occur using a tonometer that over-read by 1mmHg.[5] Within-subject variation may also contribute. In the Barbados Eye Study, a sample of 2856 individuals without glaucoma or suspected glaucoma were re-examined on a separate occasion. Of the 361 subjects who were receiving treatment or had an IOP >21mmHg at baseline, 30% had IOP \leq 21mmHg on repeat assessment.[6]

Diurnal variations in IOP occur in normal subjects,[7, 8] and can be exaggerated in patients with glaucoma.[9] A study of glaucoma subjects admitted for 24-hour monitoring found that 52% of peak IOP values were recorded outside office hours, resulting in a change in clinical management for 23 participants (79%).[10] Repeating IOP measurements over the course of a day is typically limited to office hours and can be impractical in a busy clinic setting. An alternative option is for patients to monitor their own IOP. This concept has become a real possibility with the development of home tonometers that do not require the use of topical anaesthesia. The value of home monitoring by patients has long been recognised in the diagnosis and management of systemic hypertension.[11]

This study evaluates the performance of the Icare Home, a hand-held tonometer designed for self-use. The tonometer uses the same rebound technology of Icare One (preceding model), but integrates *EyeSmart* eye recognition and *EasyPos* alignment features to improve use-ability. IOP is determined by impact duration or

deceleration of a magnetic solenoid probe directed at the central cornea[12], and computed from 6 consecutive measurements. The Icare One has shown good agreement with the current reference standard Goldmann Applanation Tonometer (GAT) when used for self-measurement by adults,[13-16] and by a caregiver on a child.[17] The device has also demonstrated good repeatability.^{[13], [16]}

The Icare Home tonometer has been recently released and, to date, a single abstract reports the accuracy of IOP estimates using this machine. This study aimed to determine the proportion of subjects who may be taught to obtain a measure of their IOP using the Icare Home tonometer, to undertake a methods comparison study with GAT, and determine the acceptability of the device to subjects. A secondary aim was to assess the feasibility of third party IOP measurement using the Icare Home tonometer.

MATERIALS AND METHODS

The study had institutional review board approval from the School of Health Sciences Research and Ethics Committee, City University London. All subjects provided informed consent and the study adhered to the tenets of the Declaration of Helsinki. Subjects aged 18 years and older were recruited from clinics, and via a request for volunteers in an International Glaucoma Association newsletter. Exclusion criteria were anomalies of the anterior segment which affect corneal integrity, and those unable to speak fluent English.

A standardised training protocol for Icare Home tonometry was developed using manufacturers' recommendations.[18] The training process is illustrated in Figure 1 and described in more detail in online supplementary Figure S1. IOP data are saved in the tonometry memory by date, time, and measured eye. They can only be viewed by download to a computer. Unreliable measurements with a high standard deviation were excluded for analysis. Icare data were acquired without the use of topical anaesthesia.

Details of hand dominance and self-reported dexterity, contact lens wear, refractive error and corneal astigmatism (Topcon KR 8000), vertical palpebral aperture (VPA), and visual acuity (computerised logMAR) were obtained. Each subject was instructed on proper use of Icare Home self-tonometry with their dominant hand and by a single experienced trainer. Once confident with use of the device, the subject was asked to obtain 3 reliable IOP measurements of each eye (right first). The subject was classified as being able to perform self-tonometry if four criteria amended from manufacturers' guidelines[18] were satisfied:

- 1) The median of three IOP measurements by the trainer and subject differ by ≤ 5 mmHg.
- 2) For IOP readings between 7-23mmHg the range of three measurements by the subject is ≤ 5 mmHg, and ≤ 7 mmHg for IOP readings > 23 mmHg.
- 3) The positioning of the tonometer by the subject is correct as judged by the trainer.

- 4) The subject took ≤ 30 minutes from the start of training to obtain 3 reliable IOP measurements of each eye without trainer interaction

GAT was performed following all Icare Home measurements. The clinician was masked to Icare Home results. A median of three recordings was used for analysis.[19] The dial was set to 10mmHg between readings, and not observed until the end-point had been determined. GAT and comparison self-tonometry measurements were performed within a 15-minute period. Central corneal thickness (CCT) (Accutome Pachpen) was then determined from the mean of nine measurements. Finally, each subject was asked to complete a questionnaire comprising 5-point Likert scales to score the acceptability of Icare Home tonometry.

The secondary aim of this study was to determine whether an accompanying person could be taught to use the Icare Home. Following consent, the accompanying person underwent the training procedure described in Figure 1. Their ability to perform Icare Home tonometry on the primary subject was assessed against the four-point checklist above.

