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Treatment of severe amblyopia with weekend atropine: Results from two randomized clinical trials

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Abstract

Purpose—To determine the effectiveness of weekend atropine for severe amblyopia from strabismus, anisometropia, or both combined among children 3 to 12 years of age.

Methods—We enrolled children into two prospective, randomized multicenter clinical trials of amblyopia therapy. Herein we report the results for severe amblyopia, 20/125 to 20/400. In Trial 1, 60 children 3 to 6 years of age (mean, 4.4 years) were randomized to weekend atropine plus a plano lens or weekend atropine plus full spectacle correction for the sound eye. In Trial 2, 40 children 7 to 12 years of age (mean, 9.3 years) were randomized to weekend atropine or two hours of daily patching. The visual acuity outcome was assessed at 18 weeks in Trial 1 and 17 weeks in Trial 2.

Results—In Trial 1, visual acuity improved by an average of 4.5 lines in the atropine plus correction group (95% CI, 3.2-5.8 lines) and 5.1 lines in the atropine plus plano lens group (95% CI, 3.7-6.4 lines). In Trial 2, visual acuity improved by an average of 1.5 lines in the atropine group (95% CI, 0.5-2.5 lines) and 1.8 lines in the patching group (95% CI, 1.1-2.6 lines).

Conclusions—Weekend atropine can improve visual acuity in children 3 to 12 years of age with severe amblyopia. Improvement may be greater in younger children.

Introduction

Atropine eyedrops, when administered to the sound eye, have been found to improve the visual acuity of eyes with moderate amblyopia.[1-4] We have recently completed two clinical trials in which we enrolled children aged 3 to 12 years with moderate amblyopia (visual acuity 20/40 to 20/100 in the amblyopic eye).[1,2] In each of these studies, we also enrolled otherwise eligible subjects who had severe amblyopia (20/125-20/400) to explore the effectiveness of weekend atropine treatment for severe amblyopia. The purpose of this report is to provide those results for severe amblyopia.

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*A listing of the Writing Committee appears at the end of this article. The members of the Pediatric Eye Disease Investigator Group are listed in e-Supplement 1, available at jaapos.org.

A list of the members of the Pediatric Eye Disease Investigator Group participating in the study has been published.

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Methods

The two protocols have been published[1,2] and are available on the Pediatric Eye Disease Investigator Group (PEDIG) Web site (www.pedig.net). The randomized clinical trials are listed on www.clinicaltrials.gov, identifiers NCT00315302 and NCT00315328. Both trials were supported through a cooperative agreement with the National Eye Institute of the National Institutes of Health. The respective institutional review boards approved the protocol and Health Insurance Portability and Privacy Act–compliant informed consent forms. The parent or guardian of each study participant gave written informed consent. Key aspects pertinent to this exploratory study are described below. Both trials enrolled children with unilateral severe amblyopia defined as best corrected visual acuity 20/125 to 20/400 and limited to cases associated with strabismus, anisometropia, or both. The first trial (hereafter, Trial 1) enrolled children 3 to 6 years old and compared weekend atropine plus a plano lens for the sound eye with weekend atropine with full spectacle correction for the sound eye.[1] For brevity, the weekend atropine plus spectacle correction group is hereafter termed atropine only. The second trial (hereafter, Trial 2) enrolled children 7 to 12 years old and compared weekend atropine with patching 2 hours per day.[2] Eligibility criteria for the two trials were similar, except for age and that Trial 1 required that the subject have hypermetropia ≥ +1.50 D spherical equivalent in the sound eye. The primary outcome was visual acuity measured at 18 weeks using the ATS HOTV visual acuity testing procedure[5] in Trial 1 and at 17 weeks using the electronic ETDRS visual acuity testing procedure (E-ETDRS)[6] in Trial 2. Parents were queried at each visit for side effects.

Neither study for subjects with severe amblyopia was formally powered for treatment group comparisons. LogMAR values for the visual acuity scores were used for analysis, with a logMAR change of 0.1 being considered a one line change. For both trials, point estimates and 95% confidence intervals were calculated for mean visual acuity improvement from baseline in the amblyopic eye.

Results

Baseline characteristics of the children in each trial are provided in Table 1.

Trial 1: Weekend atropine compared with weekend atropine plus a plano lens in children 3 to 6 years of age

Between February 2005 and June 2007, 60 subjects with severe amblyopia were enrolled by 22 sites, with 26 assigned to the weekend atropine only group and 34 to the weekend atropine plus plano lens group.

