

# A Randomized Trial of Atropine Versus Patching for Treatment of Moderate Amblyopia

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## Abstract

**Background:** Amblyopia is a major cause of visual impairment in children. The goal of our study was to compare the patching method with atropine penalization as a treatment for moderate amblyopia in children between 4 and 10 years of age.

**Patients and Methods:** This prospective, randomized clinical trial included 120 patients between 4 and 10 years of age suffering from moderate amblyopia in the range of 20/40 and 20/100 between 2004 and 2007. Subjects were randomly divided into equal-sized groups and received either the patch therapy or twice-weekly atropine penalization, and were followed for 2 years. Successful treatment was defined as an increase of 2 or more lines of visual acuity or a final visual acuity of 20/25 or better.

**Results:** By the end of the follow-up period, visual acuity in the amblyopic eye had improved from baseline by a mean of 3.8 lines in the patching group and 3.7 lines in the atropine group. The average visual acuity in both groups was 0.5 Log MAR acuity, which increased to 0.18 in the patching group and 0.2 in the atropine group.

**Conclusions:** Twice-weekly atropine penalization and patching resulted in similar levels of visual acuity improvement in patients between the age of 4 and 10 years treated for moderate amblyopia.

**Keywords:** Moderate amblyopia; Patch therapy; Atropine penalization

## Introduction

Amblyopia is the most common cause of monocular visual loss in children (1). Patching and atropine penalization of the sound eye are currently the primary treatments for this disorder (2-4). Simons *et al.* (5) reported that atropine therapy (one drop per week) could be used as a successful treatment. The Pediatric Eye Disease Investigation Group (6) reported that 2 hours of patching improved moderate to severe amblyopia in children of 3 to 7 years of age, This group also reported that daily atropine or patching resulted in similar levels of improvement in moderate amblyopia (2-4). We conducted a randomized clinical trial to compare the success rate of twice-weekly atropine administration with 2 hour of patching for the

treatment of moderate amblyopia.

## Patients and Methods

This prospective randomized clinical trial included 120 subjects. Patients that met the following criteria were enrolled into the study.

- 1: Aged 4-10 years
- 2: Visual acuity (VA) in the amblyopic eye between 20/40 and 20/100
- 3: Difference in VA between eyes equal to or more than 3 Log MAR
- 4: Difference in refractive error between eyes equal to or more than 1 diopter for hyperopia and 1.5 diopter for astigmatism.
- 5: Wearing corrective eyewear for a minimum of 4 weeks
- 6: Available for at least 2 years of follow-up

Informed consent was obtained from the subjects prior to treatment. The patient records were randomized; the even numbers were assigned to 3-hour patch therapy

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and the odd numbers underwent twice-weekly penalization with 0.5% atropine. There were a total of 60 subjects in each group. Cycloplegic refraction was performed with 0.5% cyclopentolate. Suitable corrective lenses were prescribed and VA was checked using an E chart (nidek projector) at the beginning of the treatment and at each visit.

Successful treatment was defined as an improvement of 2 or more lines in VA or a VA of 20/25 or better in the amblyopic eye. The mean final VA of the amblyopic eye and the rate of successful treatment in both groups was evaluated using SPSS version 16. This study was approved by the ethics committee of Guilan Medical Science University.

### Results

A total of 120 subjects entered the study between January 2004 and January 2007. Sixty patients were assigned to the patching group and the same number was assigned to the penalization group. Approximately 45% of the patients were female and 55% were male. The mean VA in the patching and penalization groups at the beginning of treatment was 0.46 and 0.45 log MAR, respectively. The patient history is summarized in Table 1.

### Patching group

A total of 60 subjects were enrolled into the patching group. Patients with a difference of two lines of acuity between each eye began 2-hour patch therapy and patients with a difference of three or more lines of VA began 3-hour patch therapy. The treatment success rate was approximately 76%. Approximately 50% of the patients achieved a VA of 20/25 or more by the end of the follow-up. The frequency of patients that achieved specific levels of VA in both groups is summarized in Table 2. The mean increase in VA from baseline was 3.6 lines. Approximately 35% achieved stereo acuity of 400 seconds of arc by the end of the study. The improvements in VA after 2 years are summarized in Table 2.

