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# A combined therapy using stimulating auricular acupoints enhances lower-level atropine eyedrops when used for myopia control in school-aged children evaluated by a pilot randomized controlled clinical trial☆,☆☆

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**KEYWORDS**
Myopia;
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**Summary**
*Objective:* This study was designed to compare the reduction in myopia progression in patients treated with atropine eyedrops alone with patients treated with a combined treatment of atropine and stimulation of the auricular acupoints.
*Methods:* This study was a randomized single-blind clinical controlled trial. A total of 71 school-aged children with myopia, who fulfilled the eligibility criteria, were recruited. They were randomly assigned into three groups. These were 22 treated with the 0.25% atropine (0.25A) only, 23 treated with the 0.5% atropine (0.5A) only and 26 treated with 0.25% atropine together with stimulation of the auricular acupoints (0.25A+E). The differences in the post-treatment effects among these three groups were statistically assessed.

*Abbreviations:* D/Y, Diopter per year; IOP, Intraocular pressure; ALE, Axial length elongation.

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☆☆ Clinical trial registration number: NCT00457717 on http://clinicaltrials.gov.

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The primary outcome parameter was myopia progression, which was defined as diopter change per year (D/Y) after cycloplegic refraction measurement.

*Results:* The mean myopia progression of the 0.25A group was $0.38 \pm 0.32$ D/Y. No significant difference in mean myopia progression was found between the 0.5A ($0.15 \pm 0.15$ D/Y) and 0.25A+E ($0.21 \pm 0.23$ D/Y) groups. However, there was a markedly reduced myopia progression in the 0.25A+E group compared to the 0.25A group ($p < 0.05$). Furthermore, there was no statistical difference among these three groups in axial length elongation (ALE) of eye during this stage of the investigation.

*Conclusions:* This study demonstrates that there was efficacy in stimulating the auricular acupoints and this enhanced the action of 0.25% atropine as a means of myopia control. The result was an effect almost equal to that of 0.5% atropine alone. There is also a need that the ALE of the eye should be further investigated over a longer period using the combined therapy.



## Introduction

Myopia has become a worldwide public health issue in recent years. In the United States and Europe, the prevalence among adults is 20—50%,[1–3] while in several Asian countries such as Taiwan, Hong Kong and Singapore, the prevalence in young adults is 60—80%.[4–6] The rate of myopia progression is highest in children and the average age of stabilization of myopia is approximately 16 years.[7] Hence if myopia occurs at a relatively young age, there is a higher risk of high myopia that is more than 6.0 diopter (D), during adulthood. A prevalence survey conducted in 1995 among 11,178 school children in Taiwan revealed a myopia prevalence of 12% at six years of age and 84% for 16—18-year-old teenagers. Among the latter, 20% were high myopes.[8] Since high myopia is potentially associated with complications that may lead to blindness,[9,10] the prevention of myopia progression is very important, especially among young children.

The suggested mechanisms leading to the development of myopia include excessive accommodation and uncoordinated eye growth mediated by retinal signals in response to prolonged near work.[11,12] Environment—gene interaction is considered a major factor in myopia progression.[13] Actually, the genetic basis of myopia has not been fully explained as yet.[14] Useful treatments have been evaluated for many years. Contact lenses may flatten the cornea or retard axial elongation.[15] Adrenergic β-blocking drugs may reduce elevated intraocular pressure (IOP) in high myopia.[16] Bifocal lenses may reduce defective accommodative effort and improve retinal image quality in patients with high accommodative lag and thereby prevent potential aberrant eye growth.[17] However, these studies have all yielded unsatisfactory results with respect to the control of myopia progression.

Three randomized controlled clinical trials have shown that atropine eyedrops are able to retard myopia progression.[18] As a non-selective muscarinic antagonist, atropine may act through the muscarinic receptors to paralyze accommodation or it may have a direct effect on scleral growth.[19,20] Different concentrations of atropine eyedrops have been tried as a means of controlling myopia progression.[21] Although 0.5% atropine eyedrops have been found to have a greater effect than 0.25 or 0.1% atropine eyedrops, the photophobia caused by the 0.5% atropine eyedrops often results in poor compliance. In addition, there are possible side effects, which may include cataract formation and retinal toxicity and these factors are still unexplored in humans receiving long-term treatment.

Stimulation of the auricular acupoints has been described in several Chinese reports as an approach to treating myopia[22–24]; however, only low grade myopia (less than −3.0 D) was shown to be improved by acupuncture, auricular acupuncture or auricular acupressure in these studies. Furthermore, the efficacy of auricular acupoint stimulation has not been demonstrated using cycloplegic refraction in a randomized controlled clinical trial. A combined therapy of the auricular acupoints stimulation and atropine eyedrops can thus be considered as a new modality for the treatment of myopia. Therefore, we performed a randomized controlled clinical trial using cycloplegic refraction to compare this combined therapy with different levels of atropine eyedrops (0.25 and 0.5%) alone for the control of myopia progression.

## Materials and methods

### Study design and patient population

We undertook a single-blinded randomized controlled clinical trial to evaluate the efficacy of 0.25% atropine eyedrops combined with auricular stimulation in school-aged myopic children. The study protocol was approved by the Institutional Review Board (IRB) of China Medical University Hospital in Taiwan and informed consent was requested and obtained from all study participants. The school-aged children were recruited from a regional hospital in Hsinchu, Taiwan from July 2005 to 2006.

### Inclusion and exclusion criteria

We recruited children who came to our hospital for a first time inspection of visual acuity and were eligible under the following criteria. The inclusion criteria were: (1) all included patients, age from 6 to 15 years had myopia (spherical equivalent greater than −0.5 D) after cycloplegic refraction; (2) the astigmatism and anisometropia were less than 2.0 D and (3) their intraocular pressure was less than 21 mmHg. The exclusion criteria were: (1) the presence of a related disease such as infection, ulceration, eyelid disease, ocular disorders and auricular disorders, (2) individuals with amblyopia or strabismus, (3) individuals who were receiv-