The 18-week primary outcome examination was completed by 24 of 26 (92%) subjects in the atropine-only group and by 31 of 34 (91%) subjects in the atropine plus plano group. Visual acuity improved by an average of 4.5 lines in the atropine-only group (95% CI, 3.2-5.8 lines) and 5.1 lines in the atropine plus plano group (95% CI, 3.7-6.4 lines) (Table 2). Visual acuity in the amblyopic eye was 20/40 or better in 21% of the atropine-only group and in 39% of the atropine plus plano group and 20/25 or better in 4% and 13%, respectively. Visual acuity data after 5 and 10 weeks of treatment are listed in Table 2.

Of the 60 children who received atropine and completed the 18-week outcome examination, 54 had fixation preference determined at the 5-week visit with cycloplegia in the sound eye. Two switched fixation to the amblyopic eye, while 7 alternated fixation, 22 preferred the sound eye, and 23 fixated only with the sound eye. The mean improvement for the 45 who either preferred or only fixated with the sound eye was 4.8 lines.

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For 1 (4%) subject in the atropine-only group and 6 (19%) subjects in the atropine plus plano lens group, sound eye acuity was worse than 20/20 and reduced by 1 or more lines from baseline at the 18-week visit (Table 3). Sound eye acuity returned to baseline or better when retested after 4 weeks with no treatment in all but one subject in the atropine plus plano lens group. Ocular side effects were reported by 6 (11%) subjects, most commonly light sensitivity. Facial flushing was reported by 1 subject.

Trial 2: Weekend atropine compared with 2 hours daily patching for children 7 to 12 years of age

Between November 2005 and June 2007, 40 subjects with severe amblyopia were enrolled by 21 sites, with 22 assigned to the atropine group and 18 to the patching group. At the 5-week follow-up visit, 8 atropine group subjects were increased to daily atropine and 5 patching group subjects were prescribed increased patching as mandated by the protocol.

The 17-week primary outcome examination was completed by 20 of 22 (91%) subjects in the atropine group and by 13 of 18 (72%) subjects in the patching group. Visual acuity improved from baseline by an average of 1.5 lines in the atropine group (95% CI 0.5 to 2.5 lines) and 1.8 lines in the patching group (95% CI, 1.1-2.6 lines) (Table 4). Visual acuity was 20/40 or better in 1 subject in the atropine-only group and none in the patching group and 20/25 or better in 1 and 0 subjects, respectively.

Of the 20 children who received weekend atropine and completed the 17-week outcome examination, 13 had fixation preference determined at baseline with cycloplegia in the sound eye. None switched fixation to the amblyopic eye, while one alternated fixation and 12 preferred the sound eye. The mean improvement for these 12 patients was 2.2 lines.

For 1 (5%) subject in the atropine group and none in the patching group, sound eye acuity was worse than 20/20 and reduced by 1 or more lines from baseline at the 17-week visit (Table 3). This subject tested 8 letters worse than baseline in the sound eye and was randomized to the atropine treatment group and performed patching from the time of enrollment. This subject is included in the atropine group analysis under the intention to treat principle.

In the atropine group, light sensitivity was reported by 3 (15%) subjects. Systemic side effects were reported by 2 (10%) subjects using atropine (1 reported irritability, and another reported urinary urgency, dry mouth, and excessive thirst).

Discussion

These two randomized exploratory studies of weekend atropine for the treatment of severe amblyopia in children from 3 to 12 years of age demonstrated that severe amblyopia can improve with weekend atropine. However, residual amblyopia was present after 4 months of treatment in most cases. The degree of improvement in the 3 to 6 years age group was similar to that found in a prior study of patching for severe amblyopia, as was the degree of residual amblyopia.[7] There did appear to be an age effect when comparing Trial 1 with Trial 2, with greater improvement seen in the younger subjects. However, this study was not designed to specifically evaluate this relationship and so this finding should be interpreted cautiously. Atropine was well tolerated by most subjects as has been observed in our earlier studies, with the most common concern light sensitivity.[4,8,9]

Reports on the use of atropine for the management of severe amblyopia have been limited. In most studies, daily atropine has been used. A prospective randomized study of patching versus daily atropine included 12 subjects with severe amblyopia (6/36 or worse) treated with daily atropine.[10] After treatment, 11 (92%) of the children in the daily atropine group were 20/80

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or better and 7 (58%) were 20/40 or better. Retrospective case series have also reported improvement, although residual amblyopia was common.[11-15] Kaye and colleagues used daily atropine penalization plus plano lens for residual amblyopia following occlusion therapy in children younger than 7 years of age.[16] They noted that mean acuity improved with atropine treatment from 0.85 to 0.28 logMAR, an improvement of more than 5 lines.

