Impact of Patching and Atropine Treatment on the Child and Family in the Amblyopia Treatment Study

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Objective: To assess the psychosocial impact on the child and family of patching and atropine as treatments for moderate amblyopia in children younger than 7 years.

Methods: In a randomized, controlled clinical trial, 419 children younger than 7 years with amblyopic eye visual acuity in the range of 20/40 to 20/100 were assigned to receive treatment with either patching or atropine at 47 clinical sites. After 5 weeks of treatment, a parental quality-of-life questionnaire was completed for 364 (87%) of the 419 patients.

Main Outcome Measure: Overall and subscale scores on the Amblyopia Treatment Index.

Results: High internal validity and reliability were demonstrated for the Amblyopia Treatment Index questionnaire. The overall Amblyopia Treatment Index scores and the 3 subscale scores were consistently higher (worse) in the patching group compared with the atropine-treated group (overall mean, 2.52 vs 2.02, P<.001; adverse effects of treatment: mean, 2.35 vs 2.11, P= .002; difficulty with compliance: mean, 2.46 vs 1.99, P<.001; and social stigma: mean, 3.09 vs 1.84, P<.001, respectively).

Conclusion: Although the Amblyopia Treatment Index questionnaire results indicated that both atropine and patching treatments were well tolerated by the child and family, atropine received more favorable scores overall and on all 3 questionnaire subscales.

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THE AMBLYOPIA Treatment Study 1 was a randomized, controlled clinical trial designed to compare atropine sulfate 1% eyedrops and eye patching (referred to subsequently as "patching") as treatments for moderate amblyopia (visual acuity 20/40 to 20/100) in children younger than 7 years.[1] The results of the study disclosed that substantial improvement in the visual acuity of the amblyopic eye occurred with both the patching and the atropine treatment regimens. Improvement was more rapid in the patching group, but by 6 months the difference in visual acuity between groups was small (about one third of a line) and clinically inconsequential.[1]

A secondary outcome measure of the clinical trial was the results of a questionnaire, the Amblyopia Treatment Index (ATI), that was developed to assess the acceptability of treatment and its impact on the child and family.[2] As such, the questionnaire might be considered a method of assessing some quality-of-life domains during treatment for amblyopia. The ATI explores several aspects of the impact of treatment for amblyopia in children, including parental stress, concern about how others may perceive the child, strained family relationships, and difficulty with treatment adherence.

In a prior publication,1 we provided a brief summary of the ATI questionnaire results, which showed that atropine treatment was significantly better accepted than patching, although both treatments were reported to be generally well tolerated by the patient and parent(s). Herein, we provide further details of these results, assess the relationship of patient characteristics to ATI questionnaire responses, and report on the internal validity and reliability of the questionnaire.

METHODS

STUDY PROTOCOL

The study protocol has been detailed in prior publications[1,3] and is summarized below. The study was conducted by the Pediatric Eye Disease Investigator Group at 47 clinical sites and

Table 1. Amblyopia Treatment Index*

Patching Questionnaire	Atropine Questionnaire
1. My child does not seem to mind wearing the patch once it is on.	1. My child does not seem to mind using the drops.
2. I worry that by wearing the patch, my child may miss out on fun activities (such as games and parties).	2. I worry that by using the drops, my child may miss out on fun activities (such as games and parties).
3. Wearing the patch affects my child's learning.	3. Using the drops affect my child's learning.
4. Wearing the patch makes it hard for my child to play outside, such as running, jumping, or riding a bike or tricycle.	4. Using the drops makes it hard for my child to play outside, such as running, jumping, or riding a bike or tricycle.
5. I have trouble putting on my child's patch and keeping it on.	5. I have trouble putting the drops in my child's eye.
6. Wearing the patch is a source of tension or conflict in my relationship: a. with my child. b. with another family member. c. with my child's babysitter or teacher.	6. Using the drops is a source of tension or conflict in my relationship: a. with my child. b. with another family member. c. with my child's babysitter or teacher.
7. Wearing the patch makes it difficult for my child to draw, color, or write.	7. Using the drops makes it difficult for my child to draw, color, or write.
8. I worry that my child will become injured when wearing the patch.	8. I worry that my child will become injured when using the drops.
9. My child can see well when wearing the patch.	9. My child can see well when using the drops
10. My child complains when it is time to wear the patch.	10. My child complains when it is time to put in the drops.
11. Wearing the patch makes my child's eye or eyelids red or irritated.	11. Using the drops makes my child's eye or eyelids red or irritated.
12. I worry that my child does not wear the patch enough.	12. I worry that my child does not get the drops often enough.
13. My child is more clumsy and uncoordinated than usual when wearing the patch.	13. My child is more clumsy and uncoordinated than usual when using the drops.
14. I notice that other children stare at my child when the patch is on.	14. I notice that other children stare at my child when the drops are in.
15. I believe that wearing the patch will improve my child's vision.	15. I believe that using the drops will improve my child's vision.
16. Wearing the patch makes it difficult for my child to play with blocks or toys.	16. Using the drops makes it difficult to my child to play with blocks or toys.
17. I sometimes forget to put the patch on my child.	17. I sometimes forget to put the drops in my child's eye.
18. I worry that wearing the patch will make my child feel different from other children.	18. I worry that using the drops will make my child feel different from other children.

