

ICARE® ONE REBOUND VS GOLDMANN APPLANATION TONOMETRY IN CHILDREN WITH KNOWN OR SUSPECTED GLAUCOMA

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PURPOSE: To compare Icare ONE tonometry by clinic examiner and parent/guardian to Goldmann applanation in children with known/suspected glaucoma; to evaluate the trend in intraocular pressure (IOP) with 4 repeated measurements using Icare ONE; and to evaluate the feasibility of instructing parents on the use of the Icare ONE device in the clinic setting.

DESIGN: Nonrandomized, prospective clinical study.

METHODS: Patients with known or suspected glaucoma were recruited from the Duke pediatric glaucoma clinic. Parent(s) of all subjects gave informed consent (and children gave assent) for participation in this research study. IOP was measured using Icare ONE by clinic examiner and parent/guardian, then using Goldmann applanation (masked physician). Each parent/guardian completed an ease-of-use survey.

RESULTS: Sixty eyes (60 children) were included. Absolute value of mean IOP difference (Icare ONE clinic examiner vs Goldmann applanation) was 3.3 4.0 mm Hg (P .001). Icare ONE IOP by clinic examiner was within 3 mm Hg of Goldmann applanation in 68% (n 41 eyes). In eyes with >3 mm Hg difference, Icare ONE was higher than Goldmann applanation in 84%. IOP demonstrated a statistically significant downward trend with repeated sequential measurements with Icare ONE (P .0053, r2 0.9894). All parents accomplished Icare ONE tonometry on at least 1 eye; 98% reported it was "easy to learn to use."

CONCLUSION: Icare ONE tonometry appears accurate and well-tolerated compared to Goldmann applanation, and holds promise for clinic and home tonometry in children. IOP trends downward with successive measurements using Icare ONE, demonstrating a possible effect from presumed patient relaxation.

QUOTES FROM THE FULL STUDY

"Icare ONE tonometry appears accurate and well-tolerated compared to Goldmann applanation, and holds promise for clinic and home tonometry in children. IOP trends downward with successive measurements using Icare ONE, demonstrating a possible effect from presumed patient relaxation."

"The original Icare device is commercially available in the United States and has been shown to be well tolerated and to give reproducible results in the pediatric population. Flemmons and associates demonstrated good correlation between Icare and Goldmann applanation tonometry in pediatric patients with known and suspected glaucoma, and showed that parents are able to use the device for home tonometry in children."

"A recent study demonstrated good correlation of Icare ONE to Goldmann applanation tonometry in the adult population."

"There was a good linear correlation between Icare ONE IOP measured by the parent and by the examiner (R2 0.95) and between Icare ONE and Goldmann applanation tonometry."

"The relationship of certain ocular characteristics with the magnitude of difference between IOP by Icare ONE vs Goldmann applanation tonometry was assessed using a Fisher exact test. None of the following variables was found to be statistically significantly associated with a clinically significant (3 mm Hg) difference between Icare ONE and Goldmann applanation IOP readings: visual acuity, nystagmus, strabismus, corneal abnormalities, CCT, number of prior glaucoma surgeries (data not shown)."

"53 of 54 parents (98%) "agreed" or "strongly agreed" that the Icare ONE was "easy to learn how to use." Fifty-two of 54 parents (96%) reported that they would feel comfortable using Icare ONE to obtain IOP on their child at home. Forty of 51 parents (78%) rated the Icare ONE equally or better tolerated than Goldmann applanation for checking the IOP in their children (3 parents did not answer the question)."

"Although Goldmann applanation tonometry was used as the "gold standard" in this study, it is not clear that this is the most accurate way to measure IOP in children. There is evidence to suggest that applanation underestimates the true IOP in children."

"The ease with which parents are able to use the device, and its correlation to Goldmann applanation, make the Icare ONE promising for home tonometry in children. One of the goals of home tonometry is to identify IOP fluctuations that are not identified during standard clinic hours. Icare ONE may be useful as a screening tool to capture such fluctuations and to identify those patients requiring more careful monitoring."

