Request # 35671932
Email (PDF) To: mrllove@aoa.org
American Optometric Association
Clinical Resources Group
243 N Lindbergh Blvd
St Louis, MO 63141-7881

DOCLINE: Journal Copy EFTS Participant
Title: Ophthalmology
Title Abbrev: Ophthalmology
Article: Systematic review of the agreement of tonometers with Goldma
Author: Cook J; Botello A; Elders A; Fathi Ali A; Azuara-Blanco A; Fraser
NLM Unique ID: 7802443 Verify: PubMed
PubMed UI: 22578443
ISSN: 0161-6420 (Print) 1549-4713 (Electronic)
Fill from: Any format
Publisher: Elsevier, New York :
Copyright: Copyright Compliance Guidelines
Authorization: Danette Miller
Need By: JAN 31, 2014
Maximum Cost: Any cost
Patron Name: American Optometric Association
Referral Reason: Other
Phone: 1.314.983-4155
Fax: 1.314.991-4101
Alt Delivery: Fax
Routing Reason: Routed to MOUCXY in Serial Routing - cell 1
Received: Jan 29, 2014 (10:16 AM ET)
Lender: MERCY SPRINGFIELD/SPRINGFIELD/ MO USA (MOUCXY)

This material may be protected by copyright law (TITLE 17, U.S. CODE)

Bill to: MOUZRM
American Optometric Association
Clinical Resources Group
243 N Lindbergh Blvd
St Louis, MO 63141-7881
Systematic Review of the Agreement of Tonometers with Goldmann Applanation Tonometry

Jonathan Alistair Cook, PhD, BSc, Adriana Paola Botello, MSc, Andrew Elders, MSc, BSc, Alia Fathi Ali, MSc, Augusto Azuara-Blanco, PhD, FRCOphth, Cynthia Fraser, MA (Hons), Dip Lib, Kirsty McCormack, MSc, BSc, Jennifer Margaret Burr, MRCOphth, MSc, for the Surveillance of Ocular Hypertension Study Group*

Objective: To assess the agreement of tonometers available for clinical practice with the Goldmann applanation tonometer (GAT), the most commonly accepted reference device.

Design: A systematic review and meta-analysis of directly comparative studies assessing the agreement of 1 or more tonometers with the reference tonometer (GAT).

Participants: A total of 11,582 participants (15,525 eyes) were included.

Methods: Summary 95% limits of agreement (LoA) were produced for each comparison.

Main Outcome Measures: Agreement, recordability, and reliability.

Results: A total of 102 studies, including 130 paired comparisons, were included, representing 8 tonometers: dynamic contour tonometer, noncontact tonometer (NCT), ocular response analyzer, Ocuton S, handheld applanation tonometer (HAT), rebound tonometer, transpalpebral tonometer, and Tono-Pen. The agreement (95% limits) seemed to vary across tonometers: 0.2 mmHg (−3.8 to 4.3 mmHg) for the NCT to 2.7 mmHg (−4.1 to 9.6 mmHg) for the Ocuton S. The estimated proportion within 2 mmHg of the GAT ranged from 33% (Ocuton S) to 66% and 59% (NCT and HAT, respectively). Substantial inter- and intraobserver variability were observed for all tonometers.

Conclusions: The NCT and HAT seem to achieve a measurement closest to the GAT. However, there was substantial variability in measurements both within and between studies.

Financial Disclosure(s): The author(s) have no proprietary or commercial interest in any materials discussed in this article.


*Group members listed online (available at http://aaojournal.org).

Increased intraocular pressure (IOP) is the most important risk factor for developing glaucoma and is the only one that is treatable. The risk of developing glaucoma and worsening of existing disease rises with increasing IOP.1,2,3,4 In the United Kingdom, there is considerable debate about the role and optimal organization of a monitoring service for those patients with ocular hypertension and whether other health professionals (e.g., nurses and optometrists) might be safely involved in measuring IOP. To be used in such a setting, a tonometer needs to be accurate, precise, and easy to use.

The Goldmann applanation tonometer (GAT), a contact tonometer, is currently the tonometer most widely used by ophthalmologists. A thick or thin cornea can lead to measurement error in tonometry, including the GAT.5,6 New tonometers are available that account for the biomechanical properties and thickness of the cornea. In addition, noninvasive self-measurement devices are available and may be highly appropriate and relevant as monitoring devices. The aim of this systematic review was to compare the agreement of the tonometers used in clinical practice with the GAT as the reference tonometer.

