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Further Validation of the Amblyopia Treatment Index Parental Questionnaire

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Abstract

Background—The Amblyopia Treatment Index (ATI) is a parental questionnaire that has been used to assess the impact of patching or atropine treatment on the child and family in several amblyopia treatment studies. The 18-item parental questionnaire was designed with versions for treatment with patching or atropine. We pooled data across studies to further evaluate the validity of the ATI, to further assess the presence or absence of factors (subscales) and to evaluate redundancy within the questionnaire.

Methods—A parent or guardian completed the ATI for 794 children who participated in one of four randomized clinical trials. Internal-consistency reliability was assessed using Cronbach's alpha and factor analysis was performed. Redundancy was assessed by re-calculating Cronbach's alpha with each item deleted.

Results—The ATI demonstrated high internal-consistency reliability with a Cronbach's alpha of 0.88 (95% confidence limits: 0.87, 0.89). Factor analysis revealed the same 3 minimally overlapping factors found in the original validation study, which were again labeled; "adverse effects," "treatment compliance" and "social stigma." Two of the 18 items did not load with any factor and could reasonably be omitted from future ATI administrations. Only one of the remaining 16 items could be deleted without decreasing the reliability of a subscale, indicating minimal redundancy within each subscale.

Conclusion—The ATI is a useful instrument for assessing the impact of patching or atropine treatment on the child and family.

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Introduction

The Pediatric Eye Disease Investigator Group (PEDIG) previously developed a parental questionnaire to quantify the impact of amblyopia treatment on the child and family.^{1, 2} This 18-item questionnaire is called the “Amblyopia Treatment Index”¹ (ATI), and was initially validated by administration to parents of the first 64 patients enrolled into an amblyopia treatment trial that compared part-time patching with daily atropine drops.^{1, 3} Using factor analysis, three factors (subscales) were identified in that initial study: “adverse effects,” “treatment compliance” and “social stigma,” but only 11 of the 18 items loaded on one of the 3 factors. In a subsequent analysis on the entire cohort in our first amblyopia treatment study,³ comparing part-time occlusion to atropine (364 patients for whom the questionnaire had been completed), we found 16 of the 18 items loaded with one of these subscales.²

The purpose of the present study was to analyze ATI questionnaire data from nearly 800 children enrolled in four randomized clinical trials to evaluate further the validity of the ATI, to assess the presence or absence of factors (subscales) and to evaluate redundancy within the questionnaire.

Methods

The ATI questionnaire was completed by a parent or guardian, who accompanied the child, after the initial 5 weeks of treatment, in one of four randomized treatment trials 1) part-time occlusion versus atropine in moderate amblyopia,³ 2) prescribed two hours/day patching versus prescribed six hours/day in moderate amblyopia,⁴ 3) prescribed six hours/day patching versus prescribed fulltime patching in severe amblyopia,⁵ and 4) prescribed daily atropine drops versus prescribed weekend atropine drops in moderate amblyopia.⁶ These studies were supported through a cooperative agreement with the National Eye Institute of the National Institutes of Health and were conducted by the Pediatric Eye Disease Investigator Group (PEDIG). The protocols and Health Insurance Portability and Accountability Act (HIPAA) compliant informed consent forms were approved by institutional review boards, and a parent or guardian (referred to subsequently as “parent”) of each study patient gave written informed consent. Study oversight was provided by an independent data and safety monitoring committee. The full protocols are available on the PEDIG website (www.pedig.net).

The major eligibility criteria were common to all 4 trials and included children age <7 years and ability to complete the study’s visual acuity testing protocol^{7, 8} (which created an effective lower age limit of about 3 years old), an inter-eye acuity difference ≥ 3 logMAR lines, and the presence of or a history of an amblyogenic factor meeting study-specified criteria for strabismus or anisometropia. Additional eligibility criteria, specific to each trial have been previously published.^{3–6}

As described previously, the ATI was completed by the parent who accompanied the child to the office at the time of the first follow-up visit, which was after five weeks of treatment.^{3–6} The original questionnaire^{1, 2} consisted of 20 Likert-type items (Table 1, available as e-supplement 1) with five response choices ranging from “strongly agree” to “strongly disagree,” with higher scores (i.e., “disagree”) indicating more (adverse) impact; a sixth choice of “not applicable” was offered for two of the questions. At the clinic visit, the parent was given brief verbal instructions and then completed the written questionnaire. The questionnaire was completed before results of visual acuity testing were known. The parent placed the questionnaire in a pre-addressed postage-paid envelope, sealed it and the envelope was mailed to the Study’s Central Coordinating Center. If the child was not accompanied to the visit by a parent who was involved in administering the treatment, a questionnaire was not completed.