Sample size

Based on Icare One it was anticipated that 75% of subjects would potentially be able to perform self-tonometry.[14] A sample size of 75 would demonstrate this proportion $\pm 10\%$ with 95% confidence. For a standard deviation of the mean difference in measurements of 2.7mmHg between Icare One and GAT,[14] a sample size of 56 (75% of 75) would demonstrate agreement between instruments of ± 1.2 mmHg with 95% confidence.[20]

Analysis

Icare Home measurements were downloaded using iLink software and statistical analysis was performed using SPSS 22.0 software (www.ibm.com/SPSS_Statistics). Based on a pilot study, a decision was made to use a median of three Icare Home IOP measurements of a given eye for analysis in place of a single reading. Demographic characteristics were compared between subject groups using

parametric or non-parametric statistical tests as appropriate. The chi-squared test was used to compare categorical variables. For all tests, $P < 0.05$ was considered statistically significant.

Using data from a randomly selected eye, Bland-Altman analysis was used to examine consistent bias between IOP measurements by Icare Home tonometry and reference standard GAT and to plot the variability about this difference. The upper and lower 95% limits of agreement represented the mean difference between the devices ± 1.96 SD of the differences between data sets.

Responses to the user acceptability survey using Likert scales were aggregated into summary tables. Free-text responses were coded and assigned to categorical variables.

RESULTS

76 subjects (N=42, 55% female) entered the study. Their median age was 68 years (interquartile range 55-81). On self-reported history, 49 (65%) had OAG, 9 (12%) angle closure glaucoma, 4 (5%) ocular hypertension and 14 (18%) no glaucoma related diagnosis. The majority (N=69, 91%) were right hand dominant, and 18 (24%) reported problems with hand mobility/ dexterity (e.g. arthritis, tremor) in their dominant hand. A summary of clinical measurements is provided in Table 1.

Measurement	Mean +/- SD
Visual acuity (logMAR)	0.2±0.5
Mean refractive error (DS)	-0.8±4.1
Corneal astigmatism (DC)	-0.9±0.9
Vertical palpebral aperture (mm)	9.8±1.6
CCT (µm)	540.4±43.1
GAT (mmHg)	15.4±5.0
Icare Home – self (mmHg)*	15.1±5.9
Icare Home – trainer (mmHg)*	14.2±5.9

Table 1: A summary of clinical measurements representing data from the randomly selected eye from subjects in the tonometry methods comparison study.

* Results for the 56 subjects able to perform self-tonometry using Icare Home

56 subjects (74%, 95%CI 64-84) were able to correctly perform self-tonometry (41/58 (71%) with glaucoma, 15/18 (83%) without glaucoma, χ^2 p=0.3). Of the 20 subjects who were unable to perform the technique, 12 (60%) positioned the probe incorrectly at the central cornea, 4 (20%) handled the device poorly, and 4 (20%) failed to meet IOP validation criteria. The mean time taken from the start of training to being able to reliably obtain 3 measurements of each eye without trainer interaction was 21 minutes (SD 5, range 11 to 30 minutes).

No association was observed between a subjects' ability to perform self-tonometry and gender (p=0.1), previous or current contact lens wear (p=0.1), hand-dexterity (p=0.7), educational level (p=0.3), refractive error (p=0.3) or vertical palpebral

aperture ($p=0.3$). Of the 5 subjects who measured a visual acuity of 1.0 logMAR (6/60 Snellen equivalent) or less in one or both eyes, 3 were unable to perform self-tonometry.

21 accompanying persons ($N=4$, 19% female, median age 69 years (interquartile range 56 to 82 years)) underwent Icare Home partner-training. 18 (86%, 95% CI 71 to 100) correctly performed Icare Home tonometry taking a mean time of 19 minutes (SD 4, range 12 to 25 minutes) from the start of training to obtain 3 reliable measurements of each eye. Of the 3 subjects who failed to perform partner-tonometry correctly; 2 had poor positioning and 1 failed to satisfy the validation criteria. 2 of the 21 subjects reported problems with mobility in their dominant hand; one with a mild hand tremor succeeded in partner-tonometry, but the other with mild arthritis failed to correctly perform the technique. Of the six subjects unable to correctly perform Icare Home self-tonometry, 3 had accompanying persons who adequately completed partner-tonometry.

Bland-Altman plots comparing Icare Home and GAT are shown in Figure 2. There is a systematic tendency for the Icare Home tonometer to slightly underestimate IOP. The least mean bias was in self-tonometry (underestimate 0.3mmHg (95% limits of agreement -4.6 to 5.2). Measurement by the trainer and partner had similar bias of 1.2mmHg (-3.9 to 6.3) and 1.1mmHg (-3.2 to 5.3) respectively. The difference between self and third party Icare Home measurement error was significant (t-test, $p=0.003$).

