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

Priya L Dabasia, John G Lawrenson, Ian E Murdoch

ABSTRACT

Background/aims To compare the accuracy of self-obtained, partner-obtained 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 prespecified 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 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 to 84) were able to correctly perform self-tonometry. Mean bias (95% limits of agreement) was 0.3 mm Hg (−4.6 to 5.2), 1.1 mm Hg (−3.2 to 5.3) and 1.2 mm Hg (−3.9 to 6.3) for self-assessment, partner-assessment and trainer-assessment, respectively, suggesting underestimation of IOP by Icare Home tonometry. Differences between GAT and Icare Home IOP were greater for central corneal thickness below 500 μm and above 600 μm 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%).

Conclusions Icare Home tonometry can be used for self-measurement by a majority of trained subjects. IOP measurements obtained using Icare Home tonometry by self-assessment 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). 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 1 mm Hg. Conversely, 58% false-positive screening tests would occur using a tonometer that over-read by 1 mm Hg. 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 > 21 mm Hg at baseline, 30% had IOP ≤ 21 mm Hg on repeat assessment.

Diurnal variations in IOP occur in normal subjects,6 and can be exaggerated in patients with glaucoma. A study of glaucoma subjects admitted for 24 h monitoring found that 52% of peak IOP values were recorded outside office hours, resulting in a change in clinical management for 23 participants (79%). 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.12

This study evaluates the performance of the Icare Home, a handheld 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 usability. IOP is determined by impact duration or deceleration of a magnetic solenoid probe directed at the central cornea,12 and computed from six 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. 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

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. 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 SD 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 three 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 were satisfied:

1. The median of three IOP measurements by the trainer and subject differ by ≤5 mm Hg.
2. For IOP readings between 7 mm Hg and 23 mm Hg the range of three measurements by the subject is ≤5 mm Hg, and ≤7 mm Hg for IOP readings >23 mm Hg.
3. The positioning of the tonometer by the subject is correct as judged by the trainer.
4. The subject took ≤30 min from the start of training to obtain three 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. The dial was set to 10 mm Hg between readings, and not observed until the end point had been determined. GAT and comparison self-tonometry measurements were performed within a 15-min 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 4-point checklist above.

**Sample size**
Based on Icare One it was anticipated that 75% of subjects would potentially be able to perform self-tonometry. A sample size of 75 would demonstrate this proportion ±10% with 95% confidence. For a SD of the mean difference in measurements of 2.7 mm Hg between Icare One and GAT, a sample size of 56 (75% of 75) would demonstrate agreement between instruments of ±1.2 mm Hg with 95% confidence.

**Analysis**
Icare Home measurements were downloaded using iLink software and statistical analysis was performed using SPSS V22.0 software (http://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 χ² 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**
Seventy-six subjects (N=42, 55% female) entered the study. Their median age was 68 years (IQR 53–81). On self-reported history, 49 (63%) had OAG, 9 (12%) angle closure glaucoma, 4 (5%) OHT 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 (eg, arthritis, tremor) in their dominant hand. A summary of clinical measurements is provided in table 1.

Fifty-six subjects (74%, 95% CI 64% to 84%) were able to correctly perform self-tonometry (41/58 (71%) with glaucoma, 15/18 (83%) without glaucoma, χ² 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 three measurements of each eye without trainer interaction was 21 min (SD 5, range 11–30 min).

No association was observed between a subject’s 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 VPA (p=0.3). Of the five subjects who measured a visual acuity of 1.0 logMAR (6/60 Snellen equivalent) or less in one or both eyes, three were unable to perform self-tonometry.

Twenty-one accompanying persons (N=4, 19% female, median age 69 years (IQR 56–82 years) underwent Icare Home partner-training. 18 (86%, 95% CI 71% to 100%) correctly performed Icare Home tonometry taking a mean time of 19 min (SD 4, range 12–25 min) from the start of training to obtain three reliable measurements of each eye. Of the three subjects who failed to perform partner-tonometry correctly, two had poor positioning and one failed to satisfy the validation criteria. The mean time taken from the start of training to being able to reliably obtain three measurements of each eye was 25 min (SD 5, range 11–30 min).

No association was observed between a subject’s ability to perform partner-tonometry and gender (p=0.3), previous or current contact lens wear (p=0.3), hand dexterity (p=0.7), educational level (p=0.3), refractive error (p=0.3) or VPA (p=0.3). Of the five subjects who measured a visual acuity of 1.0 logMAR (6/60 Snellen equivalent) or less in one or both eyes, three were unable to perform self-tonometry.

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 usable by three quarters (78%) of subjects who entered the study completed the acceptability survey. 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 six subjects commented on problems opening the measurement probe container, and positioning the probe in the device to obtain a measurement. Three subjects suggested modification of the device to improve usability such as an auditory indicator to determine correct positioning.

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.

