Rasch-calibrated Intermittent Exotropia Symptom Questionnaire for Children

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SIGNIFICANCE: A rigorously designed and calibrated symptom questionnaire for childhood intermittent exotropia would be useful for clinical care and for research.

PURPOSE: The aim of this study was to Rasch-calibrate and evaluate the previously developed Child Intermittent Exotropia Symptom Questionnaire using data gathered as part of a randomized clinical trial.

METHODS: The questionnaire was administered to 386 children aged 3 to 10 years with intermittent exotropia who were enrolled in a randomized clinical trial comparing overminus with nonoverminus spectacles. Participants were followed at 6 and 12 months while on treatment and at 18 months off treatment. Factor analysis determined dimensionality, and Rasch analysis evaluated questionnaire performance. Logit values were converted to 0 (best) to 100 (worst). We evaluated differences in questionnaire scores between treatment groups and time points, and correlations with control scores.

RESULTS: The Child Intermittent Exotropia Symptom Questionnaire was unidimensional. Rasch analysis indicated that there was no notable local dependence and no significant differential item functioning for sex or age. There was suboptimal targeting (mean logit, −1.62), and person separation was somewhat poor (0.95). There were no significant differences in the Child Intermittent Exotropia Symptom score between overminus spectacles and nonoverminus spectacles at 6, 12, and 18 months. Combining data from both treatment groups, there was significant improvement from baseline at all follow-up visits (e.g., mean change from baseline to 12 months, −6.6 points; 95% confidence interval, −8.6 to −4.6). Child Intermittent Exotropia Symptom scores were not correlated with distance or near control scores at 12 months.

CONCLUSIONS: The seven-item Rasch-scored Child Intermittent Exotropia Symptom Questionnaire is limited by suboptimal performance. Future study is needed to determine whether it may be useful for clinical practice and for research.

Patient-reported outcome measures are used in the assessment of health conditions and response to treatment. For childhood health conditions, patient-reported outcome measures may be directed at the child or the parent (by proxy, to obtain the parent’s perception of the child’s experience; distinct from the child’s own perception of their experience). An initial 22-item symptom questionnaire had been previously developed for childhood intermittent exotropia, based on interviews of children with intermittent exotropia and their parents. The questionnaire had been reduced to seven items by selecting items that were associated with reduced health-related quality of life. The purpose of the present study was to Rasch-calibrate and evaluate the performance of the seven-item Child Intermittent Exotropia Symptom Questionnaire, using data gathered as part of a randomized clinical trial comparing overminus and nonoverminus spectacles in childhood intermittent exotropia.

METHODS

Child Intermittent Exotropia Symptom Questionnaire

In the present study, the seven-item questionnaire, with three response options (“never,” “sometimes,” and “all the time”; Fig. 1), was administered to young children (3 to <7 years old) by study personnel or self-administered by children 7 to 10 years old, with assistance from study personnel if needed.

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Data Collection

The randomized trial,\textsuperscript{5} from which the current data were derived, was funded by the National Eye Institute of the National Institutes of Health and conducted according to the tenets of the Declaration of Helsinki by the Pediatric Eye Disease Investigator Group at 56 clinical sites. The study protocol and Health Insurance Portability and Accountability Act–compliant informed consent forms were approved by the respective institutional review boards, a parent or guardian (subsequently referred to as parent) of each participant gave written consent, and children 7 years and older gave written assent. The study is listed on www.clinicaltrials.gov (NCT02807350, accessed September 28, 2021), and the full protocol is available at www.pedig.net (accessed September 28, 2021).

In the randomized trial, 386 children, aged 3 to <11 years (243 aged 3 to <7 years and 143 aged 7 to <11 years) with intermittent exotropia, were enrolled and randomly assigned 1:1 to either overminus (−2.50 D) or nonoverminus spectacles.\textsuperscript{5} Follow-up examinations occurred at 6 and 12 months (in study spectacles; on treatment) and at 18 months (after reducing overminus at 12 months and discontinuing at 15 months).

FIGURE 1. Child Intermittent Exotropia Symptom Questionnaire. The seven-item questionnaire was administered to children aged 3 to <7 years by study personnel or self-administered by children 7 to 10 years old, with assistance from study personnel if needed. Response options for each question were “never,” “sometimes,” and “all the time.”