*On the questionnaire, each item has 5 response choices: strongly agree, agree, neither agree nor disagree, disagree, strongly disagree. In addition to the 5 responses, questions 6b and 6c also had the response choice of "not applicable."

supported through cooperative agreements with the National Eye Institute of the National Institutes of Health, Bethesda, Md. The protocol and informed consent forms were approved by the participating institutional review boards. The parent or guardian (referred to subsequently as "parent") of each study patient gave written informed consent. The major eligibility criteria for the trial included the following: being younger than 7 years and having the ability to complete the study's visual acuity testing protocol[4,5] (which created an effective lower age limit of about 3 years old), having a visual acuity in the amblyopic eye between 20/40 and 20/100 (inclusive), having an intereye visual acuity difference of 3 or more logMAR lines, having or having a history of an amblyogenic factor meeting study-specified criteria for strabismus or anisometropia, and undergoing no more than 2 months of amblyopia treatment in the prior 2 years. Each patient was randomly assigned to treatment with either patching (ranging from 6 hours per day to full time at investigator discretion) or 1 drop per day of atropine sulfate 1%. The main outcome measure was visual acuity in the amblyopic eye at 6 months, measured using the Amblyopia Treatment Study visual acuity testing protocol.4-5 The ATI scores were a secondary outcome.

The ATI questionnaire was completed by the parent who accompanied the child to the office at the time of the first follow-up visit, that is, after 5 weeks of treatment (visit time window, 3-7 weeks). The questionnaire consists of20 Likert-type items (Table 1) with 5 response choices ranging from "strongly agree" to "strongly disagree," with higher scores (ie, "disagree") indicating more (adverse) impact; a sixth choice of "not applicable" was offered for 2 of the questions. At the clinic visit, the parent was given brief verbal instructions and then asked to complete the ATI questionnaire. The questionnaire was completed before the child's ophthalmological examination was performed and specifically before the results of visual acuity testing were known. The parent placed the questionnaire in a preaddressed postage-paid envelope and sealed it; 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 for that child.

STATISTICAL ANALYSIS

As an initial analysis, the internal validity and reliability of the ATI questionnaire were assessed. Broadly defined, *validity* is the property of measuring what one intends to measure. Validity may be measured externally by correlating questionnaire results to results on preexisting questionnaires that should be either positively or negatively associated with the novel questionnaire. Alternatively, internal validity may be measured by examining the factor structure of the novel questionnaire, namely, how the individual items on the questionnaire correlate with underlying factors.[6,7] Such factors could initially be labeled "A," "B," "C," etc, and then, by examining the specific items that are highly associated with each factor, they could be relabeled as "subscales." In the present case, concepts related to the treatments, for example, compliance or adherence, were used to name the subscales. Defined in this way, high internal validity is the result of a simple factor structure with high correlations (eg, 0.5) between individual items and the underlying factors. Internal validity is of particular importance when preexisting questionnaires are scarce.