Materials and Methods

Directly comparative studies, that is, those that assessed the agreement of 1 or more tonometers, compared with the reference standard tonometer (GAT) in the same group of people (paired data) were included. Clinic (e.g., case-control and cohort design) and population (e.g., cross-sectional) studies were eligible provided they incorporated paired data for the GAT and at least 1 other tonometer that could be used in clinical practice. The following tonometers were not included because they were not commercially available or were judged not suitable for monitoring ocular hypertension in routine clinical practice: applanation resonance tonometer,7 ocular blood flow instrument,8 Schiotz (Sklar Instruments, West Chester, PA),9 SmartLens (ODC, Zurich, Switzerland),10 pneumatonometer,11 and manometry.12 Studies published in a non-English language and conference abstracts were excluded. All patients aged 16 years or more, including those with a diagnosis of ocular hypertension or glaucoma or representative of the general population, were eligible for inclusion. When the age range was not reported, confirmation from the authors was sought. If there was still uncertainty, a formula was applied (mean and standard deviation [SD], mean − 3× SD; or median and interquartile range [IQR], median − 3× [IQR/1.35]) to assess inclusion and
prevent exclusion purely on the failure to report the age criteria. Participants with corneal abnormalities were excluded (corneal pathology including keratoconus, bullous keratopathy, or at least one corneal graft). Measurements performed by any type of examiner (e.g., optometrists, ophthalmologists, nurses, technicians, or patients) were considered. The outcomes of interest were the agreement (mean difference and limit of agreement [LoA]) between a tonometer and the reference standard, the reliability (inter- and intraobserver variation) associated with measurements, and the proportion of participants with a recorded IOP measurement within 2 mmHg of the GAT (Haag Streit, Koeniz, Switzerland), with 8 different types of tonometer: dynamic contour tonometer (Pascal, SMT Swiss Microtechnology, Port, Switzerland); rebound tonometer (icare, Helsinki, Finland); Tono-Pen (Mentor O&O Inc., Santa Barbara, CA); Ocuton S (EPSa Elektronik & Präzisionsbau, Saalfeld, Germany); handheld applanation tonometer (HAT: Kowa HA-2, Kowa, Japan; Perkins, Haag Streit, Koeniz, Switzerland); noncontact tonometer (NCT; Canon USA Inc., Lake Success, NY); and transpalpebral tonometer, which includes the pressure phosphene tonometer (Proview eye pressure monitor, Bausch & Lomb Inc., Rochester, NY) and the TGDc-01 (Ryanz State Instrument-making Enterprise, Ryazan, Russia), also known as the Diaton tonometer (BiCOM Inc., Long Beach, NY). Quality assessment results are summarized in Figure 2. Apart from participant selection and accounting for all participations, it was often uncertain whether individual quality criteria were met. Rarely was the noncompliance with a criteria item explicitly reported; for exam-
ple, it was clear in only 1 study that tonometers were not calibrated, whereas for most studies this was not stated.

Ninety-nine studies (125 paired comparisons) were included in the meta-analyses of agreement; 3 did not report sufficient data. Comparison across tonometers was difficult given the indirect nature of the analysis. A summary of the main analyses for all candidate tonometers is provided in Tables 1 and 2. The proportion (%) of results within 2 mmHg of the GAT, based on the main analysis mean difference and random error, is also presented. On the basis of the meta-analyses, the expected difference varied

---

Figure 1. Flow diagram of the selection process.

---

Figure 2. Quality assessment of included studies.
Cook et al. • Tonometers with Goldmann Applanation Tonometry