The importance of a switch in fixation to the amblyopic eye has been considered to be an important predictor of success with penalization techniques including atropine. In both trials we found that amblyopia can improve even when fixation preference testing indicated a failure to switch fixation to the amblyopic eye. We have reported a similar finding for younger children (3 to <7 years) with moderate amblyopia in two prior trials using atropine cycloplegia.[4,17] We speculate that vision in the amblyopic eye improves because the patient may fixate periodically with the amblyopic eye, especially when viewing objects nearer than the 1/3 meter used in the fixation test.

In our previous prospective studies of atropine treatment for moderate amblyopia[3,4] we had excluded severe amblyopia because many investigators thought treatment was unlikely to be effective. This pilot study provides data suggestive that weekend atropine may improve severe amblyopia, particularly in 3- to 6-year-olds. It is hard to imagine that the 4- to 5-line improvement in the younger children was due to learning, maturation or testing effects. However, the results are far from definitive and a prospective randomized comparison of atropine to patching for severe amblyopia is needed.

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Table 1

Baseline data

	Trial 1		Trial 2	
	Atropine only N = 26	**Atropine + plano lens N = 34**	**Atropine only N = 22**	**Patching 2 hrs/day N = 18**
Gender, *n* (%)				
female	8 (31)	16 (47)	12 (55)	4 (22)
Race/ethnicity, *n* (%)				
White	23 (88)	28 (82)	18 (82)	16 (89)
African American	1 (4)	3 (9)	1 (5)	2 (11)
Hispanic or Latino	2 (8)	3 (9)	3 (14)	0
Asian	0	0	0	0
Unknown/not reported	0	0	0	0
Age at enrollment, *n* (%)				
3 to <4 years	10 (38)	16 (47)	-	-
4 to <5 years	7 (27)	9 (26)	-	-
5 to <6 years	8 (31)	7 (21)	-	-
6 to <7 years	1 (4)	2 (6)	-	-
7 to <8 years	-	-	9 (41)	6 (33)
8 to <9 years	-	-	4 (18)	0
9 to <10 years	-	-	3 (14)	5 (28)
10 to <11 years	-	-	2 (9)	4 (22)
11 to <12 years	-	-	1 (5)	2 (11)
12 to <13 years	-	-	3 (14)	1 (6)
Mean (SD)	4.5 (0.9)	4.4 (1.0)	9.2 (1.8)	9.5 (1.5)
Prior treatment for amblyopia at enrollment, *n* (%)				
None	24 (92)	28 (82)	18 (82)	13 (72)
Patching	1 (4)	6 (18)	3 (14)	2 (11)
Atropine	0	0	0	1 (6)
Patching and atropine	1 (4)	0	1 (5)	2 (12)
Cause of amblyopia, *n* (%)				
Strabismus	10 (38)	11 (32)	4 (18)	4 (22)
Anisometropia	5 (19)	8 (24)	9 (41)	6 (33)
Strabismus & anisometropia	11 (42)	15 (44)	9 (41)	8 (44)
Distance visual acuity in amblyopic eye, *n (%)*				
20/400	0	8 (24)	1 (5)	0
20/320	8 (31)	2 (6)	1 (5)	0
20/250	1 (4)	3 (9)	4 (18)	2 (11)
20/200	5 (19)	5 (15)	3 (14)	8 (44)