Statistical Analysis

Results were pooled across the four treatment trials and across all treatment groups. Responses for patients missing two or fewer items were imputed based upon an average response across all completed questions for that patient. The decision to limit this to two or fewer items was arbitrary. Questionnaires of 5 patients missing more than two responses were excluded from the analysis (1 from the patching for moderate amblyopia study⁴ and 4 from the atropine for moderate amblyopia study⁶). A separate analysis was also performed restricted to questionnaire that has no missing items, and the results were similar. Questions 6b and 6c did not apply to all respondents and were not included in the factor analysis. Question 5 used in the patching versus atropine study³ for the patching treatment group (“I have trouble putting on my child’s patch and keeping it on”) was split into two questions for the patching regime studies^{4,5} “I have trouble putting on my child’s patch” and “I have trouble keeping my child’s patch on.” An analogous question was not applicable in the subsequent atropine study.⁶ For purposes of the present study, question 5 was analyzed as it was administered, a combined question in the patching versus atropine study³ and as the first part of that question in the patching regime studies.^{4,5} Question 19 in the patching regime studies,^{4,5} “I have trouble keeping my child’s patch on,” was omitted from analysis, because it had no counterpart in the atropine questionnaire used in studies that involved atropine.^{3,6}

Internal-consistency reliability was assessed by Cronbach’s standardized alpha which is performed on a single test administration, and defined as $\alpha = k\bar{r}/[(1+(k-1)\bar{r})]$, where k is the number of scale items and $\bar{r}$ is the average inter-item correlation. We consider a reliability between 0.7 and 0.9 as good, and a reliability of >0.9 as excellent.

As we have described previously,² validity was assessed by examining the factor structure of the questionnaire; namely how the individual items on the questionnaire correlate with underlying factors. Such factors could initially be labeled arbitrarily and then, by examining the specific items that load highly on each factor, could be relabeled as named subscales. Any factor with an eigenvalue (i.e., the amount of combined item variance accounted for by the factor) greater than 1 was retained for interpretation. We also examined the form of a scree plot (Figure, available as e-supplement 2). Rounded item loadings (i.e., an estimate of the correlation between the item and the underlying factor) ≥ 0.5 were considered to contribute to a given factor. Factor analysis was performed using a varimax orthogonal rotation in SAS ver 9.1. Subscales scores were calculated as the mean of the scores in that subscale, where 1 is assigned to strongly disagree and 5 to strongly agree for each question, thus the subscale scores range from a minimum of 1 to a maximum of 5.

Results

Questionnaires were completed for 794 children across the 4 treatment trials. Data from 364 of these patients enrolled in the trial comparing part-time occlusion versus atropine in moderate amblyopia,³ have been reported previously.^{1, 2} For the 794 children, the mother was the respondent for 634 (80%) of patients, the father for 123 (15%), and another individual for 37 (5%). Forty-eight percent of the respondents indicated that they were the individual responsible for the treatment all of the time and an additional 32% indicated that they were responsible for the treatment most of the time. Similar results (internal reliability and factor structure) were found restricting the analysis to these 80% of respondents who gave all or most of the care (data not shown).

Responses

There were few missing responses on the questionnaire items. Only 196 (1%) of 14292 possible item-responses were missing from questionnaires completed by 186 of the 809 respondents.

Seventeen of the 18 items demonstrated adequate variability by visual inspection frequency distributions for item-responses (Table 2, available as e-supplement 3). One item (#15: “I believe that treatment will improve my child’s vision”) was limited in the response range with 88% of the responses congregated in the ‘strongly agree’ or ‘agree’ category.