Reliability may be viewed as the repeatability of test items and is often measured either by the correlation of test-retest administrations or by the Cronbach a on a single test administration.8 A desirably strong reliability (eg, 0.8) suggests that

Table 2. Amblyopia Treatment Index: Questionnaire Responses by Treatment Group*

Item (Abbreviated)	Strongly Agree (5)	Agree (4)	Neither Agree nor Disagree (3)	Disagree (2)	Strongly Disagree (1)	Mean Response† (1-5)
Patching Group (n = 186)						
1. Child does not seem to mind treatment‡	7	13	9	47	24	2.31
2. Worry child may miss out on fun activities	2	11	13	51	23	2.19
3. Treatment affects child's learning	2	6	15	50	28	2.04
4. Treatment makes it hard for child to play	1	24	15	44	17	2.49
5. Trouble applying treatment to child	6	10	10	46	28	2.21
6. Treatment is a source of tension for me						
a. with child	6	12	7	43	32	2.16
b. with another family member§	2	3	6	45	38	1.80
c. with my child's babysitter or teacher§	1	2	4	44	34	1.74
7. Difficult for child to draw, color, or write	2	11	13	54	20	2.22
8. Worry child will be injured on treatment	0.5	18	12	49	20	2.31
9. My child can see well while on treatment‡	3	20	27	41	8	2.70
10. Child complains when it is time for treatment	18	30	14	28	9	3.20
11. Child's eye or eyelids become red or irritated	7	27	16	41	8	2.84
12. Worry that child not getting enough treatment	6	14	13	46	20	2.40
13. Child clumsy on treatment	4	26	18	42	10	2.71
14. Other children stare at child	15	49	17	17	3	3.56
15. Treatment will improve child's vision‡	1	0.5	5	52	42	1.68
16. Treatment makes it difficult for child to play	1	6	14	59	20	2.10
17. Sometimes forget to apply treatment to child	2	22	6	36	33	2.24
18. Worry that child feels different	8	28	19	33	12	2.87
Atropine Group (n = 178)						
1. Child does not seem to mind treatment‡	8	10	7	38	38	2.13
2. Worry child may miss out on fun activities	1	10	7	43	39	1.90
3. Treatment affects child's learning	2	11	18	39	31	2.14
4. Treatment makes it hard for child to play	3	7	8	48	34	1.97
5. Trouble applying treatment to child	4	9	6	39	42	1.93
6. Treatment is a source of tension for me						
a. with child	2	4	6	41	47	1.73
b. with another family member§		2	2	35	52	1.49
c. with my child's babysitter or teacher§		0.6	1	34	43	1.48
7. Difficult for child to draw, color, or write	2	12	11	42	34	2.07
8. Worry child will be injured on treatment	2	12	11	40	35	2.04
9. My child can see well while on treatment‡	3	24	28	35	10	2.76
10. Child complains when it is time for treatment	7	21	11	33	28	2.46
11. Child's eye or eyelids become red or irritated	0.6	6	7	45	42	1.78
12. Worry that child not getting enough treatment	0.6	3	8	44	45	1.70
13. Child clumsy on treatment	0.6	19	10	41	29	2.20
14. Other children stare at child	1	6	6	41	46	1.76
15. Treatment will improve child's vision‡		2	16	48	34	1.86
16. Treatment makes it difficult for child to play	0.6	3	13	43	40	1.80
17. Sometimes forget to apply treatment to child	1	17	7	34	41	2.04
18. Worry that child feels different	3	10	7	41	38	1.98

*Data are given as percentages unless otherwise indicated.
†The average of all responses excluding "not applicable" responses on a 5-point Liker! scale.
:j:Data for questions 1, 9, and 15 have been reversed so that a higher score implies a negative connotation.
§"Not applicable" responses for 6b and 6c (see Table 1) were as follows: 6b, 7% in the patching group and 9% in the atropine group; 6c, 15% in the patching group and 22% in the atropine group.

subjects given the questionnaire on 2 different occasions (close enough in time such that the underlying process being measured has not changed) would score similarly.

Frequency tables were used to describe the item-response distributions and to assess whether any items had limited range. Factor anal$_{y\ s}$is was conducted combining patients from both treatment groups. Responses for 22 patients missing 1 item were imputed based on an average response across all completed questions for that child. Questions 6b and 6c did not apply to all respondents and were not included in the factor analysis, leaving 18 items for inclusion in the factor analysis. Any factor with an *eigenvalue* (the amount of combined item variance accounted for by the factor) greater than 1 was retained for interpretation.[7] Item loadings, an estimate of the correlation between the item and the underlying factor, that rounded to 0.5 or greater were considered noteworthy.[7] To simplify the factor structure, items that (1) did not load strongly on any factor, (2) loaded on several factors equally, or (3) whose removal notably increased the internal consistency reliability were not included in the final exploratory factor analysis nor included in subscales. A subscale name was defined for each factor by examining the theme of items that loaded strongly on that factor. The numerical value of each subscale was calculated as the mean of the individual items composing the subscale. Therefore, subscale scores took values from 1 to 5, with higher values indicating higher agreement. Internal-consistency reliability for the subscales was estimated by the Cron-

