Reproducibility of Mobile Auto Refractor Measurements in a Colombian Children Population

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Summary

Purpose: To Evaluate the inter-observer reproducibility of a mobile pediatric auto refractor in an infant Colombian population. Methodology: Quantitative longitudinal prospective study. Variables of age, sex, ocular history and refractive defect were measured. The sample size was estimated assuming as values of the intraclass correlation coefficient (ICC). The descriptive statistical analysis of the variables was performed and the ICC was calculated to evaluate the reproducibility of the data taken independently by two examiners. Results: 138 participants were included, median age was 42 months. 51% of the sample were females and hypermetropic astigmatism was the prevalent refractive defect with a 67.39% occurrence. The ICC for sphere, cylinder and axis, showed an almost perfect degree of agreement. Conclusions: A mobile pediatric auto refractor brings reliable data when evaluating the refractive status without cycloplegia in children aged 24-67 months. Although it is suggested to classify the refractive error as the average of three consecutive measurements and correlate the result with the clinical history of optometry to define the final formula.

Keywords: Reproducibility, intraclass correlation coefficient, diagnostic test, auto refractor, refractive error.

Introduction

The refractive state of the eye is determined by the relation of four variables: corneal power, anterior chamber depth, lens power and axial eye length. During eyeball growth, the refractive state undergoes a gradual variation due to the changes presented in the mentioned variables, reason for which it is fundamental to make periodic evaluations, with the purpose of identifying in a timely manner the appearance of ametropias that interfere in the process of emmetropization and generate risk of amblyopia.

In addition to the decreased irreversible visual acuity, amblyopia is characterized by the effects on the quality of life and the normal development of children, its prevalence varies between 1.39% to 5%. According to several studies, refractive assessment at an early age and the identification of risk factors associated with amblyopia in a timely manner, followed by appropriate treatment, constitute an effective strategy to reduce the frequency and severity of visual impairment in adulthood.

Consequently with the aforementioned, the refractive examination of pediatric patients is fundamental; but this procedure is a challenge for the professional, due to the poor collaboration and variability in the magnitude of the refractive error, due to the changes in the fixation point. A successful evaluation is subject to diverse factors, such as: clinical expertise, professional experience and patient collaboration, among others. Such aspects have promoted the search for tools such as auto refractors to streamline the process of consultation and obtain results about the refractive state, the degree of ocular alignment, the pupillary distance and the pupillary diameter.

When using this type of diagnostic equipment, it is necessary to know the reliability of the obtained results, and one effective way of evidencing it, is inquiring: Is the obtained data the same, when repeating the test under similar conditions? This concern led us to pose the objective of the present study, to evaluate the inter-observer reproducibility of the mobile pediatric auto refractor in an infant Colombian population.

Methods

A quantitative longitudinal prospective study was conducted to evaluate the inter-observer reproducibility of the mobile pediatric auto refractor. This study was approved by the Santo Tomas University Ethical Committee and followed the tenets of the Declaration of Helsinki. The informed consent from the parents and / or guardians of the participating minors was obtained.
Studied Population

Children between 24 and 67 months of age from two educational institutions in the city of Bucaramanga (Colombia) were included. We excluded children with a history of congenital cataract, significant media opacities, retinopathy, strabismus, nystagmus and a pupil diameter less than four millimeters.

A sample size of 138 eyes was estimated, and the SAMPICC (Sample Size and Power Estimation for single ICC) command of the Stata software was used for the calculation, using as reference data the CCI of 0.81 (P1-Hypothetical Value) and 0.72 (PO -Value null) reported in the study by Peterseim, et al. The participants were selected between January and July of 2016 using the convenience sampling [Figure 1].

The Equipment

An auto refractor (PLUSOPTIX A 12C), whose optical principle is based on the emission of 820 nm of infrared light, which projects into the retina without affecting pupil diameter with visible light emissions was used in this study. Depending on refractive error the light forms a specific brightness pattern inside the pupil, to calculate the sphere, cylinder and axis component, such process are repeated in three meridians.

The auto refractor is indicated for children older than six months and non-cooperating patients. It handles spherical and cylindrical ranges between -7.0 / + 5.0 dpt in steps of 0.25 dpt, and the axis range is between 1 and 180 in steps of 1 degree.

To employ the equipment, it should be located one meter away and requires the pupillary size is between 4.0 and 8.0 mm.

Data obtained includes information on refractive status, pupillary size, pupillary distance and corneal reflexes. The average time to obtain the reading is 0.8 second and it is possible to evaluate the patient both monocular and binocular.

Data Collection

A structured interview was conducted with parents and/or responsible adults of the participants, to obtain information about: sex, age in months and ocular antecedents (defined in the exclusion criteria). Subsequently, the participants’ pupillary diameter was measured and the refractive status was evaluated using the auto refractor. Two refractive evaluations were done using the equipment, in which two previously trained examiners intervened, who took the data collection and recording independently. For the data analysis was randomly selected the information of one eye for each participant.