### Atropine group

Sixty subjects received penalization with 0.5% atropine twice weekly. After there was some improvement in VA, the penalization dose was decreased to one drop per week. The success rate of the treatment was approximately 74%. Approximately 50% of the patients achieved a VA of 20/25 or more by the end of the follow-up. Approximately 30% achieved stereo acuity of 400 seconds of arc

Table 1. Pre-treatment patient data

	Total patients (n=120)	Patching group (n=60)	Penalization group (n=60)
<b>Sex</b>			
Male, %	55	54	56
Female, %	45	46	46
<b>Age, No.</b>			
4-6	50	26	24
6-8	50	24	26
8-10	20	10	10
<b>VA<sup>a</sup> in Amblyopia</b>			
<b>Snellen</b>	<b>Log MAR</b>		
20/100	0.7	8	7
20/80	0.6	8	9
20/60	0.48	15	16
20/50	0.4	13	12
20/40	0.3	16	16
<b>Mean Log MAR</b>	0.45	0.45	0.45
<b>VA in sound eye</b>			
<b>Snellen</b>	<b>Log MAR</b>		
20/20	0	41	39
20/25	0.1	9	11
20/30	0.2	7	8
20/40	0.3	3	2
<b>Amount of anisometropia</b>			
1-2		31	29
2-3		15	15
3-4		9	11
4-5		5	5

<sup>a</sup> VA: Visual activity

**Table 2.** Frequency of patients that developed specific levels of vision at the end of 2 years

		Patching (n=60)	Penalization (n=60)	Total (n=120)
<b>VA<sup>a</sup></b>				
<b>Snellen</b>	<b>Log MAR</b>			
20/100	0.7	100%	100%	100%
20/80	0.6	100%	100%	100%
20/60	0.48	99%	97%	98%
20/50	0.4	95%	93%	94%
20/40	0.3	88%	88%	88%
20/30	0.2	74%	76%	75%
20/25	0.1	51%	49%	50%
20/200	0	25%	25%	25%
<b>Mean Log MAR</b>		0.15	0.17	0.16

<sup>a</sup> VA: Visual activity

at the end of the follow-up.

### Total patients

In this study, there were a total of 120 patients. VA testing at the end of the treatment in both groups is summarized in Table 2. The success rate of the treatment was approximately 75 %. Approximately 50 % of the patients achieved a VA of 20/25 or more by the end of follow-up. The frequency of patients that achieved specific levels of VA in both groups is summarized in Table 2.

### Discussion

In this study, we compared the effects of patching and atropine penalization for the treatment of moderate amblyopia in 120 subjects between 4 and 10 years of age in a randomized clinical trial. In both groups, the mean VA at the end of treatment was 0.18 log MAR or 20/30. VA in the amblyopic eye increased from baseline by a mean of 3.8 lines in the penalization group and 3.6 lines in the penalization group. There were no statistically significant differences between the two groups. The success rates of penalization and patching treatments were 74 % and 76 %, respectively. There was no significant difference between the groups in terms of mean VA or line improvement. Approximately 35 % of the patching group and 30 % of the atropine group achieved stereo acuity of 400 seconds of arc by the end of the follow-up. In a randomized trial of atropine vs. patching for the treatment of moderate amblyopia, the Pediatric Eye Disease Investigation Group (PEDIG) (3) reported that 51 % of the patching group and 49 % of the atropine group achieved a VA of 20/25 or better. Furthermore, at the end of the follow-up, VA improved from baseline by a mean of 3.7 lines in the patching group and 3.6 lines in the atropine group. In another study "Randomized trial of atropine vs. patching for treatment of amblyopia for follow-up at age 10 years," PEDIG showed that patching and penalization with atropine resulted in comparable VA improvement in the amblyopic eye. Our results corroborate their study. In yet another study, PEDIG (2) showed that VA improved

from baseline by 3.16 lines in the patching group and 2.84 lines in the atropine group. The treatment success rates were 79 % in the patching group and 74 % in the atropine group. Simons (5) reported that atropine treatment may produce better binocular function than patching treatment. Our study showed that patching treatment and penalization with atropine have equivalent therapeutic effects for the treatment of moderate amblyopia in patients between 4 and 10 years of age.

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None declared.

### Conflict of interest

None declared.

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