



## Original Research Article

## Placebo-controlled, safety and efficacy study of topical atropine (0.01%) in myopic children

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## ABSTRACT

**Purpose:** To evaluate the safety and efficacy of (0.01%) topical atropine in controlling the progressive myopia in children.**Materials and Methods:** Clinical study entitled as Placebo-controlled, safety and efficacy study of (.01%) topical atropine in children with progressive myopia. In this prospective case control study 80 children with regular follow-up were divided into a subgroup of 40 children who received atropine eyedrops (0.01%) every night, and a subgroup of 40 children, who remained untreated, served as controls.

The changes in refraction and axial length of 160 eyes in 80 children were collected and compared for patients treated with 0.01% atropine eyedrop and those with 0.5% carboxymethylcellulose eye drops (control) at 6 months, 12 months and 24 months.

The initial spherical equivalent of refractive status range was between –1.5 and –14.25 DS.

**Result:** Mean myopia progression for the group of patients treated with 0.01% atropine eye drop was  $-0.34 \pm 0.43$  DS/year, significantly lower than that of the control group of  $-1.08 \pm 0.57$  DS/year and axial length  $0.12+0.23$ mm/year (cases) compared to controls  $0.48+0.29$ mm/year with p value <0.05.**Conclusion:** 0.01% atropine is effective in controlling progression of myopia in children age group 5-16 years with no side effects.© This is an open access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>) which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

## 1. Introduction

Myopia is one of the common eye pathology in humans.<sup>1</sup> Aristotle first observed about myopic persons blinks very frequently and they tend to read and write from very near distance.<sup>2</sup> In 1761, Morgagni appear to prove about eyeball's axis lengthening in myopia. Guerin also proposed relationship between increased accommodative effort and myopia. In 1864, Donders coined the hypothesis of hereditary effect of myopia. After three years, Cohn proved that with increase in school attendance there is proportional increase in degree and number of near sightedness. Currently, number of myopic people around the world is estimated to be 1.3 billion.<sup>3</sup> latest reports are

suggesting that incidence are still growing of this lifestyle illness.<sup>4</sup> This is also appears to be linked to specific human races and societies in whom more civilizational development has occurred. There is also an impact genetics and environmental conditions.

How near-sightedness develops is still unclear. Chronic near work causing excessive accommodation and uncontrolled release of some retinal mediators to stimulate eyeball length during excessive near work may be the cause.<sup>5</sup> Convergence during near work instead of accommodation may be the cause of eyeball lengthening.<sup>6</sup> Additionally, genetics also could be the causative factor.<sup>5-7</sup>

During the preceding decades, a noteworthy increase in myopia prevalence has been reported in many countries, including in Southeast Asia. This increase, which has occurred over only 25 to 50 years, has focused renewed

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attention on the crucial effect of environmental factors and has prompted a growing interest in pharmacological treatments that can help stop the progression of myopia.<sup>8–14</sup>

Heritability has been identified for more than a century as an influencing factor, and its link to myopia has been confirmed by many genetic and epidemiological studies during the last 50 years.<sup>14–24</sup>

### 1.1. Atropine

Atropine is a parasympatholytic drug which act as antagonist of muscarinic receptor. Atropine blocks the stimulation of the parasympathetic nervous system. In therapeutic doses, atropine has negligible effect on central nervous system. In doses which are toxic, it induces anxiety, hyperexcitability, disorientation, hallucinations, delirium, and psychotic states. Therefore atropine is used to prevent nausea, vomiting, and increasing saliva secretion in motion sickness.

Antimuscarinics, when administered systematically and conjunctively, they act by blocking M receptors of pupillary sphincter, dilates pupil and cause photo-phobia. On ciliary muscle it acts by relaxing them and cause cycloplegia which in result causes disruption of near sight. Atropine is mainly used as a mydriatic and cycloplegic in ophthalmological diagnostic procedures. Atropine also prevents adhesions in between iris and lens inflammations of the iris and cornea. It can raise IOP in person with closed angle glaucoma by causing pupillary block.

Questions regarding mechanism of action of prevention of myopia progression by atropine are (1) Exact location of action of atropine in preventing myopic progression? Is it retina, sclera, choroid? (2) Are muscarinic receptors site of action, if yes, which receptors are involved (m1, m2, m3, m4, m5), and their location ?