HOME TONOMETRY FOR MANAGEMENT OF PEDIATRIC GLAUCOMA

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PURPOSE: To use Icare rebound tonometry in the home setting for documentation of diurnal intraocular pressure (IOP) fluctuations in children.

Design Nonrandomized, prospective clinical study.

METHODS: Pediatric ophthalmology clinic patients were recruited between October 2009 and February 2010 who were able to cooperate with IOP measurement by Icare rebound tonometry and whose caregiver was willing and able to obtain Icare measurements at home. The child's IOP was measured first by Icare tonometry followed by a second method (Goldmann applanation [GAT]). The caregiver was instructed on the use of the Icare tonometer. The subject's IOP was measured by the caregiver at home at designated time periods for at least 2 consecutive days.

RESULTS: Seventeen children (17 eyes) with known or suspected glaucoma and 11 normal children were included. Excellent reliability was obtained

by caregivers in 70% of Icare measurements. Mean difference between Icare and GAT in clinic was 2.0 4.0 mm Hg, P .08. Daily IOP fluctuation occurred in both subjects with glaucoma and normal subjects. In children with known or suspected glaucoma, relative peak and trough IOPs occurred in the early morning (45%) and late evening (43.5%), respectively. Comparison of the peak IOP measured at home vs in the clinic was >6 mmHg in 5 of 16 subjects (31%) and affected glaucoma management in several subjects.

CONCLUSIONS: In selected children with glaucoma, home tonometry by Icare rebound tonometry was reliable, easily performed by caregivers, and well tolerated, and offered IOP information valuable in clinical management.

EVALUATION OF THE ICARE® REBOUND TONOMETER AS A HOME INTRAOCULAR PRESSURE MONITORING DEVICE

J Glaucoma 2010; Sanjay Asrani, MD, Ashmita Chatterjee, BSc, David K. Wallace, MD, MPH, Cecilia Santiago-Turla, MD, and Sandra Stinnett, DrPH

PURPOSE: (a) To investigate whether the Icare rebound tonometer can provide accurate measurements of intraocular pressure (IOP) in the hands of an inexperienced user compared with Icare measurements and Goldmann tonometry by a trained technician and (b) to assess the intrauter reproducibility of IOP measurements and the learning curve among patients using the Icare rebound tonometer.

METHODS: A trained technician used the Icare rebound tonometer to measure the IOP of the right eye of 100 glaucoma patients. The technician then instructed each patient on use of the Icare tonometer. Each patient then measured his/her own pressure using the Icare tonometer. Finally, a different technician, who was masked to both of the earlier readings, measured IOP by Goldmann applanation tonometry. Thirty patients repeated the Icare measurement 3 times (once every 5 min) 20 minutes after the initial IOP measurement.

RESULTS: Of the 100 patients, 82 of patient Icare and the technician Icare readings were within 3mm Hg of each other, and 75 of the patient Icare and Goldmann applanation tonometry measurements were within 3mm Hg of each other. Intraclass correlations between self-administered Icare measurements 1 and 2, 1 and 3, and 2 and 3 were 0.69, 0.71 and 0.81, respectively.

CONCLUSION: In this study, the Icare rebound tonometer was accurate and reliable in the hands of patients. Patients can easily learn to self-administer this test, possibly allowing for home monitoring of IOP.

QUOTES FROM THE FULL STUDY

"Raised intraocular pressure (IOP) is known to be a major risk factor for glaucoma development and progression. IOP measurements during the office hours have been shown to incorrectly identify IOP peaks and its range. Recently some studies have shown that short-term IOP fluctuations and intervisit IOP variations are prognostic factors for glaucoma progression. However, data on IOP fluctuations are limited owing to the impractical nature of measuring IOP in the office over several hours or days. A home tonometer would provide these data and could aid in the management of individual patients."

"The measurements taken with the Icare tonometer by both experienced and inexperienced technicians were comparable with GAT measurements."