Statistical Methods

Factor analysis was performed to determine the dimensionality of the Child Intermittent Exotropia Symptom Questionnaire by evaluating eigenvalues (eigenvalue >1 indicating multiple factors) and factor loadings. The factor analysis was stratified by follow-up visit to allow for a potential time effect.

Rasch analysis was performed using the Andrich Rating Scale Model to evaluate questionnaire performance and obtain logit values that were then converted to a 0-point (no symptoms) to 100-point (worst symptoms) scale. Rasch analysis included confirmation of unidimensionality by principal component analysis of residuals (desired eigenvalue, <2), response ordering, local item dependence (desired value, <0.6),\textsuperscript{6} differential item functioning by age (3 to <7 vs. 7 to <11 years) and sex (male vs. female) (desired contrast, <1 logit), item misfit (desired range of mean square, 0.7 to 1.3), targeting of the questionnaire to the sample (desired range, −1 to 1 logit), and person separation index (desired value, >2) as described in previous studies.\textsuperscript{4,7–9} Data were combined from the enrollment and follow-up visits for these Rasch analyses.
We evaluated whether there were treatment group differences (between overminus and nonoverminus) in Child Intermittent Exotropia Questionnaire scores, at 6, 12, and 18 months, using analysis of covariance adjusted for the baseline Child Intermittent Exotropia Questionnaire score, and evaluated changes from baseline using the paired t test (both treatment groups were combined for this analysis because no difference was found between treatment groups). The effect sizes of the changes were calculated by dividing the mean change from baseline at each time point by the standard deviation of the change. For ease in interpretation, summary statistics for group differences and changes, such as means, medians, mean changes from baseline, and 95% confidence intervals (CIs), were calculated for the 0- to 100-point scores. The P values for the treatment group differences at 6, 12, and 18 months were calculated for the logit scores and adjusted to control the false discovery rate at 5%.10

Spearman rank correlation coefficients ($r_s$) and 95% CIs were calculated at each visit between the Child Intermittent Exotropia Symptom Questionnaire logit score and the exotropia control score (0- to 5-point scale, where 0 is pure phoria and 5 is constant tropia)11 rated separately for distance and near. The exotropia control score was the mean of three assessments obtained over the course of an office visit.5,12 Scatterplots were also created to display those relationships.

No imputation was performed for missing data. Rasch analysis was performed using Winsteps version 4.2.0 (Winsteps Software Technologies, Seattle, WA); all the other analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC).

RESULTS

Questionnaire Performance

The Child Intermittent Exotropia Symptom Questionnaire was found to be unidimensional by factor analysis (at each of the study time points, 6, 12, and 18 months). Unidimensionality was reconfirmed by principal component analysis (Appendix Table A1, available at http://links.lww.com/OPX/A566).

By Rasch analysis, response ordering was appropriate for the three-response Child Intermittent Exotropia Symptom Questionnaire (Fig. 2). There was no notable local dependence (Appendix Table A2, available at http://links.lww.com/OPX/A566) and no significant differential item functioning for sex or age. The level of misfit was acceptable (Appendix Table A3, available at http://links.lww.com/OPX/A566). There was suboptimal targeting (mean, $-1.62$ logits; Fig. 3), and person separation was somewhat poor (0.95).

Difference in Symptom Score between Overminus and Nonoverminus Spectacle Treatment

Comparing children in overminus spectacles with those in nonoverminus spectacles, we found no significant differences in Child Intermittent Exotropia Symptom Questionnaire scores at 6 or 12 months (on treatment) or at 18 months (after treatment had been weaned) (Table 1). Because there were no treatment group differences at each time point, the data from both treatment groups were combined for all subsequent analyses.

Change in Symptom Scores from Baseline

In a combined cohort with both treatment groups, Child Intermittent Exotropia Symptom scores all showed significant improvement from baseline to 6, 12, and 18 months (Table 2).