Animal studies have suggested about neurochemical signalling cascade at retinal level to be cause of myopia. Sign of defocus changes seen in amacrine cells of retina are in support of this.<sup>25</sup> Other studies are also there which are suggesting that muscarinic antagonist are controlling initiation of myopia at scleral level.<sup>26</sup>

Previously it was thought that the site of action could be sclera instead of retina because of relatively high dose of atropine was required in experimental studies to control myopia progression. ATOM studies have established that progression of myopia can be controlled even at lower concentrations of atropine.<sup>27–29</sup> So according to these studies retina seems to be the site of action of atropine.

Experimentally induced myopia can be prevented effectively by highly selective muscarinic antagonists MT3 (M4 receptor antagonist) and MT7 (M1 receptor antagonist) as demonstrated by experimental evidences from mammal free shrew even at nanomolar concentrations.<sup>30</sup> One more evidence about prevention of choroidal thinning by MT3 (M4 receptor antagonist) in chicks by inhibiting progression

of induced myopia.<sup>31</sup> These animal studies are suggesting that retina is the site of action rather than choroid or sclera.

M1-specific antagonist and highly selective M4 antagonists are implicated in inhibiting myopia progression by some studies conducted<sup>30–32</sup> This strongly indicates that both the M1 and M4 muscarinic receptor signalling pathways are involved in the mechanism by which atropine prevents myopia. Atropine was also found to control the growth of eyeball by affecting release of dopamine neurotransmitter from cellular stores.<sup>33</sup>

## 2. Material and Methods

The present clinical study entitled “Placebo-controlled, safety and efficacy study of topical atropine (.01%) in myopic children” was conducted in the Upgraded Department of Ophthalmology, JLN Medical College & Hospital, AJMER.

It is an clinic-based, placebo controlled effectiveness study. All children younger than 18 years of age presenting with progressive myopia were eligible for the study.

### 2.1. Sample size

In our study we have included all the children age 6-18 years presenting in Eye OPD at Upgraded Department of Ophthalmology, JLN Medical college & Hospital, AJMER with progressive myopia fulfilling all the inclusion criteria from time period August 2017 to November 2017 and follow-up done till November 2019.

### 2.2. Inclusion criteria

1. Age: 6 to 18 years.
2. Children with spherical equivalent (SE)  $>-1D$  and SE progression rate  $\geq 1D/year$  under cycloplegic conditions.

### 2.3. Exclusion criteria

1. Myopia related to retinal dystrophies or collagen syndromes, and developmental disorders
2. Amblyopia
3. Ocular hypertension / Glaucoma
4. Prior intraocular surgery
5. Allergy to atropine eye drops
6. Systemic diseases associated with myopia such as Marfan syndrome, Stickler syndrome
7. History of cardiac or significant respiratory diseases
8. Lack of consent for participating in the study.

## 3. Materials and Methods

Eligible children and parents received a patient information leaflet followed by oral consultation. After providing written informed parental consent (parents or legal guardians for children  $\leq 12$  years), participants received a prescription

of atropine eye drops 0.01% and control group 0.5% carboxy methyl cellulose eye drops. Both eyes were treated by atropine eye drops once daily before bedtime by the parent. The study and protocol adhered to the tenets of the Declaration of Helsinki, and were approved by the Medical Ethics Committee of the J L N Medical College Ajmer.

After taking informed consent, all the subjects were asked a detailed ocular and systemic history and they undergo a thorough ophthalmic examination.

1. Preliminary eye examination include visual acuity
2. [Distant and Near vision].
3. Intraocular pressure was recorded using Schiotz tonometer / non contact tonometer.
4. Fundus examination was done by using Direct ophthalmoscope and Indirect ophthalmoscope.
5. The refractive error is measured with a auto refractometer; and in very young children refractive error was determined by performing retinoscopy under mydriatic and cycloplegic 2% homatropine by Priestley smith mirror retinoscope and streak retinoscope and lenses according to standard protocols. The same devices were used throughout the study period.
6. Spherical equivalent is calculated using the standard formula: (SE=sphere+1/2 cylinder). Axial length was measured with the A scan at each visit.
7. At baseline, full cycloplegia is obtained 90 minutes after administration of 2% Homatropine eye drops.

### 3.1. Follow up

A standardized ophthalmological examination is performed at 1 month, 6 months, 12 months and 24 months after initiation of atropine treatment and in control group 0.5% CMC eye drop.

