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The effect of low dose atropine 0.01% in myopic children attending Tripura Medical College, a tertiary care hospital.

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Abstract

Background: Myopia is an increasingly prevalent refractive disorder among children and is associated with a higher risk of vision-threatening ocular complications later in life. Low-dose atropine (0.01%) has emerged as a promising intervention to retard myopia progression while minimizing adverse effects. This study evaluated the efficacy and safety of 0.01% atropine eye drops in myopic children attending a tertiary care hospital. ***Methods:*** This experimental study was conducted in the Department of Ophthalmology, Tripura Medical College and Dr. BRAM Teaching Hospital, Agartala, from April 2023 to October 2024. A total of 90 children aged 6–14 years with myopia were enrolled and divided into two groups: 45 children received spectacle correction along with once-daily 0.01% atropine eye drops (case group), while 45 children received spectacle correction alone (control group). Comprehensive ophthalmic examinations, including cycloplegic refraction and keratometry were performed at baseline and during follow-up. Statistical analysis was carried out using SPSS version 22.0, with $p<0.05$ considered statistically significant. ***Results:*** Baseline demographic and clinical characteristics were comparable between the two groups. The atropine-treated group demonstrated significantly lower progression of spherical refraction in both eyes compared with the control group ($p<0.05$). Mild adverse effects were reported in seven (15.6%) children receiving atropine, with photophobia being the most common complaint. No serious ocular or systemic adverse events were observed. ***Conclusion***: Low-dose (0.01%) atropine is a safe and effective treatment for slowing myopia progression in children by significantly reducing spherical equivalent progression. Its favourable safety profile supports its routine clinical use, although larger studies with longer follow-up are warranted to confirm long-term efficacy and safety.

Keywords: Myopia, Low-dose atropine, 0.01% atropine, Children, Myopia progression, Spherical equivalent refraction, Refractive error, Paediatric ophthalmology.

INTRODUCTION

Myopia is an abnormal condition breaking the emmetropization process progressing rapidly from onset at an early age and continuing until early adulthood. The most common definition of myopia is spherical equivalence −0.5 D or greater [1-3]. Myopia has become a critical public health problem among both children and adults, especially in some Asian countries such as India, China and Singapore. A 2016 review predicted that approximately half of the world's population will have myopia by 2050, with 10% being high myopia [4]. High myopia, defined as a refractive error more than -6.0 diopters (D) or ocular axial length of more than 26–26.5 mm, is associated with an increased risk of developing vision-threatening retinopathies including retinal detachment, choroidal neovascularization, chorioretinal atrophy and macular atrophy [5,6]. Following a similar trend to the worldwide data, the prevalence of myopia among school children in India has increased from 5.6% in 2002 to 13.1% in 2015 [7,8]. Myopia is a risk factor for myopic maculopathy, retinal detachment, cataract and glaucoma in adult life and the risk increases with the degree of myopia. All these conditions are more challenging to treat than myopia itself, and reducing the risk for any of them requires interventions to slow myopia progression and thus decrease a child's severity of myopia in the long term rather than correct it optically with spectacles. Strategies to control progression of myopia are particularly meaningful in the context of WHO initiatives to eliminate preventable causes of blindness [9-11].

The currently considered therapies for myopia include optical correction including concave spectacle lenses, contact lenses, additional time spent outdoor, and pharmaceutical agents such as topical atropine. Topical atropine has emerged as the most effective and promising treatment modality in myopia control for over several decades. Previous reviews and meta-analyses reported that among various treatment options available, topical atropine shows a maximum reduction in myopia

progression (MP) [12]. The use of high concentration atropine eye-drops (0.5–1.0%) for the treatment of myopia is well documented [13]. More recently, the prescription of low-dose atropine eye-drop preparations (0.01%) for the treatment of myopia in children has gained popularity. Low-dose atropine has several advantages over higher concentrations including lower rebound axial growth and refractive error following treatment cessation and lower incidences of side-effects such as allergic reactions, glare and near visual loss compared with higher concentration preparations whilst still showing efficacy in slowing the progression of myopia [14,15]. Recently, different studies have shown that low-dose (0.01%) atropine has a better treatment to side-effect ratio and is an effective and safe treatment modality in myopia control when compared to its higher doses. But to date, there is paucity in the literature concerning studies that have directly evaluated the lower concentration of atropine (0.01%) against a placebo [16].

Atropine at low concentration has been shown to be safe and effective in slowing myopia progression in children of Chinese ethnicity, but its safety and effectiveness in Indian-derived populations has not been adequately assessed in a controlled trial [17]. The objectives of the study are to see the effect of low dose atropine 0.01% in myopic children aged between 6-14 years in the form of:

1. Change in the refractive error between each visit in the form of spherical equivalent.
2. Change in the keratometric value in Dioptric power in each visit.

MATERIALS AND METHODS

The present experimental study was conducted in dept of Ophthalmology, Tripura medical college & Dr. BRAM teaching Hospital, Agartala from April 2023 to Oct 2024. The study was done after clearance from the ethical committee of the institute. The study included children with diagnosed myopia and two groups were formed i.e.:

Group- I: Children after prescribing the spectacle was enrolled for once daily dosing of atropine 0.01% eye drops.

Group- II: Those children after prescribing the spectacle correction without atropine eye drops was kept as control.