Statistical Analysis

The descriptive analysis of the collected variables was performed in the Stata 12.0 Software, frequencies were used for the nominal variables, mean and standard deviation for the

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Table 1. Studied population Characteristics. Bucaramanga, Colombia 2016

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total n:138 eyes</th>
<th>Male n: 68 eyes</th>
<th>Female n: 70 eyes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (months)a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 a 37 months (%)</td>
<td>27.54</td>
<td>29.41</td>
<td>25.71</td>
</tr>
<tr>
<td>38 a 47 months (%)</td>
<td>31.88</td>
<td>29.41</td>
<td>34.29</td>
</tr>
<tr>
<td>48 a 62 months (%)</td>
<td>30.43</td>
<td>35.29</td>
<td>25.71</td>
</tr>
<tr>
<td>63 a 67 months (%)</td>
<td>10.14</td>
<td>5.88</td>
<td>14.29</td>
</tr>
<tr>
<td>Sphere Sample 1 (dpt)b</td>
<td>0.85 (1)</td>
<td>0.99 (1)</td>
<td>0.71 (0.75)</td>
</tr>
<tr>
<td>Cylinder Sample 1 (dpt)</td>
<td>-0.81 (0.75)</td>
<td>-0.95 (0.75)</td>
<td>-0.66 (0.75)</td>
</tr>
<tr>
<td>Sphere Sample 2 (dpt)</td>
<td>0.87 (1)</td>
<td>0.97 (1)</td>
<td>0.77 (1)</td>
</tr>
<tr>
<td>Cylinder Sample 2 (dpt)</td>
<td>-0.77 (0.75)</td>
<td>-0.95 (0.75)</td>
<td>-0.60 (0.50)</td>
</tr>
<tr>
<td>Refractive Defect (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypermetropic astigmatism</td>
<td>67.39</td>
<td>66.17</td>
<td>68.57</td>
</tr>
<tr>
<td>Myopic Astigmatism</td>
<td>7.24</td>
<td>10.29</td>
<td>4.29</td>
</tr>
<tr>
<td>Mixed Astigmatism</td>
<td>18.12</td>
<td>20.59</td>
<td>15.71</td>
</tr>
<tr>
<td>Hyperopia</td>
<td>4.35</td>
<td>2.94</td>
<td>5.71</td>
</tr>
<tr>
<td>Myopic</td>
<td>0.72</td>
<td>0</td>
<td>1.43</td>
</tr>
<tr>
<td>Emmetropia</td>
<td>2.17</td>
<td>0</td>
<td>4.29</td>
</tr>
</tbody>
</table>

a. Median (interquartile range)
b. Dpt: Diopters
Table 2. Intraclass correlation coefficient

<table>
<thead>
<tr>
<th></th>
<th>Sphere</th>
<th>Cylinder</th>
<th>Axis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>0.83 (0.69 – 0.98)</td>
<td>0.90 (0.79 – 1.01)</td>
<td>0.99 (0.98 – 0.99)</td>
</tr>
<tr>
<td>Females</td>
<td>0.69 (0.43 – 0.95)</td>
<td>0.92 (0.81 – 1.03)</td>
<td>0.99 (0.98 – 0.99)</td>
</tr>
<tr>
<td>Males</td>
<td>0.87 (0.75 – 0.98)</td>
<td>0.89 (0.77 – 1.01)</td>
<td>0.99 (0.98 – 0.99)</td>
</tr>
<tr>
<td>24 to 37 months</td>
<td>0.66 (0.36 – 0.96)</td>
<td>0.87 (0.69 – 1.05)</td>
<td>0.62 (0.25 – 0.99)</td>
</tr>
<tr>
<td>38 to 47 months</td>
<td>0.91 (0.82 – 1.00)</td>
<td>0.93 (0.86 – 1.01)</td>
<td>0.99 (0.98 – 1.00)</td>
</tr>
<tr>
<td>48 to 62 months</td>
<td>0.88 (0.76 – 1.01)</td>
<td>0.92 (0.81 – 1.02)</td>
<td>0.92 (0.81 – 1.02)</td>
</tr>
<tr>
<td>63 to 67 months</td>
<td>0.75 (0.41 – 1.01)</td>
<td>0.74 (0.39 – 1.01)</td>
<td>0.74 (0.39 – 1.01)</td>
</tr>
</tbody>
</table>

a. Intraclass correlation coefficient (95% confidence range)

variables with normal or median distribution and interquartile range, in the case of not presenting this distribution.

The normality analysis was performed using the Shapiro Wilk test and the null hypothesis was rejected with an alpha error of 5%. To evaluate the reproducibility, the general intraclass correlation coefficient was calculated and stratified by sex and age, with the objective of determining the presence of changes or variations linked to these two variables.

**Results**

138 participants were included between 24 and 67 months of age, the median age was 42 months with an interquartile range of 20 months, 34.29% was place in the group between 38 and 47 months. 51% of the sample were females and the refractive defect that prevailed with 67.39% was hypermetropic astigmatism. When evaluating the normal distribution of the quantitative variables (age, sphere and cylinder) were proved with a value of P ≤ 0.00 which not presented a normal distribution [Table 1].