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3. Intraocular pressure was recorded using Schiotz tonometer / non contact tonometer.
4. Fundus examination was done by using Direct ophthalmoscope and Indirect ophthalmoscope..
5. The refractive error is measured with a auto refractometer; and in all children refractive error was also determined by performing retinoscopy under mydriatic and cycloplegic 2% homatropine by Priestley smith mirror retinoscope and streak retinoscope and lenses according to standard protocols. The same devices were used throughout the study period..
6. Spherical equivalent is calculated using the standard formula: (SE=sphere+1/2 cylinder). Axial length was measured with the A scan at each visit.

### 3.2. Risk factors and adverse events

At baseline, and after 3, 6 and 12 months after the start of atropine 0.01% eye drops children were examined and parents were asked about any adverse effect in form of blurring of vision, photophobia, decreased near vision, redness and systemic side effects.

## 4. Observation and Results

Table 1 shows there was no change in spherical equivalent and axial length of children treated with 0.01% atropine eye drop at 1 month interval but on subsequent visits children showed increase in average SE by 0.39 D, average axial length by 0.19 mm at 12 months and 0.75D in SE & 1.31mm in average axial length at 24 months follow up ( $p < 0.05$ ).

Table 2 shows there was no change in spherical equivalent and axial length of children treated with 0.5%cmc eye drop (group B) at 1 month interval but on subsequent visits children showed increase in average SE by 1.41 D, average axial length by 0.55mm at 12 months and 2.49 in SE & 1.09 mm in average axial length at 24 months follow up ( $p < 0.05$ ).

Table 3 shows comparison between Group A (cases) and Group B (control) for changes in spherical equivalent and axial length on follow up at various time interval which shows there is more progression in Group B (control) as compared to Group A (cases) with  $p$  value  $< 0.05$ .

## 5. Discussion

In our study in Group A (cases) the age of patients varied between 5-14 years and in Group B (controls) the age of patients varied between 7-13 years. Mean age in Group A (cases) was  $10.03 \pm 2.281$  years and in Group B (controls) it was  $10.15 \pm 1.673$  years.

Different studies done by Chau et al. 2006 (6-12 year), Chia et al. 2012 (6-12 Year), Yi et al. 2015 (7-12 year) and Wang et al. 2017 (5-10 years) have also included this age group.

In our studies there were 52.5% male, 47.5% female in Group A (cases) while in Group B (controls) there was 65% male and 35% female which was statistically significant with  $p$  value  $< 0.05$ .

In our study we studied 80 children and allocated them randomly into Group A (case) 40 children and Group B (controls) 40 children, though this sample size was much smaller as compared with studies done by various authors in which sample size varied between 126-438.

In our study children treated with atropine 0.01% eye drop Group A showed less progression of myopia with change in SE ( $-0.34 \pm 0.43$  D/y) and axial length ( $0.12 \pm 0.23$  mm /y) as compared with change in SE ( $-1.08 + 0.57$  D/y) and axial length ( $0.48 \pm 0.29$  mm/y) in Group B (control) and is found statistically significant with  $p$  value  $< 0.05$ .

**Table 1:** Follow up of group A (cases) (refractive error and axial length)

Time interval	Average Spherical Equivalent (DS)	Average Axial Length (mm)
Baseline	- 4.7 ± 2.5	24.98 ± 0.665
1 Months	- 4.7 ± 2.6	24.98 ± 0.665
6 Months	- 4.78 ± 2.58	25.02 ± 0.656
12 Months	- 5.09 ± 2.62	25.17 ± 0.662
24 Months	- 5.45 ± 2.67	25.29 ± 0.677

**Table 2:** Follow up of group B (Control) (Refractive error and axial length)

Time interval	Average Spherical Equivalent (DS)	Average Axial Length (mm)
Baseline	- 3.09 ± 1.26	24.55 ± 0.417
1 Months	- 3.09 ± 1.26	24.55 ± 0.417
6 Months	- 3.7 ± 1.23	24.8 ± 0.470
12 Months	- 4.5 ± 1.22	25.1 ± 0.478
24 Months	- 5.58 ± 1.25	25.64 ± 0.477