Table 3. Correlation Between Items and Factors From Factor Analysis of 364 Respondents

Factor Loadings for Retained Items*	Type of Subscale: Adverse Effects of Treatment	Lack of Treatment Compliance	Social Stigma
Items composing the adverse effects of treatment subscale			
2. Worry that child on treatment may miss out on fun activities	**0.5**	0.1	0.4
3. Treatment affects child's learning	**0.7**	0.1	0.0
4. Treatment makes it hard for child to play outside	**0.6**	0.2	0.4
7. Difficult for my child to draw, color, or write	**0.7**	0.2	0.1
8. Worry that child on treatment will become injured	**0.5**	0.1	0.4
9. Child can see well on treatment†	**0.6**	0.2	0.1
13. Child clumsy on treatment	**0.6**	0.1	0.4
16. Treatment makes it difficult for child to play	**0.6**	0.2	0.3
Items composing the lack of 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	0.3	**0.7**	0.2
10. Child complains when it is time for treatment	0.1	**0.7**	0.3
12. Worry child not getting enough treatment	0.1	**0.5**	0.3
Items composing the social stigma subscale			
11. Treatment makes my child's eye or eyelids red or irritated	0.2	0.3	**0.5**
14. Other children stare at child	0.0	0.1	**0.8**
18. Worry that child feels different	0.3	0.2	**0.7**

*Estimated factor loadings greater than 0.5 are in boldfaced type. Items 15 and 17 did not load strongly *(r<0.5)* on any single factor and are not listed. Questions 6b and 6c (see Table 1) did not apply to all of the respondents and were not included in the factor analysis.

†For ease of interpretation, data for this question have been reversed so that a higher score implies a negative connotation.

bach a.8 There were no obvious differences in the creation of subscales or subscale reliabilities when the analyses were conducted stratified by treatment group (data not shown). For each patient, an overall score was computed as a weighted average of the 3 subscale scores (weighted based on the number of items in the subscale).

Treatment group differences for the overall ATI questionnaire score and subscale scores were assessed with independent sample *t* tests. Interaction between baseline factors (age, visual acuity of the amblyopic eye, cause of amblyopia, and a history of amblyopia treatment) and treatment group on the ATl questionnaire score was assessed by including interaction terms in linear regression models. Within each treatment group, the associations between patient factors and the overall ATI questionnaire scores were evaluated using linear regression, with the questionnaire score as the dependent variable and the patient factor as the independent variable (all factors were analyzed as continuous variables except for prior treatment and cause of amblyopia which were analyzed as categorical variables). All reported *P* values are 2-sided. Statistical analyses were performed using SAS statistical software (PC Version 8.01; SAS Institute Inc, Cary, NC).

RESULTS

The ATI questionnaires were completed for 364 (87%) of the 419 patients enrolled in the Amblyopia Treatment Study 1: for 186 (87%) of 215 patients in the patching group and for 178 (87%) of 204 patients in the atropine group. Eleven patients missed the 5-week visit at which the ATl questionnaire was to be completed, 4 patients were not accompanied to the visit by a parent or guardian involved in administering the treatment, and 12 patients were enrolled at a site that did not have institutional review board approval for the completion of the questionnaire. Among the other 28 patients for whom a questionnaire was not completed, for 5 patients the site personnel neglected to distribute the questionnaire, for 13 patients a questionnaire was distributed but was not returned, and for 10 patients the reason for noncompletion was not documented. There were no meaningful differences comparing the demographic and clinical characteristics of the 55 patients for whom a questionnaire was not completed with those of the 364 patients for whom a questionnaire was completed (data not shown).