The Icare Home operating manual notes that the device has not been validated for CCT outside the range of 500-600 μ m and corneal astigmatism >3 DC.[18] The measurement error was examined using this CCT cut-off and suggested a greater systematic difference outside of this reference range (Table 2). This was also the case for three subjects with corneal astigmatism >3 DC (mean underestimation 2mmHg). No pattern was observed between the difference in self-Icare Home measurements and GAT tonometry by age, mean spherical equivalent, visual acuity, VPA, and baseline GAT. Mean differences between Icare Home and GAT revealed

greater under-estimation for the right eye compared with the left eye in all three observers; trainer (R 1.7, L 0.7mmHg), self (R 0.6 L 0.0mmHg) and partner (R 1.6 L 1.0mmHg).

Central corneal thickness (CCT) (µm)	N (%)	Mean difference GAT/ Self-Icare Home IOP (mmHg)
<500µm	8 (14.3)	1.9 (SD 1.7)
500-600µm	43 (76.8)	-0.1 (SD 2.6)
>600µm	5 (8.9)	1.0 (SD 1.7)

Table 2: Mean IOP difference between GAT and self-Icare Home tonometry by central corneal thickness (CCT)

All subjects who entered the study completed the acceptability survey. Five of the 20 subjects who failed to perform self-measurements were aware of this performance outcome. Responses to the survey are summarised in Table 3. A greater proportion of subjects able to perform self-tonometry reported the device as easy to use, quick, comfortable, and were willing to use Icare Home again. Free text comments included 23 noting problems aligning the device, of which 7 referred to difficulty in viewing the green indicator base light when performing self-measurement, particularly in an eye with poorer vision or more extensive glaucomatous visual field loss. A further 6 subjects commented on problems opening the measurement probe container, and positioning the probe in the device to obtain a measurement. 3 subjects suggested modification of the device to improve use-ability such as an auditory indicator to determine correct positioning.

Statement	Agree N (%)					
	Self-tonometry			Partner-tonometry		
	Able to perform tonometry	Unable to perform tonometry	All subjects	Able to perform tonometry	Unable to perform tonometry	All subjects
The self-pressure device was easy to use	52 (93)	12 (60)	64 (84)	16 (89)	3 (100)	19 (90)

The reading was quick to obtain	53 (95)	14 (70)	67 (88)	18 (100)	3 (100)	21 (100)
The measurement was comfortable	55 (98)	17 (85)	72 (95)	---	---	---
I would use this device again	55 (98)	14 (70)	69 (91)	17 (94)	3 (100)	20 (95)
I would use this device at home	55 (98)	14 (70)	69 (91)	18 (100)	3 (100)	21 (100)

Table 3: Aggregated Likert scale responses to Icare Home self- and partner-measurement acceptability in response to five statements

Of the 21 accompanying persons who took part in the study, over 90% had positive views about the device (Table 3). The majority of negative comments made reference to difficulties in aligning the device at the cornea.

DISCUSSION

The ideal self-tonometer needs to be safe, reliable, reproducible, easy to use, and accurate over a wide range of IOP measurements. The present study has shown that the Icare Home rebound tonometer was useable by three quarters (78%) of subjects (self-measurement or assessment by a partner), demonstrated reasonable agreement with reference standard GAT, and was well received by a predominantly older population.

Comparisons with previous literature are largely based on reports of the preceding model (Icare one). A study of 126 subjects observed a similar proportion (75%) able to perform self-tonometry using the Icare One,[14] although two later reports found higher patient success rates of 99%[15] and 100%.[16] However, both studies sampled a younger population with a lower proportion of subjects with glaucoma. Furthermore, the methods used to evaluate a subjects' ability to perform self-tonometry were not outlined in previous reports, and the manual for the Icare One tonometer does not include validation criteria.[21] Our study suggested that individuals with poor vision were more likely to have difficulties performing self-tonometry. Following this observation, subjects with Humphrey Field Analyzer mean deviation (MD) of -6dB or better were compared with those with MD worse than -6dB. 8 of 33 (24%) with a good MD compared to 5/13 (38%) with a poor MD were unable to perform self-tonometry. This did not represent a statistically significant difference (χ^2 $p=0.3$). Subjects with glaucoma had a mean MD of -8.04 ± 9.40 dB. No pattern was observed between glaucoma severity and ability to perform self-tonometry.