Internal Reliability

Cronbach’s alpha for the 18 questions was 0.88, which suggests good internal consistency reliability.

Factor Analysis

A three-factor solution was suggested by the finding that 3 factors had an eigenvalue greater than one (Figure, available as e-supplement 2).

Sixteen of the 18 items were correlated strongly (≥ 0.5) with one of these three underlying factors (Table 1) and these three factors could be designated as the same subscales identified in our previous studies^{1, 2} of smaller subsets of these patients 1) ‘adverse effects’ of treatment (8 items), 2) difficulties with ‘compliance’ (5 items), and 3) ‘social stigma’ of treatment (3 items). The internal-consistency reliability of the 8-item ‘adverse effects’ subscale was 0.85, the 5-item ‘compliance’ subscale reliability was 0.85 and the 3-item ‘social stigma’ subscale reliability was 0.71.

There were 2 questions that did not load strongly on any of the 3 factors, “I believe that wearing the patch will improve my child’s vision/using the drops will improve my child’s vision” and “I sometimes forget to put the patch on my child/put the drops in my child’s eyes.” The question on improving vision was also the one question that did not have a varied distribution of responses.

Redundancy

Cronbach’s alpha was recalculated for each of the 3 factors, while removing each of the questions loading on that subscale. None of the individual questions could be removed without decreasing the Cronbach’s alpha for the subscale, with the exception of one question “I worry that my child does not wear the patch enough/I worry that my child does not get the drops often enough” where the Cronbach’s alpha for the “compliance” subscale was unchanged when the question was removed.

Discussion

Using results from completed questionnaires across 4 randomized clinical trials with nearly 800 participants, we have confirmed that the Amblyopia Treatment Index parental questionnaire has strong internal-consistency reliability and a clear factor structure, with 3 independent subscales of “adverse effects,” “treatment compliance,” and “social stigma.”

The Amblyopia Treatment Index has already proven useful in several randomized clinical trials. In a study of part-time patching versus daily atropine drops in moderate amblyopia,³ the ATI results indicated atropine drops had better acceptance by the parent and the child, with lower scores on all 3 subscales of “adverse effects,” “treatment compliance,” and “social stigma.” In a study of 2 hours/day prescribed patching to 6 hours/day prescribed patching,⁴ the ATI scores indicated a higher social stigma score in the 6-hour group than the 2-hour group, despite similar scores on adverse effects and treatment compliance subscales. In a study of prescribed fulltime patching versus prescribed 6 hours/day,⁵ ATI results showed no significant difference between parental perception of the two treatment regimens. In a study of daily versus weekend atropine,⁶ the treatment compliance subscale scores were worse in the weekend

group, suggesting that the children became accustomed to a daily regimen, and complained more when the drop was only given at the weekend. These ATI results have been particularly useful when assessing the balance between treatment effectiveness and impact of the treatment on the child and family.

In our analysis of data from 4 clinical trials, we found minimal redundancy in the questionnaire. Only two questions (#15 and #17, Table 2, available as e-supplement 3) did not load on either of the three subscales and one of these questions also had a poor distribution of responses, heavily weighted toward strongly agree and agree. These 2 questions “I believe that wearing the patch will improve my child’s vision/using the drops will improve my child’s vision” and “I sometimes forget to put the patch on my child/put the drops in my child’s eyes,” could be removed from future administration of the questionnaire.

For more recent patching studies, original question #5 “I have trouble putting on my child’s patch and keeping it on (putting the drops in my child’s eye)” was split into 2 questions “I have trouble putting on my child’s patch” (new question #5) and “I have trouble keeping the patch on my child” (new question #19). No analogous additional question was used in the subsequent atropine study,⁶ because it was not applicable. In the current analysis, question 5 continues to load on the compliance subscale, and so we suggest that question 19 of the patching questionnaire also be included as part of the compliance subscale.