### Table 2

<table>
<thead>
<tr>
<th>CCT (µm)</th>
<th>N (%)</th>
<th>Mean difference GAT/self-Icare Home IOP (mm Hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;500</td>
<td>8 (14.3)</td>
<td>1.9 (SD 1.7)</td>
</tr>
<tr>
<td>500–600</td>
<td>43 (76.8)</td>
<td>-0.1 (SD 2.6)</td>
</tr>
<tr>
<td>&gt;600</td>
<td>5 (8.9)</td>
<td>1.0 (SD 1.7)</td>
</tr>
</tbody>
</table>

CCT, central corneal thickness; GAT, Goldmann Applanation Tonometer; IOP, intraocular pressure.
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, although two later reports found higher patient success rates of 99% and 100%. However, both studies sampled a younger population with a lower proportion of subjects with glaucoma. Furthermore, the methods used to evaluate a subject’s ability to perform self-tonometry were not outlined in previous reports, and the manual for the Icare One tonometer does not include validation criteria. 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 −6 dB or better were compared with those with MD worse than −6 dB. Eight of 33 (24%) with a good MD compared with 5/13 (38%) with a poor MD were unable to perform self-tonometry. This did not represent a statistically significant difference ($\chi^2 p=0.3$). 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 2 mm Hg of GAT, compared with 52% of rebound tonometry measurements. The present study found that 66% and 84% of Icare Home self-readings were within 2 mm Hg and 3 mm Hg of GAT, respectively, comparing well with previous reports of self-use by Icare One (56% within 2 mm Hg, 67% and 63% within 3 mm Hg).

Overall, the Icare Home tonometer generated slightly lower IOP measurements to GAT. This difference was smaller with self-measurement (0.3 mm Hg) than with third-party assessment (1.1–2.2 mm Hg). We found a single conference abstract evaluating the Icare Home, which also reported underestimation of IOP readings compared with GAT for CCT outside the recommended range of 500–600 μm. 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-observation, partner-observation and trainer-observation. 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 assessments. 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 assessments.

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, while another study found no relation between these variables. Present study findings reveal greater underestimation of Icare Home self-readings compared with GAT for CCT outside the recommended range of 500–600 μm. 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-observation, partner-observation and trainer-observation. 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 assessments. 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 assessments.

It is estimated that two in three patients with systemic hypertension regularly practice home monitoring in developed countries. More frequent self-monitoring of blood glucose levels has also been shown to provide better control of diabetes. 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 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

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

<table>
<thead>
<tr>
<th>Statement</th>
<th>Agree N (%)</th>
<th>Self-tonometry</th>
<th>All subjects</th>
<th>Partner-tonometry</th>
<th>All subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>The self-pressure device was easy to use</td>
<td>52 (93)</td>
<td>12 (60)</td>
<td>64 (84)</td>
<td>16 (89)</td>
<td>3 (100)</td>
</tr>
<tr>
<td>The reading was quick to obtain</td>
<td>53 (95)</td>
<td>14 (70)</td>
<td>67 (88)</td>
<td>18 (100)</td>
<td>3 (100)</td>
</tr>
<tr>
<td>The measurement was comfortable</td>
<td>55 (98)</td>
<td>17 (85)</td>
<td>72 (95)</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>I would use this device again</td>
<td>55 (98)</td>
<td>14 (70)</td>
<td>69 (91)</td>
<td>17 (94)</td>
<td>3 (100)</td>
</tr>
<tr>
<td>I would use this device at home</td>
<td>55 (98)</td>
<td>14 (70)</td>
<td>69 (91)</td>
<td>18 (100)</td>
<td>3 (100)</td>
</tr>
</tbody>
</table>

GAT which was, by and large, consistent across a wide range of IOPs, although reliability was limited to a CCT of 500–600 µm.

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.

Over time, advances in self-measurement technology are anticipated to further improve usability and measurement characteristics. This report outlines initial findings that confirm the accuracy of Icare Home tonometry for self-assessment. Work is currently ongoing to ascertain the feasibility of using the Icare Home for self-measurement in a home setting.

Acknowledgements The authors thank the patients, and accompanying friend/family member for volunteering to participate in this study.

Contributors PLD, JGL, and IEM contributed substantially to the study design, drafting of this report and final approval of the submitted manuscript. PLD was additionally involved in data acquisition.

Funding The International Glaucoma Association (IGA), UK provided the funding to conduct this work.

Competing interests None declared.

Ethics approval City University London School of Health Sciences Research and Ethics Committee.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

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

Priya L Dabasia, John G Lawrenson and Ian E Murdoch

Br J Ophthalmol  published online November 27, 2015

Updated information and services can be found at:
http://bjo.bmj.com/content/early/2015/11/27/bjophthalmol-2015-307674

These include:

Supplementary Material
Supplementary material can be found at:
http://bjo.bmj.com/content/suppl/2015/11/27/bjophthalmol-2015-307674.DC1.html

References
This article cites 24 articles, 2 of which you can access for free at:
http://bjo.bmj.com/content/early/2015/11/27/bjophthalmol-2015-307674#BIBL

Email alerting service
Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Notes

To request permissions go to:
http://group.bmj.com/group/rights-licensing/permissions

To order reprints go to:
http://journals.bmj.com/cgi/reprintform

To subscribe to BMJ go to:
http://group.bmj.com/subscribe/