A 2012 systematic review on the accuracy of tonometers available in clinical practice suggested that non-contact tonometry showed the least variability. Two thirds of non-contact tonometry readings were within 2mmHg of GAT, compared with 52% of rebound tonometry measurements.[22] The present study found that 66% and 84% of Icare Home self-measurements were within 2mmHg and 3mmHg of GAT

respectively, comparing well with previous reports of self-use by Icare One (56% within 2mmHg,[13] 67%[15] and 63%[16] within 3mmHg).

Overall, the Icare Home tonometer generated slightly lower IOP measurements to GAT. This difference was smaller with self-measurement (0.3mmHg) than with third party assessment (1.1-1.2mmHg). We found a single conference abstract evaluating the Icare Home, which also reported underestimation of IOP measurements (mean bias 0.95mmHg).[23] Furthermore, the authors observed greater underestimation of Icare Home measurements when used by an ophthalmologist than compared with self-measurement (mean under-read 0.21mmHg). This observation may be due to apprehension and eye squeezing during self-measurement resulting in an artefactual rise in IOP. It may also be a result of poorer positioning and angling of the probe at the central cornea.[24] The majority of previous comparisons between Icare One and GAT demonstrate overestimation of self-readings with the largest mean difference being 2.3mmHg.[14-16] Icare One and Icare Home tonometers use the same rebound technology but the updated model integrates features that may influence the accuracy of measurements. An earlier report observing similar underestimation of self-measurement using Icare One tonometry also found a negative correlation between subject age and GAT-Icare One differences. This raises the suggestion that discrepancies between our study results and those using previous Icare models may also be attributed to characteristics of the populations studied, including demographic and clinical variations.

Researchers have previously investigated the relationship between CCT and self-tonometry measurement error. Three previous reports observed increasing IOP differences with higher CCT using Icare One tonometry,[13, 14, 16] while another study found no relation between these variables.[15] Present study findings reveal greater underestimation of Icare Home self-readings compared with GAT for CCT outside the recommended range of 500 to 600µm. Our finding of a discrepancy between right and left eye measurements by Icare Home has not been previously reported. The greater underestimation of right eye IOP estimates was common to self-, partner- and trainer- observations. In all instances, the right eye was measured

before the left, and the trainer/ partner remained on the same side of the subject during right and left eye assessment. One might expect higher IOP in the first eye measured as subjects are more likely to squeeze their eyes in apprehension leading to an artefactual rise in IOP. However, our results followed an opposite trend which may be explained by differences in positioning and angling of the probe relative to the central cornea between right and left eye assessment. [24] Interestingly, the 3 left-handed individuals who reliably performed self-tonometry did not observe this trend, but the low number of subjects in this group precludes further analysis.

It is estimated that 2 in 3 patients with systemic hypertension regularly practice home monitoring in developed countries.[25] More frequent self-monitoring of blood glucose levels has also been shown to provide better control of diabetes.[26] Over the years, a number of technologies have emerged to enable similar adoption of ocular pressure monitoring (e.g. contact lens telemetry), but none have been widely adopted for use in clinical practice. The introduction of self-tonometry may provide data on variability in IOP to assist both the diagnosis and management of the glaucomas. Being a portable device that does not require the use of anaesthesia, the Icare Home tonometer has potential for self-measurement and home monitoring. Present study findings show a small under-read compared with GAT which was, by and large, consistent across a wide range of IOPs, although reliability was limited to a CCT of 500-600 μ m.

Strengths of this study include a wide IOP range for the comparison between Icare Home and GAT, and sampling of a predominantly elderly population with glaucoma/ OHT. This improves generalisability of the study findings to a population who are likely to benefit from self-tonometry in the future. Conversely, the majority of subjects were highly motivated with self-interest in their eye condition, which may have lead to an overestimation in the proportion able to perform self-measurement.

Overtime, advances in self-measurement technology are anticipated to further improve use-ability and measurement characteristics. This report outlines initial findings that confirm the accuracy of Icare Home tonometry for self-assessment.

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Work is currently ongoing to ascertain the feasibility of using the Icare Home for self-measurement in a home setting.

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Competing Interests

None declared

Contributorship statement

Priya L Dabasia, John G Lawrenson, and Ian E Murdoch contributed substantially to the study design, drafting of this report, and final approval of the submitted manuscript. Priya L Dabasia was additionally involved in data acquisition.

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Legends for display items (Figures)

Figure 1: Standardised training procedure for use of the Icare Home tonometer

Figure 2: Bland-Altman difference plots evaluating agreement between GAT and Icare Home tonometry for a) Self-measurement, b) Partner-measurement, illustrated with mean bias (dashed line) and 95% limits of agreement (dotted lines)