Table 1. Pooled Estimates and Summary 95% Limits of Agreement*

<table>
<thead>
<tr>
<th>Comparator</th>
<th>No. Studies</th>
<th>MD</th>
<th>95% CI</th>
<th>RE</th>
<th>95% CI</th>
<th>95% LoA</th>
<th>% within 2.0 mmHg</th>
</tr>
</thead>
<tbody>
<tr>
<td>DCT</td>
<td>32</td>
<td>1.8</td>
<td>1.4 to 2.2</td>
<td>2.4</td>
<td>2.1 to 2.6</td>
<td>−2.9 to 6.5</td>
<td>48</td>
</tr>
<tr>
<td>HAT</td>
<td>4</td>
<td>−1.2</td>
<td>−2.8 to 0.4</td>
<td>2.1</td>
<td>1.3 to 2.8</td>
<td>−5.2 to 2.8</td>
<td>59</td>
</tr>
<tr>
<td>NCT</td>
<td>26</td>
<td>0.2</td>
<td>−0.1 to 0.6</td>
<td>2.1</td>
<td>1.8 to 2.3</td>
<td>−3.8 to 4.3</td>
<td>66</td>
</tr>
<tr>
<td>Ocuton S</td>
<td>3</td>
<td>2.7</td>
<td>−1.2 to 6.6</td>
<td>3.5</td>
<td>2.4 to 4.6</td>
<td>−4.1 to 9.6</td>
<td>33</td>
</tr>
<tr>
<td>ORA</td>
<td>12</td>
<td>1.3</td>
<td>0.9 to 2.2</td>
<td>2.8</td>
<td>2.5 to 3.1</td>
<td>−3.9 to 7.0</td>
<td>46</td>
</tr>
<tr>
<td>RT</td>
<td>14</td>
<td>0.9</td>
<td>0.4 to 1.4</td>
<td>2.6</td>
<td>2.1 to 3.2</td>
<td>−4.3 to 6.1</td>
<td>52</td>
</tr>
<tr>
<td>Tono-Pen</td>
<td>14</td>
<td>−0.2</td>
<td>−1.0 to 0.5</td>
<td>3.1</td>
<td>2.5 to 3.7</td>
<td>−6.2 to 5.8</td>
<td>48</td>
</tr>
<tr>
<td>Transpalpebral</td>
<td>20</td>
<td>−0.5</td>
<td>−1.3 to 0.3</td>
<td>3.3</td>
<td>2.8 to 3.7</td>
<td>−6.9 to 5.9</td>
<td>46</td>
</tr>
</tbody>
</table>

CI = confidence interval; DCT = dynamic contour tonometer; HAT = handheld applanation tonometer; LoA = limits of agreement; MD = mean comparator minus mean GAT value; NCT = noncontact tonometer; ORA = ocular response analyzer; RE = random error (estimated standard deviation of the differences); % within 2.0 mmHg unless otherwise stated.

Discussion

We identified a large body of evidence comparing tonometers with the GAT. However, poor reporting limited the assessment of the quality of the included studies and the synthesis of the evidence.

The results of this study suggest that, when compared with the GAT, the NCT was the tonometer with the least amount of variability in IOP. Approximately two thirds of measurements with the NCT were estimated to be within 2 mmHg of the GAT measurement. The second lowest variability was observed for the HAT, with 59% of measurements within 2 mmHg, which was not surprising because it is also an applanation tonometer. The HAT has the same low at 50%. For the NCT, Ocuton S, and transpalpebral tonometer, a value in the range of 70% to 90% was observed in a single study, which could be considered problematic if representative of a monitoring scenario (Table 3). Reliability data were reported for all except the HAT (Table 4, available at http://aaojournal.org), although a variety of metrics were reported. Inter- and intraobserver reliability data were available for only 5 of the 8 tonometers (37 studies). Generally, relatively large levels of variability were observed for inter- and intra-reliability, with the GAT seeming to have lower levels of variability than most if not all of the other tonometers.

Table 2. Pooled Estimates with 95% Prediction Intervals*

<table>
<thead>
<tr>
<th>Comparator</th>
<th>No. Studies</th>
<th>Mean Diff</th>
<th>95% Pred Int</th>
<th>Ran Err</th>
<th>95% Pred Int</th>
</tr>
</thead>
<tbody>
<tr>
<td>DCT</td>
<td>32</td>
<td>1.8</td>
<td>−0.4 to 4.0</td>
<td>2.4</td>
<td>1.1 to 3.6</td>
</tr>
<tr>
<td>HAT</td>
<td>4</td>
<td>−1.2</td>
<td>−4.4 to 2.0</td>
<td>2.1</td>
<td>0.6 to 3.6</td>
</tr>
<tr>
<td>NCT</td>
<td>26</td>
<td>0.2</td>
<td>−1.4 to 1.9</td>
<td>2.1</td>
<td>0.8 to 3.3</td>
</tr>
<tr>
<td>Ocuton S</td>
<td>3</td>
<td>2.7</td>
<td>−4.0 to 9.4</td>
<td>3.5</td>
<td>1.7 to 5.3</td>
</tr>
<tr>
<td>ORA</td>
<td>12</td>
<td>1.5</td>
<td>−0.6 to 3.7</td>
<td>2.8</td>
<td>1.6 to 4.0</td>
</tr>
<tr>
<td>RT</td>
<td>14</td>
<td>0.9</td>
<td>−0.9 to 2.7</td>
<td>2.6</td>
<td>0.6 to 4.7</td>
</tr>
<tr>
<td>Tono-Pen</td>
<td>14</td>
<td>−0.2</td>
<td>−3.0 to 2.5</td>
<td>3.1</td>
<td>0.9 to 5.3</td>
</tr>
<tr>
<td>Transpalpebral</td>
<td>20</td>
<td>−0.5</td>
<td>−3.8 to 2.8</td>
<td>3.3</td>
<td>1.2 to 5.4</td>
</tr>
</tbody>
</table>