The general intraclass correlation coefficient for sphere, cylinder and axis, evidenced a degree of almost perfect concurrence; a fact that is sustained when doing stratified analysis by sex and age variables, except in the case of the CCI of the sphere in women (0.69), sphere (0.66) and axis (0.62) in the 24 to 37 months group, and sphere (0.75), cylinder (0.74) and axis (0.74) in the 63 to 67 months group. These values evidenced a substantial degree of agreement, according to the scale proposed by Landisy Koch12 [Table 2], so an alternative to retinoscopy to measure refractive error, is the use of auto refractors, as a type of diagnostic test that can be used with the purpose of screening ametropias as well as monitoring refractive defects.

**Discussion**

Understanding amblyopia as a decreased of visual acuity caused by vision deprivation or abnormal binocular interaction11, is clinically manifested with poor visual acuity, sensibility alteration to contrast and visual field limitation; characteristics that in some cases generate processing deficit in both spatial and temporal information6. Generally, treatment begins with the prescription of the necessary optical correction to compensate the present ametropias, additionally, as it usually occurs, conventional occlusion or penalization is employed and filters the adaptation9,10. When the treatment is not performed in a timely manner, the described clinical manifestations become permanent characteristics that affect the quality of life, therefore, it is appropriate to make optometry assessments in children populations in a timely manner and make efforts to define refractive state.

The use of automatic refractometers (auto refractors) is an alternative to evaluate refractive state. These equipment are classified as a type of diagnostic test that can be used for the purpose of screening ametropias and confirmation and monitoring refractive defects. As in every test, another diagnostic exam is necessary to make a reliable evaluation of the results. One of the options is to study the reproducibility or repeatability associated to the use of the auto refractor, because this will show the amount of error that is associated with the measurement of the refractive defect. The amount of error will be associated with the intra-observer variability of the event or pathology due to physiological changes occurred during the time of evaluation, or the inter-observer variability due to the technique used and the characteristics of the equipment11.

The statistical measurement recommended to evaluate the reproducibility is the Intraclass Correlation coefficient (ICC)12. In the case of this study the ICC of the sphere, cylinder and axle, were near to 1.0, which means that exist a very good agreement in the comparison of both refractive measurements obtained with the auto refractor. In addition, the small coefficient intervals evidence the suitable sample size to support the results.

Furthermore, the analysis of ICC revealed systematically lower degree of agreement for the sphere both in the calculation in general and stratified by age and sex, which shows less stability of the date obtained by making repeated measurements. This may be associated with the partial relaxation of the accommodation system that appears when using the equipment to one meter of distance12. In fact, the poor accommodation control also represents a difficulty when performing conventional retinoscopy in the pediatric population.
Analogously, authors like Payerols et al\textsuperscript{14} recognizes when evaluating the accuracy of the PlusOptix A09 that hyperopia is underestimated at 0.73 Dpt, just like the spherical equivalent. A conclusion which coincides with that reported by Fogel-Levin et al\textsuperscript{16}, when evaluating the accuracy of the PlusOptix A12 in 402 eyes of children with an average age of 7.63 years. An alternative to enhance the reliability of the data would be to perform at least three measurements of the refractive defect under the same conditions and calculate the average to give the final formula\textsuperscript{16}.

On the other hand, it is recognized as a strength of the present study that, having performed the evaluation of the refractive error with the auto refractor in a monocular way, so, according to Mae Millicent W et al\textsuperscript{19} when conducting the measurement, the equipment reflects an infrared light ray simultaneously in both eyes, a factor which could evidence latent deviation and affect the accuracy of the measurement when taking binocularly measurements. Although the an auto refractor is an easy to use device, in order to perform the study, the examiners (optometry students) received previous training based on the protocol of use of the equipment. Also, during the clinical evaluation of the participants the lighting conditions and distracting factors were controlled, which could affect the quality of the data. Some weaknesses to be mentioned are the non-use of cycloplexes for the refractive evaluation, because according to Harvey et al\textsuperscript{16} when the auto refractor is used under conditions of cycloplegia the obtained data is the “gold standard” of the refractive state, but it was decided not to use cycloplexes, given that these alkaloid drugs have a small degree of toxicity that generates contraindications and adverse effects\textsuperscript{17}.

In conclusion, the mobile pediatric auto refractor evidenced a degree of concurrence almost perfect in the data of the refractive state obtained without cycloplegia in children 24 to 67 months old. Which allows to endorse it as reliable equipment for the purpose of screening and/or monitoring of refractive status in children. Although it is suggested to classify the refractive error as the average of three consecutive measurements and correlate the result with the clinical history of optometry to define the final formula.

**Conflict of Interest**
The authors report no conflicts of interest and have no proprietary interest in any of the materials mentioned in this article.

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**References**