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	Trial 1		Trial 2	
	Atropine only N = 26	**Atropine + plano lens N = 34**	**Atropine only N = 22**	**Patching 2 hrs/day N = 18**
20/160	5 (19)	5 (15)	4 (18)	5 (28)
20/125	7 (27)	11 (32)	9 (41)	3 (17)
Mean (SD) logMAR	0.99 (0.16)	1.01 (0.20)	0.95 (0.15)	0.95 (0.10)
Snellen equivalent	20/200	20/200	$20/160^{-2}$	$20/160^{-2}$
Distance visual acuity in sound eye, *n* (%)				
20/40	4 (15)	7 (21)	0	0
20/32	11 (42)	12 (35)	0	0
20/25	8 (31)	7 (21)	6 (27)	1 (6)
20/20	3 (12)	8 (24)	5 (23)	8 (44)
20/16	0	0	11 (50)	9 (50)
Mean (SD) logMAR	0.16 (0.09)	0.15 (0.11)	−0.01 (0.08)	−0.04 (0.07)
Snellen equivalent	$20/32^{+2}$	$20/32^{+2}$	20/20	$20/20^{+2}$
Intereye acuity difference, *n (%)*				
Mean (SD) logMAR lines	8.3 (1.7)	8.6 (2.2)	9.5 (1.9)	9.9 (1.1)
Refractive error in amblyopic eye (SE), *n* (%)				
0 to < +1.00 D	0	0	1 (5)	1 (6)
+1.00 to <+2.00 D	1 (4)	0	2 (9)	2 (11)
+2.00 to <+3.00 D	3 (12)	0	3 (14)	1 (6)
+3.00 to <+4.00 D	3 (12)	4 (12)	4 (18)	2 (11)
≥+4.00 D	19 (73)	30 (88)	12 (55)	12 (67)
Mean (SD) D	5.25 (2.09)	5.36 (1.29)	4.18 (1.99)	4.97 (2.50)
Refractive error in sound eye (SE), *n* (%)				
0 to < +1.00 D	-	-	9 (41)	4 (22)
+1.00 to <+2.00 D	6 (23)	6 (18)	5 (23)	8 (44)
+2.00 to <+3.00 D	8 (31)	5 (15)	2 (9)	1 (6)
+3.00 to <+4.00 D	2 (8)	8 (24)	2 (9)	2 (11)
≥+4.00D	10 (38)	15 (44)	4 (18)	3 (17)
Mean (SD) D	3.60 (2.18)	3.71 (1.58)	1.98 (2.11)	2.12 (1.76)

SD, standard deviation; *D*, = diopters; *logMAR*, logarithm of the minimum angle of resolution; *SE*, spherical equivalent

Trial 1: weekend atropine with spectacle correction as clinically indicated compared with weekend atropine plus a plano lens for the sound eye in children 3 to 6 years of age.

Trial 2: weekend atropine compared with patching 2 hours per day to the sound eye for children 7 to 12 years of age.

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Table 2

Amblyopic eye visual acuity in children 3 to 6 years old in trial 1

	5-week exam		10-week exam		18-week exam	
	Atropine only N = 26	**Atropine + plano N = 30**	**Atropine only N = 24**	**Atropine + plano N = 29**	**Atropine only N = 24**	**Atropine + plano N = 31**
Lines change from baseline, *n* (%)						
2 lines worse	0	1 (3)	0	1 (3)	0	1 (3)
1 line worse	0	2 (7)	0	1 (3)	0	1 (3)
0	3 (12)	2 (7)	2 (8)	1 (3)	2 (8)	2 (6)
1 line better	4 (15)	4 (13)	2 (8)	1 (3)	2 (8)	3 (10)
2 lines better	8 (31)	8 (27)	7 (29)	5 (17)	3 (13)	1 (3)
≥3 lines better	11 (42)	13 (43)	13 (54)	20 (69)	17 (71)	23 (74)
Mean (SD) lines change	2.5 (1.7)	2.3 (2.0)	3.3 (2.3)	4.1 (2.9)	4.5 (3.1)	5.1 (3.7)
Distribution of visual acuity, *n* (%)						
20/400	0	1 (3)	0	1 (3)	0	1 (3)
20/320	1 (4)	1 (3)	0	1 (3)	0	1 (3)
20/250	2 (8)	3 (10)	1 (4)	1 (3)	1 (4)	2 (6)
20/200	4 (15)	4 (13)	2 (8)	2 (7)	0	0
20/160	1 (4)	5 (17)	3 (13)	2 (7)	2 (8)	1 (3)
20/125	4 (15)	3 (10)	4 (17)	4 (14)	4 (17)	4 (13)
20/100	4 (15)	3 (10)	2 (8)	1 (3)	1 (4)	2 (6)
20/80	5 (19)	3 (10)	4 (17)	2 (7)	1 (4)	2 (6)
20/63	3 (12)	3 (10)	2 (8)	3 (10)	5 (21)	2 (6)
20/50	1 (4)	2 (7)	1 (4)	2 (7)	5 (21)	4 (13)
20/40	0	1 (3)	3 (13)	7 (24)	3 (13)	0
20/32	1 (4)	1 (3)	2 (8)	2 (7)	1 (4)	8 (26)
20/25	0	0	0	0	0	1 (3)
20/20	0	0	0	1 (3)	1 (4)	1 (3)
20/16	0	0	0	0	0	2 (6)
Mean (SD) logMAR Score	0.75 (0.24)	0.78 (0.28)	0.65 (0.27)	0.60 (0.34)	0.54 (0.26)	0.50 (0.38)
Mean (SD) interocular difference (logMAR lines)	6.0 (2.7)	5.6 (2.9)	5.2 (2.5)	4.2 (3.5)	4.3 (2.7)	3.1 (4.1)

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Trial 1: weekend atropine compared with weekend atropine plus a plano lens for the sound eye in children 3 to 6 years of age.

