



Original research

The role of Interactive Binocular Treatment system in amblyopia therapy

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Abstract

Purpose: To determine the role of Interactive Binocular Treatment (I-BiT™) as a complementary method of patching in amblyopia therapy.

Methods: In this randomized clinical trial study, 50 unilateral amblyopic children (25 male/25 female) between 3 and 10 years with either best corrected visual acuity (BCVA) $\leq 20/30$ in the amblyopic eye or a difference of BCVA ≥ 2 lines between the two eyes were included. They were randomly classified into the case and control groups (25 in each). Patching was recommended in both groups, and cases also received I-BiT™. Cases were asked to play I-BiT™ games through appropriate glasses with conjugate colored filters. Moving and fixed targets were shown to the amblyopic and non-amblyopic eyes, respectively. Playing games was continued 20 min in each session for 5 days a week within one month (total time: 6.6 h). Patching was continued for one month more in both groups to evaluate the continuous effect of I-BiT™. BCVA was measured at baseline, one month after beginning I-BiT™, and one month after cessation of I-BiT™.

Results: BCVA of amblyopic eyes in cases and controls were 0.34 ± 0.14 and 0.33 ± 0.17 LogMAR at baseline which improved to 0.17 ± 0.14 and 0.26 ± 0.17 at one month, respectively. The difference was significant in each group ($p < 0.001$ for cases and $p = 0.024$ for controls) with more improvement in the case group ($p < 0.001$). One month after cessation of I-BiT™, BCVA difference between the two groups was not statistically significant. There was no case with recurrence of amblyopia.

Conclusion: Based on our results, I-BiT™ seems to be effective in amblyopia therapy accompanied with patching. We recommend comparing I-BiT™ alone with patching in further studies.

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Keywords: Amblyopia; Interaction Binocular Treatment (I-BiT™); Patch therapy

Introduction

Amblyopia is a unilateral or infrequently bilateral decreased best corrected visual acuity (BCVA) with no organic

ocular lesion.^{1–5} According to the literature, amblyopia prevalence ranges from 0.70% to 5% in different reports.^{6–9} Authors have found an amblyopia prevalence of 2.30% in primary school children of Tehran, Iran (2013) with a diagnostic criterion of BCVA $\leq 20/40$.¹ Anisometropia and strabismus are the most common causes of amblyopia, and in some cases, both of them might be observed simultaneously.¹

Although patching of the dominant eye is the most effective known method of amblyopia therapy, it has some limitations, especially among children with less compliance.^{10,11} VA improvement needs a long term patching, and it may even last

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as long as 400 h; therefore, it needs the continuous cooperation of the child and his/her parents.¹⁰ In addition, patching might disrupt the binocular fusion of the child.¹²

Interactive Binocular Treatment (I-BiT™) has recently been introduced as a new method of amblyopia therapy.¹³ It works by looking through special glasses with red/green filters or shutter glasses with enhancing and reducing filters for amblyopic and non-amblyopic eyes in order to dissociate two eyes from each other.¹³ Although shutter glasses induce more foveal stimulation, they are expensive, and most families cannot afford them. Implementation of a virtual reality system by applying anaglyphic (red/green) filters encompasses I-BiT™ advantages with a lower cost.¹⁴ The mechanism is based on presenting different image conditions to each eye of the amblyopic child while both eyes are open. In this regard, moving targets are presented to the amblyopic eye in order to induce more foveal stimulation, and stable targets are shown to the non-amblyopic eye.

Rastegarpour presented the theory of the I-BiT™ mechanism in details, but its clinical efficiency for amblyopia treatment was not evaluated in his study.¹⁴

One advantage of the I-BiT™ method is its effectiveness at older age (>8 years old) due to the I-BiT™ ability to activate dormant cells of the visual cortex.¹⁵ Furthermore, there is no need to patch the dominant eye during I-BiT™ exercises, so children are more eager to play with its games. Moreover, the significant improvement of VA has been reported during 6 weeks of I-BiT™ playing, while visual improvement by patching needs at least several months.¹⁵ In addition, the condition of playing could be adjusted by contrast and illumination of images; the image can be rotated in all directions so that it is possible to conjugate with the child's pupillary distance and angle of ocular deviation as well.^{12,15} The clinical efficacy of I-BiT™ has been reported by Eastgate et al.¹² with VA improvement in 42% of their cases, and it was effective even in severe amblyopic children. Moreover, in small sample case series studies, the considerable VA improvement has been reported after a short period of time.^{13,16} Foss et al. reported the efficacy of I-BiT™ on more amblyopic cases (n = 75 patients). They compared three groups: playing I-BiT™ games, non I-BiT™ games, and I-BiT™ DVD video games, but they did not compare I-BiT™ effectiveness when it is accompanied with patching.¹⁷

Our purpose was to compare the effect of combined I-BiT™ and patch therapy with patching alone in unilateral amblyopic children.

Methods

In this randomized clinical trial, 50 unilateral amblyopic children (3–10 years) referring to the tertiary referral center from December 2014 to September 2015 were studied. The study was approved by the Ethics Committee of the School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran. An informed consent, which explained the details of our project, was signed by parents of these children before any intervention. This study conformed to all local rules and complied with the principles of the Declaration of Helsinki.

All unilateral functional amblyopic children with BCVA worse than 20/30 (0.30 Logarithm angle of resolution [LogMAR]) at least in one eye or a difference of two lines of Snellen between the two eyes were included in this study and randomly divided into the case (n = 25) and control (n = 25) groups. Cases had both patching and I-BiT™ games, while controls had only conventional patch therapy for one month. The I-BiT™ was stopped while patching was continued in both groups for one month longer.

Children with a history of penalization one month prior to the study, bilateral amblyopia, eccentric fixation, nystagmus, ocular deviation more than 10 prism diopter (pd), and organic amblyopia, as well as uncooperative children who could not play or those with mental and physical disability and systemic diseases were excluded from our study.

Randomisation

For this purpose, we used the permuted-block randomization method, with the block length varied between 2 and 6. It was generated by computer program, and the sequence of randomization was concealed from investigators.

Sample size

To have a power of 80% to detect 0.20 LogMAR difference between the two groups when the standard deviation of BCVA between them was assumed to be 0.25 LogMAR, a sample size of 25 in each group was calculated.¹⁶

Clinical assessment

Cycloplegic refraction was measured 30–45 min after instillation of one drop of Cyclopentolate 1% and Tropicamide 1% with 5 min interval.

BCVA was measured after 48–72 h of cycloplegia using a Yang Vision Tester instrument (SIFI Diagnostic S.P.A-Via Castellana, 70/e-31100 T revise-Italy) with the Snellen E-chart containing 5 letters in each line at a 6-m distance and daylight conditions. It was recorded based on each letter which equates to 0.025 LogMAR units.¹⁷

Ocular alignment was evaluated with alternative prism cover test (BCVA \geq 20/200) or Krimsky method (BCVA < 20/200) for both far (6 m) and near (33 cm) distances. In addition, the function of extraocular muscles was assessed through duction and version movements by the scale of –4 to +4 grades. Furthermore, eccentric fixation was evaluated by monocular visoscopic examination.

Finally, the anterior and posterior ocular segments were evaluated by slit lamp and indirect ophthalmoscope (HEINE BETA 200; US) in order to diagnose pathologic lesions.

Definitions

Cycloplegic spherical equivalent (SE) \leq –0.50 diopters (D), \geq +2.00D, and cylindrical power \geq 0.75D were

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