Relationship of Child Intermittent Exotropia Symptom Score to Exotropia Control Scores

Child Intermittent Exotropia Symptom scores were not correlated with distance or near control scores at 6 months ($r_s = -0.01$ [95% CI, $-0.12$ to $+0.09$]) and $r_s = 0.002$ [95% CI, $-0.10$ to $+0.10$].
DISCUSSION

We have developed a seven-item Rasch-calibrated questionnaire for the assessment of child self-reported intermittent exotropia symptoms (Child Intermittent Exotropia Symptom Questionnaire). The final questionnaire had acceptable psychometric performance and was able to detect changes in child intermittent exotropia symptoms over time, but it did not detect a difference between overminus and nonoverminus spectacle treatment for intermittent exotropia.

We are unaware of other questionnaires designed to evaluate the presence and severity of symptoms in intermittent exotropia. Previous child questionnaires for intermittent exotropia have been designed to evaluate health-related quality of life associated with intermittent exotropia, whereas the Child Intermittent Exotropia Symptom Questionnaire specifically evaluates symptoms. Patient-reported outcome measures, such as the Child Intermittent Exotropia Symptom Questionnaire, provide a standardized means of detecting symptoms and scoring their frequency. In addition, the Child Intermittent Exotropia Symptom Questionnaire can be easily incorporated into clinical research (questionnaire and Rasch scoring look-up tables are freely available at www.pedig.net).

A strength of the Child Intermittent Exotropia Symptom Questionnaire is that the items were derived from interviews with children with intermittent exotropia and their parents. Deriving questionnaire items directly from individuals with the condition of interest increases the likelihood of evaluating concerns that are important to that specific population. In the present study, factor analysis and Rasch analysis confirmed the unidimensionality of the Child Intermittent Exotropia Symptom Questionnaire and provided Rasch-calibrated scoring. We had used stepwise multiple variable regression analysis to select items that were associated with reduced health-related quality of life in any of the Intermittent Exotropia Symptom Questionnaire — Holmes et al.

![FIGURE 3. Targeting of the Child IXT Symptom Questionnaire. Targeting was suboptimal for the Child IXT Symptom Questionnaire, noting the position of the mean (M) of respondents on the left of the figure and questions on the right of the figure (mean difference, −1.62 logits).](image)

TABLE 1. Child IXT Symptom Questionnaire scores by treatment group

<table>
<thead>
<tr>
<th></th>
<th>Baseline Visit</th>
<th>6-mo Visit</th>
<th>12-mo Visit</th>
<th>18-mo Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overminus</td>
<td>Nonoverminus</td>
<td>Overminus</td>
<td>Nonoverminus</td>
</tr>
<tr>
<td>Child IXT symptoms score</td>
<td>n = 181</td>
<td>n = 183</td>
<td>n = 182</td>
<td>n = 167</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>34.5 (17.2)</td>
<td>35.3 (17.4)</td>
<td>28.8 (16.9)</td>
<td>31.1 (16.6)</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>37.4 (25.7–46.1)</td>
<td>37.4 (25.7–46.1)</td>
<td>32.2 (15.7–37.4)</td>
<td>32.2 (15.7–37.4)</td>
</tr>
<tr>
<td>Range</td>
<td>0–99.9</td>
<td>0–99.9</td>
<td>0–68.1</td>
<td>0–68.1</td>
</tr>
<tr>
<td>Difference in means (95% CI)*</td>
<td>n/a</td>
<td>n/a</td>
<td>−3.05 (−6.18 to 0.09)</td>
<td>0.24 (−2.93 to 3.42)</td>
</tr>
</tbody>
</table>

*Statistical comparison of scores was not done at baseline. CI = confidence interval; IQR = interquartile range; IXT = intermittent exotropia; SD = standard deviation.

<table>
<thead>
<tr>
<th>Change from baseline</th>
<th>Baseline Visit</th>
<th>6-mo Visit</th>
<th>12-mo Visit</th>
<th>18-mo Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overminus</td>
<td>Nonoverminus</td>
<td>Overminus</td>
<td>Nonoverminus</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>n/a</td>
<td>n/a</td>
<td>−6.5 (16.7)</td>
<td>−4.0 (18.9)</td>
</tr>
</tbody>
</table>

*Treatment group differences (mean and 95% CI) in Rasch 0- to 100-point scores were estimated at 6, 12, and 18 months using an analysis of covariance model, adjusted for the baseline value of the respective score. P-values were calculated by running the same models on the Logit scores. P-values were adjusted to control the false discovery rate at a probability level of 5%.
Exotropia Questionnaire domains. An alternative method of development would have been to administer the complete 22-item questionnaire to a large cohort of children with intermittent exotropia and perform the previously described steps of binning, winnowing, and de novo Rasch analysis, but this was not the method used for this particular questionnaire.

