

## EFFICACY AND SAFETY OF LOW DOSE ATROPINE 0.01% IN SLOWING OF PROGRESSION OF MYOPIA

Dr. Shalini Gupta<sup>1</sup>, Dr. Poonam Gupta<sup>2</sup>, Dr. Rashi Verma<sup>3</sup>, Dr. Basudeb Gosh<sup>4</sup>, Dr. Rakesh Bhardwaj<sup>5</sup>

<sup>1,2,3,4,5</sup> Department of Ophthalmology, Baba Saheb Ambedkar Hospital & Medical College, Rohini, New Delhi

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**Corresponding author:** Dr. Poonam Gupta

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### Abstract

**Background:** Myopia, commonly referred to as short sightedness is a form of refractive error and is a very common cause of visual disability throughout the world.

**Methods:** Hospital based prospective study conducted on 100 patients of Myopia attending to Department of Ophthalmology.

**Results:** There was no significant difference in the age, gender distribution, baseline myopia progression or follow-up duration between patients who used night application compared with daytime atropine. Effectiveness was better with daytime application.

**Conclusion:** 1% atropine eye drops were well tolerated and efficacious for the retardation of progressive myopia in Indian eyes. Effectiveness was better with daytime application. Further studies are necessary to assess the role of 1% atropine in the rapid progressors and patients poorly responding to low-dose atropine.

**Keywords:** Myopia, Atropine, low dose.

### Introduction

Myopia, commonly referred to as short sightedness is a form of refractive error and is a very common cause of visual disability throughout the world. The condition may present as blurred distance vision, eye rubbing and squeezing of the eyes. School myopia commences around 5-15 years of age and tends to stabilize in the late teens and is mainly thought to be idiopathic. High myopia may be associated with myopic macular degeneration, cataract, glaucoma, peripheral retinal changes (such as lattice degeneration, retinal holes and tears) and retinal detachment.<sup>1</sup>

Although, the prevalence of myopia varies by the country, age and by ethnic group it is a major cause of visual impairment in both the developed and the developing world.<sup>1</sup> The prevalence of myopia has been reported to be as high as 70-90% in some Asian population with Taiwan reporting a myopic prevalence of 84% among 16-18 - years - old high school students.<sup>2,3</sup>

Uncorrected refractive errors are the most common cause of visual impairment and second major cause of avoidable blindness in India. According to the World Health Organization (WHO)-NPCB survey in 1989, 1.49% population in India is blind of which 7.35% is due to refractive errors.<sup>4</sup> The proportion of blindness due to refractive error increased to 19.7% in the NPCB-National Blindness Survey even though the overall prevalence of blindness was reduced to 1.1%.<sup>5</sup> Three fourth of visual impairment was attributed to refractive errors in the same survey.

Both concentration and frequency of atropine have been modified to minimize the side effects while trying to maintain the benefits. Chou et al. (1997) proposed that application of 0.5% atropine eye drops once per day was effective for slowing the progression of refractive error, even in children with severe myopia.<sup>6</sup> In 1999 it was suggested that because daily drops of 0.1% and 0.25% atropine were well-tolerated, those concentrations could be used initially to control the progression of myopia in children with rapid progression or in those who tended to have severe or early-onset myopia.<sup>7</sup>

### Material and method

**Study design:** Hospital based prospective study.

**Study population:** 100 patients of Myopia attending to Department of Ophthalmology.

### Inclusion Criteria:

- Age: 6 to 15 years
- Myopia  $\geq$  2.00 D (cycloplegic refraction; spherical equivalent)
- No prior or current treatment for preventing myopia progression (bifocals / progressive addition lenses / orthokeratology)

### Exclusion Criteria:

- Best corrected visual acuity  $<$  0.5 (6/12)
- Refractive Myopia
- Astigmatism  $\geq$  1.5 D
- Amblyopia

- Ocular hypertension / Glaucoma
- Prior intraocular surgery
- Allergy to atropine eye drops
- Systemic diseases associated with myopia such as Marfan syndrome, Stickler syndrome
- History of cardiac or significant respiratory diseases
- Lack of consent for participating in the study

#### Study Methodology

A total of 100 children of ages 6-16 years were randomized to two groups.

Intervention group was receiving atropine 0.01% once daily in each eye for one year. Control group will not receive any medications.

Follow up visits was scheduled every three months in Phase 1. Subsequently, medication was stopped and the study patients will be followed up every 3 months for one year. The progression of myopia (change in refractive error and axial length) was compared in the two groups by objective methods.

#### Assessment Tool

Change in refractive error and axial length

#### Data Analysis

Data were recorded on a Performa. The data analysis was computer based; SPSS-22 will be used for analysis. For category variables chi-square test was used. For continuous variables independent samples't-test was used.  $p$ -value  $<0.05$  was considered as significant.

#### Results

**Table 1:** Socio-demographic variable

Mean age	10.25±2.35 Yrs
Male : Female	56: 44
Hindu : Muslim	93:7

We included 100 eyes of myopes in this study with the mean age of 10.25±2.35 Yrs (range 5–16). The gender distribution was 44 girls and 56 boys.

**Table 2:** Comparison of the patients continuing nighttime atropine with patients switched to daytime atropine

Variable	Morning time (n=50)	Night time (n=50)	p-value
Base line myopia(D)	-5.8±3.1	-4.7±1.7	0.01
Base line progression (D)	-0.6±0.5	-0.7±0.8	0.85
Final progression(D)	-0.2±0.3	-0.2±0.3	0.99

#### Discussion

Atropine is the only medication that has been demonstrated to be consistently effective in slowing myopic progression<sup>8,9</sup> Once myopia has developed in a child, the rate of progression is estimated to be around -1 D per year in East Asians and around -0.5 D per year in Caucasians.<sup>10</sup> Several years later, a significant proportion of these children will reach the definition of high myopia. Therefore, intervention to prevent myopia progression early on in myopic children is urgent and important. The higher concentrations of atropine such as 1% or 0.5% have been shown to be very effective in retarding myopia progression, but the high rate of photophobia side-effect (in up to 100%) has been associated with high dropout rate (16–58%)<sup>11</sup> In addition, there are concerns regarding potential longterm systemic or ocular side effects. Besides, rebound effect after atropine discontinuation has also been described, and is particularly notable in higher concentration of atropine. Recently, several publications from Asia have reported efficacy of 0.01% atropine in myopia control while having lower rates of side effects. As a result, there have been renewed interests in the clinical implementation of atropine for myopia control.<sup>9-11</sup>

#### Conclusion

1% atropine eye drops was well tolerated and efficacious for the retardation of progressive myopia in Indian eyes. Effectiveness was better with daytime application. Further studies are necessary to assess the role of 1% atropine in the rapid progressors and patients poorly responding to low-dose atropine.

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