DCT = dynamic contour tonometer; HAT = handheld applanation tonometer; mean diff = mean comparator minus mean Goldmann applanation tonometer value; NCT = noncontact tonometer; ORA = ocular response analyzer; ran err = random error (estimated standard deviation of the differences); RT = rebound tonometer; pred int = prediction interval incorporating estimated between study heterogeneity.

*mmHg unless otherwise stated.
advantages and limitations as the GAT, the only substantial difference being that the HAT is a portable instrument. Other tonometers had approximately half or more of the measurement differences greater than 2 mmHg. The Ocuton S seemed to have the lowest agreement with the GAT, with only one third of measurements within 2 mmHg.

Recordability was reported for all tonometers except the HAT. Only 27 studies (26%) explicitly stated the number of participants for which a measurement was attempted as opposed to the number for which a measurement was successfully taken. In general, reported recordability was moderate to very high, with most studies reporting values of 90% and above. Reliability data were available for all tonometers except the HAT. There was a clear suggestion of sizeable inter- and intraobserver variability for all 7 tonometers when data were available. It is worth noting that the GAT reliability, although often smaller than the corresponding study’s candidate tonometer value, was also usually sizeable. This would explain the scale of heterogeneity observed in the agreement meta-analyses to some extent, although the use of repeated measurement for both the GAT and the candidate tonometer should have lessened the impact.

Although the GAT has a number of limitations for measuring IOP, it is likely to remain the standard in secondary care (i.e., hospital setting) for some time. For this reason, determining which tonometers are close to the GAT is useful. Unfortunately, variability between tonometers was substantial. Reliability data showed that variability for repeat measurement (including the GAT) was also nonnegligible. Consistent use of the same tonometer during clinical follow-up is arguably almost as important as the choice of tonometer.

To be included in this review, a tonometer had to be judged as suitable for monitoring ocular hypertension in routine clinical practice and could potentially replace the GAT. As such, our findings are only directly relevant to the GAT. As such, our findings are only directly relevant to the GAT.

There is a need to standardize the reporting of comparative studies of tonometers. The necessary statistics for meta-analysis are often not presented. The reporting is inconsistent, and in particular basic information is not always presented. Our quality assessment highlighted a lack of reporting of key study characteristics and issues such as the clustering of eyes with participants, and the number of observations used is regularly ignored. Furthermore, an in-depth exploration of factors that could influence the pressure measurements is needed for the reference standard and candidate tonometers. This could be addressed by a large primary study but also has the potential to be explored in a meta-analysis of individual patient data. Given the level of heterogeneity, it may be the case that a systematic review of limit of agreement studies requires focused study inclusion criteria akin to those recently proposed for diagnostic test accuracy. Finally, more in-depth evaluation of the role of the GAT as the default tonometer in clinical practice seems warranted.

In conclusion, there are a variety of tonometers to evaluate IOP, and the GAT is the current reference standard. The NCT and HAT seem to typically achieve the closest measurement to the GAT.

Acknowledgment. The authors thank Aachal Kotecha for helpful comments on a draft document on which this article was based.

References


Footnotes and Financial Disclosures

Originally received: May 5, 2011.
Final revision: February 17, 2012.
Accepted: February 17, 2012.

Health Services Research Unit, University of Aberdeen, Aberdeen, UK.

Financial Disclosure(s):
The author(s) have no proprietary or commercial interest in any materials discussed in this article.

Funding: This review was part of the Surveillance for Ocular Hypertension study funded by the UK National Institute for Health Research Health Technology Assessment Programme (Project No. 07/46/02). J.C. held a Medical Research Council UK fellowship (G0601938). AA-B was a grantholder on an AstraZeneca (London, UK) funded study of a new medication for glaucoma. The Health Services Research Unit receives core funding from the Chief Scientist Office of the Scottish Government Health Directorates. Views and opinions expressed are those of the authors and do not necessarily reflect those of the Chief Scientist Office, National Institute for Health Research Health Technology Assessment Programme, or the Department of Health. None of the funders had a role in the design or conduct of this research.

Correspondence:
Jonathan Alistair Cook, PhD, Health Services Research Unit, University of Aberdeen, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD. E-mail: j.a.cook@abdn.ac.uk