We did not find a significant difference in Child Intermittent Exotropia Symptom Questionnaire scores between the overminus and nonoverminus groups at any of the follow-up visits. This finding is likely a reflection of the modest improvement of intermittent exotropia control from the overminus lenses at 6 and 12 months (on-treatment) and lack of treatment effect at 18 months (off-treatment). The mean difference in control scores was 0.8 points at 12 months (95% CI, +0.5 to +1.0 points, on the 0- to 100-point scale) and 0.2 points (95% CI, −0.04 to +0.5) at 18 months. The Child Intermittent Exotropia Symptom Questionnaire may not have been sensitive enough to detect a treatment group difference at 12 months, when the mean control scores were significantly different between groups. It is also possible that overminus treatment may have been insufficient to relieve symptoms.

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An alternative explanation for the failure to find a significant difference in intermittent exotropia symptoms between overminus and nonoverminus treatment for intermittent exotropia is that children

### Table 2. Child IXT Symptom Questionnaire scores over time with treatment groups combined

<table>
<thead>
<tr>
<th></th>
<th>Baseline Visit</th>
<th>6-mo Visit</th>
<th>12-mo Visit</th>
<th>18-mo Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Child IXT symptom score</strong></td>
<td><strong>n = 364</strong></td>
<td><strong>n = 349</strong></td>
<td><strong>n = 345</strong></td>
<td><strong>n = 327</strong></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>34.9 (17.2)</td>
<td>29.9 (16.8)</td>
<td>28.3 (15.7)</td>
<td>28.7 (15.8)</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>37.4 (25.7–46.1)</td>
<td>32.2 (15.7–42.0)</td>
<td>32.2 (15.7–37.4)</td>
<td>32.2 (15.7–37.4)</td>
</tr>
<tr>
<td>Range</td>
<td>0–99.9</td>
<td>0–99.9</td>
<td>0–74.5</td>
<td>0–74.5</td>
</tr>
<tr>
<td><strong>Change from baseline</strong></td>
<td><strong>n = 335</strong></td>
<td><strong>n = 332</strong></td>
<td><strong>n = 310</strong></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)*</td>
<td>n/a</td>
<td>−5.3 (17.8)</td>
<td>−6.6 (18.9)</td>
<td>−5.7 (20.8)</td>
</tr>
<tr>
<td>95% CI for mean change*</td>
<td>n/a</td>
<td>(−7.2 to −3.4)</td>
<td>(−8.6 to −4.6)</td>
<td>(−8.1 to −3.4)</td>
</tr>
<tr>
<td>Effect size</td>
<td>n/a</td>
<td>0.30</td>
<td>0.35</td>
<td>0.28</td>
</tr>
</tbody>
</table>

*The paired t test was used to estimate mean changes from baseline to follow-up visits and the 95% CIs for the 0- to 100-point scores. P values were not reported. †This is the absolute value of the effect size for the overall improvement from baseline. First, the 0- to 100-point score at baseline was subtracted from the 0- to 100-point score at each follow-up visit for each participant. Then, this change from baseline was averaged across all participants; this average was divided by the SD of the changes to calculate the effect size. CI = confidence interval; IQR = interquartile range; IXT = intermittent exotropia; SD = standard deviation.

### Figure 4. Relationship of Child IXT Symptom Questionnaire score with distance control at 12 months. Scatterplot of distance control at 12 months versus Child IXT Symptom Questionnaire score at 12 months. The Spearman correlation coefficient, calculated on the logit scale, was −0.04 (95% confidence interval, −0.15 to 0.07), indicating no correlation; results were similar at all other visits. IXT = intermittent exotropia.
may not experience more frequent symptoms when there is worse control of intermittent exotropia. Indeed, we found no correlation between the Child Intermittent Exotropia Symptom Questionnaire score and the distance or near control score (Figs. 4, 5). It is also possible that some symptoms such as “do your eyes hurt” might be associated with good intermittent exotropia control, if the child is exerting a great deal of fusional vergence effort or accommodative effort. Other symptoms, such as “do you find it hard to stare at things,” might be associated with poor intermittent exotropia control if the child is unable to maintain binocular fusion and if binocular staring was considered binocular. When such items are combined, the net symptom questionnaire score might not correlate with the control score. It is also possible that some children with intermittent exotropia have sensory adaptations (e.g., suppression or anomalous retinal correspondence) that mitigate subjective symptoms, whereas other children with intermittent exotropia do not have these adaptations. The relationship between sensory adaptations to strabismus and symptoms is worthy of further study.