**Table 3:** Status of refractive error and axial length during follow up in both groups

Time Interval	Baseline						P value
	Group A (Cases)			Group B (Control)			
Group	RE	LE	Mean + SD	RE	LE	Mean + SD	
Axial Length	24.87±0.732	24.9±0.708	24.98±0.665	24.55±0.461	24.45±0.597	24.55±0.417	0.016
Spherical Equivalent	-4.63±2.678	-4.73±2.491	4.7±2.5	-3.04±1.319	-3.09±1.109	-3.09±1.26	0.019
<b>At 6 Months</b>							
Group	Group A (Cases)			Group B (Control)			P value
	RE	LE	Mean + SD	RE	LE	Mean + SD	
Axial Length	24.99±0.671	25.04±0.663	25.02±0.656	24.8±0.470	24.81±0.398	24.8±.470	0.021
Spherical Equivalent	-4.73±2.732	-4.78±2.562	4.78±2.58	-3.68±1.297	-3.69±1.094	-3.7±1.23	0.015
<b>At 1 years</b>							
Group	Group A (Cases)			Group B (Control)			P value
	RE	LE	Mean + SD	RE	LE	Mean + SD	
Axial Length	25.14±0.672	25.19±0.674	25.17±0.662	25.17±0.479	25.17±0.399	25.1±0.478	0.016
Spherical Equivalent	-5.04±2.771	-5.09±2.585	5.09±2.62	-4.52±1.283	-4.52±1.148	-4.5±1.22	0.009
<b>At 2 years</b>							
Group	Group A (Cases)			Group B (Control)			P value
	RE	LE	Mean + SD	RE	LE	Mean + SD	
Axial Length	25.26±0.683	25.32±0.687	25.29±.677	25.62±0.531	25.66±0.450	25.64±.477	0.012
Spherical Equivalent	-5.41±2.843	-5.43±2.609	5.45±2.67	-5.58±1.332	-5.63±1.174	-5.58±1.25	0.016

This result is also supported by study done by Yam et al. (2018) in which 0.01% atropine group showed change in SE (-0.59 ± 0.61 D/y) and in axial length (0.36 ± 0.29 mm/y) and placebo group showed change in SE (-0.81 ± 0.53 D/y) and in axial length (0.41 ± 0.22 mm/y).

## 6. Conclusion

This study was conducted in the Upgraded Department of Ophthalmology, J.L.N. Medical College, Ajmer (Rajasthan), India. Our study was a case - control, prospective and clinical based study.

The study included 80 children who were allocated randomly as Group A (cases) and Group B (control) with 40 - 40 children in each group respectively. Group A (cases)

were given commercially available 0.01% atropine drops and Group B (control) were given 0.5% CMC eye drops for use at night only to see the effect of 0.01% atropine eye drops on progression of myopia in children. The effects were assessed by change in spherical equivalent and axial length at 6 months, 12 months and 24 months.

1. In our study the mean age in Group A (cases) was  $10.03 \pm 2.281$  years and in Group B (control) it was  $10.15 \pm 1.673$  years. There were 21 (52.5%) male, 19 (47.5%) female in Group A (cases) while in Group B (control) there were 26 (65%) male 14 (35%) female.
2. Sample size in our study was 80 children. Which were divided into 40 children Group A (cases), and 40 children Group B (control).
3. In our study we used 0.01% concentration of atropine eye drop as there were less side effects compared to other higher concentration of atropine eye drop like difficulty in near vision, photophobia due to mydriasis. So, there was no interference in normal life work and study of children.
4. In our study children treated with atropine 0.01% eye drop Group A (cases) showed less progression of myopia ( $-0.34 \pm 0.43$  D/y) as compared with Group B (control) ( $-1.08 \pm 0.57$  D/y) with p value  $<0.05$  which was found statistically significant.
5. In our study Group A (cases) showed less increase in axial length  $0.012 \pm 0.23$  mm/y as compared with Group B (control)  $0.48 \pm 0.29$  mm/y with p value  $< 0.05$  which was also found statistically significant.
6. The following conclusion can be drawn from the present study :
7. Application of 0.01% atropine eye drop once at night is effective in controlling progression of myopia in children from age 5-16 years.
8. No side effects found related to accommodation loss and pupillary dilatation in concentration as low as 0.01% of atropine eye drop.
9. There is no adverse effect on daily life work and study work of children treated with 0.01% atropine eye drops.
10. Further evaluation is needed regarding rebound effect after stoppage of use of 0.01% atropine eye drops.

## 7. Source of Funding

None.

## 8. Conflict of Interest

The authors declare that there is no conflict of interest.

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