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Table 3

Sound eye visual acuity at the outcome exam

	Trial 1		Trial 2	
	18-week exam		17-week exam	
	Atropine only N = 24	Atropine + plano N = 31	Atropine only N = 20	Patching 2 hrs/day N = 13
Change from baseline,* *n* (%)				
≥2 lines worse	1 (4)	4 (13)	1 (5)	0
1 line worse	0	2 (6)	2 (10)	1 (8)
0	11 (46)	13 (42)	11 (55)	8 (62)
1 line better	9 (38)	12 (39)	4 (20)	4 (31)
≥2 lines better	3 (13)	0	2 (10)	0
Mean (SD) lines change	0.5 (0.9)	0.1 (1.0)	0.2 (1.0)	0.2 (0.6)
Distribution of visual acuity, *n* (%)				
20/63	0	1 (3)	0	0
20/50	1 (4)	3 (10)	0	0
20/40	1 (4)	4 (13)	1 (5)	0
20/32	6 (25)	7 (23)	1 (5)	0
20/25	8 (33)	7 (23)	2 (10)	1 (8)
20/20	6 (25)	7 (23)	4 (20)	4 (31)
20/16	2 (8)	2 (6)	11 (55)	5 (38)
20/12	—	—	1 (5)	3 (23)
Mean (SD) logMAR	0.10 (0.12)	0.15 (0.15)	−0.03 (0.13)	−0.07 (0.10)
Snellen equivalent	20/25	$20/32^{-2}$	$20/20^{-2}$	$20/25^{+1}$

* For Trial 2, change from baseline in logMAR rounded to nearest line for presentation.

Trial 1: weekend atropine with spectacle correction as clinically indicated compared with weekend atropine plus a plano lens for the sound eye in children 3 to 6 years of age.

Trial 2: weekend atropine compared with patching 2 hours per day to the sound eye for children 7 to 12 years of age.

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Table 4

Amblyopic eye visual acuity in children 7 to <13 years old in Trial 2

	5-week exam		17-week exam	
	Atropine N = 19	**Patching N = 17**	**Atropine N = 20**	**Patching N = 13**
Change from baseline,* *n* (%)				
1 line worse	3 (16)	0	2 (10)	0
0	6 (32)	3 (18)	6 (30)	2 (15)
1 line better	4 (21)	9 (53)	4 (20)	4 (31)
2 lines better	1 (5)	2 (12)	3 (15)	2 (15)
≥3 lines better	5 (26)	3 (18)	5 (25)	5 (38)
Mean (SD) change	1.2 (1.9)	1.4 (1.3)	1.5 (2.1)	1.8 (1.3)
Distribution of visual acuity, *n* (%)				
20/400	1 (5)	0	0	0
20/320	3 (16)	0	1 (5)	0
20/250	1 (5)	1 (6)	3 (15)	0
20/200	0	2 (12)	3 (15)	3 (23)
20/160	5 (26)	5 (29)	3 (15)	1 (8)
20/125	3 (16)	4 (24)	2 (10)	4 (31)
20/100	2 (11)	3 (18)	2 (10)	1 (8)
20/80	0	1 (6)	3 (15)	4 (31)
20/63	2 (11)	1 (6)	1 (5)	0
20/50	2 (11)	0	1 (5)	0
20/40	0	0	0	0
20/32	0	0	0	0
20/25	0	0	1 (5)	0
Mean (SD) logMAR	0.83 (0.27)	0.80 (0.15)	0.80 (0.28)	0.78 (0.16)
Snellen Equivalent	$20/125^{-1}$	20/125	20/125	$20/125^{+1}$
Mean interocular difference (logMAR lines)	8.0 (3.6)	8.5 (1.7)	7.6 (3.0)	8.3 (1.8)

* Change from baseline in logMAR rounded to nearest line for presentation.

Trial 2: weekend atropine compared with patching 2 hours per day to the sound eye for children 7 to 12 years of age.