An additional reason why we failed to find a difference in symptoms between children undergoing overminus versus nonoverminus treatment for intermittent exotropia is the possibility that children may have had a decrease in intermittent exotropia symptoms with overminus treatment, but the effect may have been masked by an increase in symptoms with the overminus treatment itself (such as strain and blur). These potentially counterbalancing effects might have resulted in no net effect. Nevertheless, in the original study, we found no marked differences between responses to spectacle-related questions between treatment groups.

We found improvement in the symptom scores from baseline to 6 months, from baseline to 12 months, and from baseline to 18 months in both treatment groups. These findings may reflect regression to the mean; although we did not specify a threshold questionnaire score for eligibility, we did specify an enrollment criterion related to a minimum severity of intermittent exotropia control (a mean distance control score of at least two, based on the mean of three assessments during a single examination). Although we did not find a relationship between the intermittent exotropia control score and the Child Intermittent Exotropia Symptom Questionnaire score, it is possible that children with worse symptoms at the time of enrollment were preferentially enrolled and thereby at risk of regression to the mean. Alternatively, improved symptom scores may reflect our previous finding that some clinical aspects of intermittent exotropia may show improvement with time (i.e., control, stereoacuity, and magnitude of deviation) over a 3-year period of observation.13 There is also a possibility of a placebo effect of glasses wear, because all participants received glasses and may have thought they were receiving overminus treatment.

There are several limitations to the present study in addition to those already described. Personnel administering the questionnaire were not masked to the participant’s treatment. The Rasch-calibrated Child Intermittent Exotropia Symptom Questionnaire did not have the desired targeting or person separation indices and so may have been insensitive to true differences between treatment groups, if they existed. Nevertheless, the problems of less than desired targeting and less than desired person separation are often found for questionnaires designed for children, for example, the PedEyeQ.9 Such suboptimal performance indices would render pediatric questionnaires less sensitive than questionnaires designed for adults. It is also possible that if we had more data using the original 22-item version of the questionnaire and if we had selected the best items using psychometric methods, rather than logistic regression, we might have developed a short

![FIGURE 5. Relationship of Child IXT Symptom Questionnaire score with near control at 12 months. Scatterplot of near control at 12 months versus Child IXT Symptom Questionnaire score at 12 months. The Spearman correlation coefficient, calculated on the logit scale, was 0.08 (95% confidence interval, −0.03 to 0.18), indicating no correlation; results were similar for other visits. IXT = intermittent exotropia.](http://journals.lww.com/optvissci)
questionnaire that may have had better targeting and measurement precision. Poorer than desired questionnaire performance was also likely when the items were not optimally separated on the person-item map (Fig. 3). It is possible that person separation might have been improved by a greater number of response categories, but children younger than 7 years typically are unable to successfully use more than three response categories.

In the present study, we have Rasch-calibrated a previously developed seven-item patient-reported outcome measure to evaluate child-reported symptoms in intermittent exotropia (the Child Intermittent Exotropia Symptom Questionnaire). The Child Intermittent Exotropia Symptom Questionnaire seems limited by suboptimal performance. Future study is needed to determine whether it may be useful for clinical practice and for research.

ARTICLE INFORMATION

Supplemental Digital Content: Appendix Table A1: Dimensionality analysis of the Child IXT Symptom Questionnaire showing undimensionality of instrument is available at http://links.lww.com/OPX/A566.

Appendix Table A2: Local dependence analysis of the Child IXT Symptom Questionnaire showing no marked local dependence is available at http://links.lww.com/OPX/A566.

Appendix Table A3: Infit and outfit errors of the Child IXT Symptom Questionnaire showing acceptable misfit is available at http://links.lww.com/OPX/A566.

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