The 364 patients for whom questionnaires were completed had a mean age of 5.2 years; 46% were female. Ninety-four patients (26%) had been treated previously for amblyopia, most often (86 patients [91%]) with patching. The mean baseline visual acuity in the amblyopic eye was approximately 20/60. These characteristics are similar to those reported for the full study cohort (N =419).[1]

The mother was the respondent for 281 patients (77%), the father for 69 patients (19%), and another individual for 14 patients (4%). Fifty percent of the respondents indicated that they were the individual who was responsible for the treatment all of the time and an additional 32% indicated that they were responsible for the treatment most of the time.

INTERNAL VALIDITY AND RELIABILITY OF THE ATI QUESTIONNAIRE

Missing responses on the questionnaire items were minimal. Only 22 (< 1%) of 6552 possible item-responses were missing by 22 different respondents. Seventeen of the 18 items demonstrated adequate variability as evidenced by the frequency distributions for item-responses (Table 2). One item (No. 15 ["I believe that treatment will improve my child's vision."]) was limited in the response

range with 94% of the responses clustered in the strongly agree or agree category.

In a factor analysis, 16 of the 18 items were correlated strongly (2:::0.5) with 1 of 3 underlying factors having an eigenvalue greater than 1 (Table 3). A 3-factor solution was also suggested by visual inspection of a scree plot. The 3 factors remained after an iterative process of removing items that did not load strongly on any factor (items 15 and 17). These 3 factors were then defined as subscales on the basis of the items that were highly associated with each factor: (1) adverse effects of treatment (8 items), (2) difficulties with compliance (5 items), and (3) social stigma of the treatment (3 items). The internal-consistency reliability of the 8-item adverse effects subscale was 0.86, the 5-item compliance subscale reliability was 0.86, and the 3-item social stigma subscale reliability was 0.75. The internal-consistency reliability for the 16-item overall scale was 0.89.

TREATMENT GROUP COMPARISON

The distribution of responses for each ATI questionnaire item is provided by treatment group in Table 2. The mean overall scale score was 2.52 in the patching group and 2.02 in the atropine group, indicating that overall both treatments were perceived to be well tolerated on the 5-point Likert scale (P<.001 favoring the atropine group). The questionnaire scores were consistently higher (worse) on all 3 subscales in the patching group compared with the atropine group (adverse effects: mean, 2.35 vs 2.11, P= .002; difficulty with compliance: mean, 2.46 vs 1.99, P<.001; and social stigma: mean, 3.09 vs 1.84, P<.001, respectively [Table 4]). There was no statistically significant interaction between baseline factors and treatment group on the overall questionnaire scores (P values for interaction= .56 for age, .38 for baseline amblyopic eye visual acuity, .82 for cause of amblyopia, and .20 for a history of amblyopia treatment).

ASSOCIATION OF BASELINE AND PATIENT FACTORS AND ATI QUESTIONNAIRE RESPONSES

Within each treatment group, the association of baseline factors with the questionnaire responses was assessed. In each treatment group, there was no significant association between the overall questionnaire scores and age, baseline amblyopic eye visual acuity, or cause of amblyopia (Table 5). In the atropine group, patients with a history of amblyopia treatment (almost always prior patching treatment) had higher (worse) scores than did patients with no history of treatment (P=.01). On evaluating the subscale scores between those with and without a history of treatment, this association was seen to be primarily because of the differences in scores on the adverse effects subscale. This association between a history of amblyopia treatment and the ATI questionnaire scores was not found in the patching group (P= .53).

Patients prescribed 10 or more hours per day of patching had similar overall ATI questionnaire scores compared with patients prescribed 6 to 8 hours per day (mean scores, 2.61 and 2.49, respectively, P=.15). In analyzing the subscale scores, there was a suggestion of higher scores on the social stigma subscale but not on the other 2 subscales for the patients prescribed the greater number of patching hours (mean scores, 3.25 and 3.04, respectively,

Table 4. The Amblyopia Treatment Index Subscale Scores According to Treatment Group*