In contrast to the ATI, most other available questionnaire instruments for assessment of quality of life in conditions affecting vision are designed for adults. Existing questionnaires available for children, such as the PedsQL,⁹ have more general questions that do not address disease- or treatment-specific issues. The Amblyopia Treatment Index was designed by PEDIG to assess the impact of amblyopia treatment, specifically the effect of patching of the sound eye and the effect of atropine drops administered to the sound eye. The questionnaire can be easily modified, by slight wording changes of each of the questions, to make it applicable to other modalities of amblyopia treatment. We are planning such modifications for an upcoming PEDIG randomized clinical trial, investigating whether blurring Bangerter filters placed on spectacles over the sound eye are equivalent to part-time patching for the treatment of amblyopia.

Other questionnaire instruments for assessment of the impact of treatment of amblyopia on quality of life are few. The Amblyopia and Strabismus Questionnaire reported by van de Graaf et al¹⁰ addresses the effect of amblyopia and strabismus on many aspects of quality of life, but several of the questions are only relevant to adults (such as driving), or culturally specific (such as “difficulty finding my way in a train station”). None of the questions in the Amblyopia and Strabismus Questionnaire address the effect of treatment, whereas the Amblyopia Treatment Index was specifically designed to address the parental perceptions of treatment. The Amblyopia and Strabismus Questionnaire¹⁰ is useful for assessing overall health related quality of life effects of amblyopia and strabismus on adults and is available at “The Amblyopia and Strabismus Questionnaire” available at <http://www.retinafoundation.org/pdf/questionnaire/asqe.pdf>, accessed March 22, 2008.

Another recently reported instrument is the Children’s Visual Function Questionnaire,^{11, 12} which has a “treatment difficulty” subscale and a “family impact” subscale. Birch and colleagues¹² have reported that the treatment difficulty subscale is sensitive to changes in treatment regime, such as starting patching therapy significantly increased the scores on that subscale. We are unaware of any comparisons of responses between the Amblyopia Treatment Index and the Children’s Visual Function Questionnaire. The Amblyopia Treatment Index has the advantage of only having 18 or 19 questions (16 or 17 once the 2 redundant questions are omitted) and is more specific than the broader Children’s Visual Function Questionnaire which

has up to 40 questions, depending on version. The Children's Visual Function Questionnaire is available at <http://www.retinafoundation.org/pdf/questionnaire/cvfq.pdf>, accessed March 22, 2008.

The Amblyopia Treatment Index parental questionnaire is a reliable instrument for assessing the impact of amblyopia treatment on the child and the family, with three robust subscales of "adverse effects," "treatment compliance" and "social stigma." The current version of the Amblyopia Treatment Index questionnaire is available free of charge at http://public.pedig.jaeb.org/PEDIG_Forms.htm.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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See acknowledgement listings in e-supplement 4.

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Table 1

Correlation between items and factors from factor analysis

Factor loadings for retained items *		Adverse effects of treatment	Treatment compliance	Social stigma
Items composing adverse effects of treatment subscale				
2	Worry that child on treatment may miss out on fun activities	0.5	0.1	0.3
3	Treatment affects child's learning	0.6	0.1	0.1
4	Treatment makes it hard for child to play outside	0.5	0.1	0.4
7	Difficult for my child to draw, color, or write	0.7	0.2	0.2
8	Worry that child on treatment will become injured	0.5	0.1	0.4
9	Child can see well on treatment [†]	0.5	0.2	0.1
13	Child clumsy on treatment	0.5	0.2	0.4
16	Treatment makes it difficult for child to play	0.6	0.3	0.4
Items composing treatment compliance subscale				
1	Child does not seem to mind treatment [†]	0.2	0.8	0.1
5	Trouble applying treatment to child	0.2	0.7	0.1
6a	Treatment is a source of tension or conflict with child	0.2	0.7	0.3
10	Child complains when it is time for treatment	0.1	0.7	0.3
12	Worry child not getting enough treatment	0.2	0.5	0.3
Items composing social stigma subscale				
11	Treatment makes my child's eye or eyelids red or irritated	0.1	0.2	0.5
14	Other children stare at child	0.0	0.1	0.7
18	Worry that child feels different	0.2	0.2	0.7

* Estimated factor loadings greater than .5 are in bold, items 15 & 17 did not load strongly (correlation <0.5) on any single factor and are not listed. Questions 6b and 6c did not apply to all respondents and were not included in factor analysis.

[†] Data for question has been reversed, so higher score implies negative connotation.