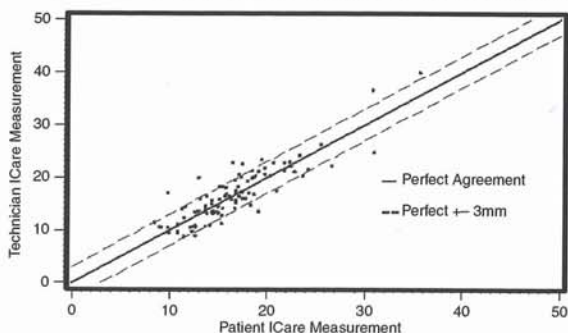


FIGURE 1. Agreement between the patient and the technician Icare tonometer measurements.

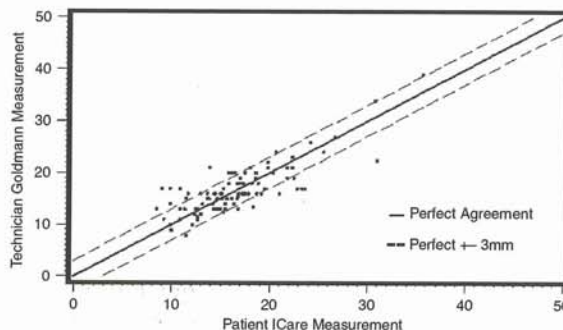


FIGURE 2. Agreement between the patient Icare tonometer measurement and the technician Goldmann applanation tonometer measurement.

"Ninetyfour percent of the participants agreed or strongly agreed that they learned to use the Icare tonometer quickly, and 93% agreed or strongly agreed that the instrument was simple and easy to use."

The gentle learning curve implies that minimal time is required for training patients in the use of the Icare instrument. The strong intraclass correlation between attempts 2 and 3 indicates a high degree of reproducibility in Icare tonometer IOP measurements in the hands of the patient. In this study, 82% of the Icare readings of the patient's measurement versus that of the trained technician were within ±3mm Hg. Meanwhile, 75% of the patient Icare measurement and the technician Goldmann measurement

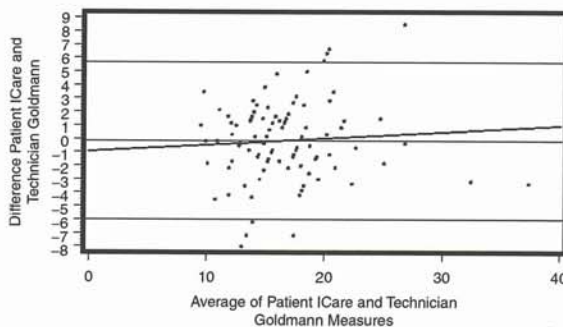


FIGURE 3. Bland-Altman plot of the average versus the difference between the patient Icare tonometer measurements and the technician Goldmann applanation tonometer measurements.

readings were within 3mm Hg of each other. The above rate of agreement implies that Icare can be used by patients to accurately measure their IOP at home."

"The IOP measurements with Icare taken from the central cornea were similar to those obtained from the peripheral cornea."

"However, as the same patient uses the probe for home tonometry, this cost may be minimized, as it is possible to store the probe aseptically in the original capped container."

"There are many benefits of home monitoring. IOP data on a patient are typically collected for 2 to 4 seconds at a time, 3 to 5 times a year owing to the need for instruments that can be used by trained ophthalmic personnel and thus limited to those in physician offices. This leads to very limited IOP data available to eye physicians for the management of a chronic condition, such as glaucoma. Future advances in therapy and the better understanding of the role of IOP fluctuations may be possible with the availability of additional IOP data in the patient's own environment. This advance may be similar to the advent of home glucose monitoring devices for the management of diabetes."

"In conclusion, IOP readings provided by the Icare tonometer are both reliable and reproducible. Its recent US FDA approval, its gentle learning curve and the absence of need for an anesthetic make it ideal for use by the patient. Thus, the Icare tonometer has the potential of providing IOP data in the patient's home environment, and may be of particular value for those patients requiring aggressive monitoring of IOP."