Average Score†	Patching Group (n = 186)	Atropine Group (n = 178)	*p* Value‡
Overall			
1 (strongly disagree)	0	3 (2)	
>1-2	36 (19)	91 (51)	
>2-3	116 (62)	72 (40)	
>3-4	29 (16)	12 (7)	
>4-5	5 (3)	0	
Mean (SD)	2.52 (0.63)	2.02 (0.63)	<.001
Difference§ (95% CI)	0.50 (0.37-0.63)		
Median (interquartile range)	2.47 (2.13, 2.87)	2.00 (1.50, 2.44)	
Adverse effects of treatment subscale			
1 (strongly disagree)	3 (2)	10 (6)	
>1-2	63 (34)	85 (48)	
>2-3	95 (51)	64 (36)	
>3-4	21 (11)	18 (10)	
>4-5	4 (2)	1 (0.6)	
Mean (SD)	2.35 (0.69)	2.11 (0.72)	.002
Difference§ (95% CI)	0.23 (0.09-0.38)		
Median (interquartile range)	2.25 (1.88, 2.75)	2.00 (1.50, 2.63)	
Lack of treatment compliance subscale			
1 (strongly disagree)	5 (3)	29 (16)	
>1-2	75 (40)	86 (48)	
>2-3	63 (34)	42 (24)	
>3-4	28 (15)	17 (10)	
>4-5	15 (8)	4 (2)	
Mean (SD)	2.46 (0.96)	1.99 (0.83)	<.001
Difference§ (95% CI)	0.47 (0.28-0.65)		
Median (interquartile range)	2.20 (1.80, 3.00)	1.80 (1.40, 2.60)	
Social stigma subscale			
1 (strongly disagree)	4 (2)	50 (28)	
>1-2	23 (12)	83 (47)	
>2-3	69 (37)	32 (18)	
>3-4	73 (39)	12 (7)	
>4-5	17 (9)	1 (0.6)	
Mean (SD)	3.09 (0.81)	1.84 (0.74)	<.001
Difference§ (95% CI)	1.25 (1.10-1.41)		
Median (interquartile range)	3.00 (2.67, 3.67)	2.00 (1.00, 2.33)	

Abbreviation: CI, confidence interval.
*Data are given as the number (percentage) of respondents unless otherwise indicated.
†A higher score is worse.
‡P value for difference in mean from *t* test.
§Positive difference indicates atropine-treated group is better.

In a randomized, controlled clinical trial of patching vs atropine treatment for moderate amblyopia, we used the ATI questionnaire to assess the impact of treatment on the child and family. In both treatment groups, the ATI

Table 5. Association of Patient Factors and Overall Amblyopia Treatment Index Questionnaire Scores

Factor	Patching Group			Atropine Group		
	No. of Children	Mean Overall Score	P Value Within Group*	No. of Children	Mean Overall Score	P Value Within Group*
Age, y						
< 4	33	2,33		30	1.96	
4-<5	37	2.51	.18	36	2.00	.67
5-<6	56	2.63		65	2.05	
6-<7	60	2.53		47	2.04	
Baseline amblyopic eye visual acuity†						
20/40	18	247		23	1.84	
20/50	41	2.55		35	1.94	
20/60	47	2.50	.75	28	2.19	.15
20/80	37	2.46		50	1.98	
20/100	43	2.58		41	2.11	
Cause of amblyopia‡						
Strabismus	71	2.53		69	2.07]	
Anisometropia	75	2.48	.66	66	1.93	.35
Strabismus and anisometropia	39	2.59		39	2.06	
Prior amblyopia treatment§						
Yes	44	2.57	.53	50	2.21	.01
No	142	2.50		128	1.95	
Improvement from baseline to 5 wk in amblyopic eye visual acuity, No. of lines						
< 2	49	2.74]		88	2.05]	
2	62	2.45	.09	57	1.96	.50
≥3	75	2.44		33	2.04	

*P value for the association between the factor and the overall score within treatment group from linear regression with the overall score as the dependent variable and the patient factor as the independent variable (all factors were analyzed as continuous variables except for prior treatment and cause of amblyopia, which were analyzed as categorical variables).

†one patient in the atropine group with a baseline amblyopic eye visual acuity of 20/125 was not included.

‡Five patients (1 in the patching group and 4 in the atropine group) with indeterminate cause for amblyopia were not included.

§For 91 % of the patients who received prior amblyopic treatment, patching was the prior treatment.

questionnaire results indicated that the initial month of treatment was usually well tolerated by the child and parent. Atropine was a more acceptable treatment than patching overall and on 3 ATI subscales of adverse effects, treatment compliance, and social stigma. However, the absolute differences between the atropine-treated and patching groups were small (about half of a unit on the 1 to 5 scale).

Although questionnaires, such as the Parenting Stress Index,[9] have been developed for assessing quality of life in children and their families in a variety of pediatric conditions,[10-11] there is a lack of published data on the quality of life during amblyopia treatment and the impact of treatment on the child and family. Searle et al[12] qualitatively assessed psychosocial effects of patching in parental interviews of 20 families with a child aged 2 to 7 years who was prescribed 2 to 7 hours per day of patching. The authors reported that many parents experienced distress related to patching. However, no quantification was provided either for the proportion of parents reporting distress or for the degree of distress. Thus, a meaningful comparison with our results cannot be made. Newsham[13] used a parental questionnaire to assess reasons for noncompliance in 31 children aged 2 to 7 years with poor patching compliance. He reported that the most common reason in 45% of cases was the parental decision to defer treatment until the child was older and presumably more cooperative.

Atropine treatment has been previously reported in several uncontrolled case series to have an excellent level of acceptability by patients and parents.[14-16] Comparing patching with atropine treatment in a prospective study of 36 children aged 2 to 9 years old, Foley-Nolan et al[17] reported superior acceptability and compliance with atropine treatment. Data from our randomized, controlled clinical trial using the ATI questionnaire support this finding of higher acceptability for atropine treatment, providing at least one rationale for the use of the atropine treatment in preference to patching. Although we found that patching was associated with worse ATI scores than the atropine treatment, the results indicated that patching generally was well tolerated, and the scores of the patching group were better than might have been anticipated based on our clinical experience.

The age of the patient, depth of amblyopia, and cause of amblyopia showed little relationship with the overall ATI questionnaire score. Within the patching group, the scores were similar in children who had been previously treated for amblyopia and those who had not. Within the atropine group, previously treated children (mostly treated with patching) had higher (worse) scores, on average, than did children who were being treated for the first time. However, the previously treated children in the atropine group still had lower (better) scores than did the previously treated children in the patching group. In view of the multiple statistical associations that were

The Pediatric Eye Disease Investigator Group

Clinical Sites

Listed in order of number of patients enrolled into the Amblyopia Treatment Study 1, with city, state, site name, and number of patients in parentheses. Personnel are listed as (I) for investigator, (C) for coordinator, and (V) for visual acuity tester.

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assessed, we think that the association between prior treatment and the ATI questionnaire scores in the atropine group was likely related to chance.

We believe that ourresults are not biased by the knowledge of response to treatment because the ATI questionnaire was completed prior to testing of visual acuity at the first follow-up visit. If the visual acuity results were known or suspected by the parent, this might bias in favor of the patching group since, as we have reported, after 5 weeks of treatment there was greater improvement in visual acuity in the patching group than in the atropine group.[1] Since the ATI questionnaire was completed only at 5 weeks, we do not know whether the better acceptance of atropine than patching would have been sustained over several months of treatment.

Regarding the internal validity and reliability of the ATI questionnaire, our present data from 364 children enrolled in the Amblyopia Treatment Study 1 confirm the findings of our original report using data from the first 64 patients.[2] We found 3 factors that could be appropriately labeled as the same 3 subscales of (1) adverse effects, (2) treatment compliance, and (3) social stigma. Increasing the sample size in the present study resulted in finding additional ATI questionnaire items that loaded with each factor or subscale, such that 16 of the possible 18 items could be used in the subscales, in contrast to 11 in the original report of the same questionnaire. In our initial pilot study, we commented[2] that the social stigma subscale was somewhat weak because it was based on only 2 items. Increasing the sample size for the current analysis has identified a third questionnaire item that loads strongly with this factor likely increasing the stability of the social stigma subscale.

Regarding generalizability, the ATI questionnaire was developed specifically for use in the age group of 3- to 6-year-olds and our results should not be applied to older or younger children. Patients in the randomized, controlled clinical trial had moderate amblyopia and the results might differ with severe amblyopia (we are using the ATI questionnaire to assess quality of life in patching treatment of severe amblyopia). Our patient population was preponderantly white and it is possible that children and their families of different races might respond differently to patching and/or atropine treatment. As with any clinical trial, patients (parents) who agree to participate may differ from the general population in ways that could influence the results.

we used the ATI questionnaire to measure the impact of patching and atropine treatments on some quality-of-life domains in a randomized, controlled clinical trial of patching vs atropine treatment for amblyopia. Overall, the atropine treatment was better tolerated than patching. However, the scores for both the atropine treatment and patching were on the whole positive and demonstrated good acceptance of both treatments by the children and their parents.

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