GAT COMPARISON

icare

PEDIATRIC

APPLICATION OF THE ICARE® REBOUND TONOMETER IN HEALTHY INFANTS

J Glaucoma 2010; Anna Lundvall, MD, PhD, Helena Svedberg, MD, and Enping Chen, MD, PhD

PURPOSE: To study the tolerability of the Icare rebound tonometer (RBT) and to establish reference values of the intraocular pressure (IOP) in healthy infants.

PARTICIPANTS AND METHODS: Forty-six children were recruited. In 6 infants aged 3 to 18 months, it was not possible to conduct the examination. Five children refused all cooperation. In 1 child, only 1 reading was obtained. In 1, partly uncooperative infant, the difference between the highest and the lowest reading exceeded 3mm Hg (a difference of 7mm Hg). These 7 infants were excluded. Totally 39 children, 22 girls and 17 boys, aged 1 month to 36 months were included in the study. The mean age was 14±9 months [mean ± standard deviation (SD)]. One randomly selected eye of each child was examined with the Icare RBT. Three consecutive readings were made. In 10 children, IOP measurements were conducted twice with an interval of 10 to 30 minutes by 2 different ophthalmologists.

RESULTS: The mean IOP value of the 39 infants was 11.82±2.67mm Hg. The median value was 10mm Hg with a range of 7.3 to 17.0mm Hg. In 10 children, the IOP was determined by 2 examiners. The results were virtually identical with differences of 0 to 1mm Hg in 9 out of 10 children. The mean difference between Examiner 1 and Examiner 2 (0.77mm Hg) was not statistically significant ($P>0.20$). The examinations were very well tolerated, and no child showed any sign of discomfort during or after the examination.

CONCLUSIONS: The hand-held RBT in the present study is easy to use, it does not require topical anesthesia and it is very well tolerated by cooperative infants. However, 7 out of 46 infants refused cooperation.

QUOTES FROM THE FULL STUDY

"Childhood glaucoma is a rare but serious condition often leading to visual impairment and even blindness. Diagnosis is important, as treatment can prevent visual handicap."

"Tonometry is a cornerstone of the diagnosis and in the management of glaucoma."

"However, infants are not cooperative and intraocular pressure (IOP) measurement with the Goldmann tonometer is not possible."

"General anesthesia is a risk for the patient and is resource demanding and may affect the IOP."

"Topical anesthesia that often causes discomfort."

"In school children, measurement of IOP with the Icare rebound tonometer (RBT) is a highly reproducible method showing high intraobserver and interobserver correlation."

"The examinations were very well tolerated by the cooperative infants and none of these children showed any signs of discomfort."

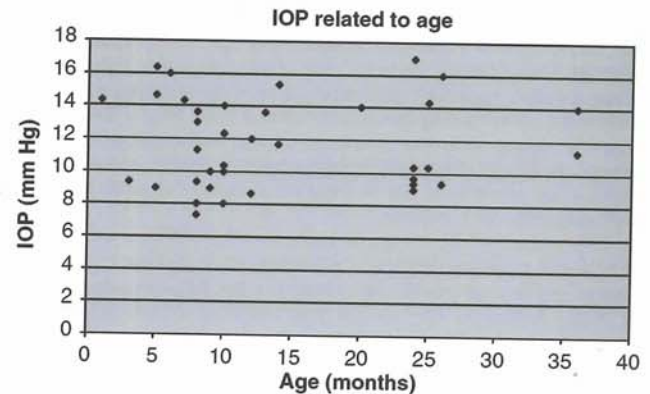


FIGURE 1. IOP in healthy infants

"The Icare RBT has been extensively evaluated in adults and was reported to give reproducible results. According to several studies, there is a good accordance between IOP values obtained with the Goldmann applanation tonometer (usually considered to be the golden standard) and IOP values obtained with the Icare RBT."