1. Children between 6 years to 14 years were taken as study subjects as it was easier to monitor them as well as they are of school going age and can easily identify the alphabets on the Snellen's visual acuity chart.

Sample size: Calculated to total 90 considering the confidence interval 95%, power 95% with effect size (d) 0.8 (difference in spherical equivalent between study and control group) [12], that is 45 numbers of patients in each group considering 5% dropout. The sample size calculation done by using G power sample size calculation software.

Sampling procedure: Nonrandom convenience sampling.

Inclusion criteria:

1. Children with Myopia.
2. School going children age between 6 to 14 years.

Exclusion criteria:

1) Not willing to give consent.
2) Child with other associated ocular disorder.
3) Child with any systemic disease.
4) Not willing to come for follow-up.
5) Children with uniocular myopia, trauma, amblyopia was excluded from the study.
6) Allergic to atropine

Operational definition:

Myopia: Myopia also known as short sightedness, is a type of refractive error in which parallel rays of light coming from the infinity are focussed in front of retina when accommodation is at rest. Myopic patients are unable to see the far objects clearly.

Study tools:

1. Predesigned pretested proforma.
a) Socio-demography
b) Anthropometry measurement
c) Ocular findings
2. Autorefractometer (Topcon KR-800).
3. Cycloplegic drops Homatropine2%.

4. Atropine: Atropine is used basically for cycloplegia, which paralyze the accommodation reflex temporarily. Since atropine causes dilatation of pupil which can lead to blurred vision, increases sensitivity to sunlight and sometime it also causes stinging sensation. To avoid all these complications the drop will be given at lower concentration 0.01% and to be instilled only at night time.

Data collection procedure: Children with myopia were enrolled for the study. All the children were taken brief history and comprehensive eye examination was done, including autorefraction & cycloplegic refraction to find out the refractive status. After taking the unaided visual acuity, nondilated autorefraction and keratometry reading were taken. Then the pupils were dilated for cycloplegia with homatropine 2% (1 drop) instilled every 15 minutes apart for 4-5 times till we obtain the full dilatation. Cycloplegia was considered full when the pupil will be fixed and minimum 6 mm in diameter. After obtaining the cycloplegia objective refraction with retinoscope was performed 30 minutes after the last administration of cycloplegic eyedrops. Subjective refraction was done after 7 days and final power of spectacle was given based on cycloplegic refraction and clinical findings. Spherical equivalent refractive error (SER) was calculated as sphere + ½ cylinder. Parents were asked to complete an extensive questionnaire including questions about the duration of time spend in a variety of near work, indoor and outdoor activities from reading to playing. Follow up was done at 6-month interval for 18 months.
Data was collected and subjected to statistical analysis.

Statistical analysis: Data so collected was tabulated in an excel sheet, under the guidance of statistician. The means and standard deviations of the measurements per group were used for statistical analysis (SPSS 22.00 for windows; SPSS inc, Chicago, USA). Difference between two groups was determined using t test as well as chi square test and the level of significance was set at $p < 0.05$.

RESULTS

A total of 90 children were enrolled, with 45 participants in each group. Females predominated in both groups. The majority of participants belonged to the 12–14-year age group (table 1).

Table 1. Demographic characteristics of the study subjects

Variable	Case (n=45)	Control (n=45)
Gender		
Female	29 (64.4%)	27 (60.0%)
Male	16 (35.6%)	18 (40.0%)
Age group (years)		
6–8	11 (24.4%)	7 (15.6%)
>8–10	11 (24.4%)	7 (15.6%)
>10–12	7 (15.6%)	4 (8.9%)
>12–14	16 (35.6%)	27 (60.0%)

Baseline UCVA was comparable between the two groups (p>0.05). The most common presenting visual acuity in both groups was 6/36.

Table 2. Baseline uncorrected visual acuity (UCVA)

UCVA	Case n (%)	Control n (%)	p value
6/12	4 (8.9)	1 (2.2)	0.29
6/18	5 (11.1)	5 (11.1)	
6/24	6 (13.3)	14 (31.1)	
6/36	20 (44.4)	21 (46.7)	
6/60	10 (22.2)	4 (8.9)	

Spherical refraction showed less progression in the atropine group, although baseline values were comparable (table 3).

Table 3. Changes in spherical refraction

Eye	Group	Baseline	6 Months	12 Months	18 Months	Mean Change (Baseline–18 Months)	p value
Right	Case	-2.22±0.63	-2.40±0.61	-2.58±0.60	-2.76±0.58	0.54 D	**0.021***
	Control	-2.03±0.52	-2.33±0.54	-2.63±0.56	-2.92±0.57	0.89 D	
Left	Case	-2.25±0.61	-2.43±0.60	-2.61±0.59	-2.80±0.58	0.55 D	**0.047***
	Control	-1.93±0.87	-2.18±0.86	-2.43±0.85	-2.68±0.84	0.75 D	

*: statistically significant

Progression of spherical equivalent refraction was significantly lower in the atropine-treated group than in the control group (table 4).

Table 4. Changes in spherical equivalent refraction (SER)

Eye	Group	Baseline	6 Months	12 Months	18 Months	Mean Change (Baseline–18 Months)	p value
Right	Case	-2.54±0.46	-2.71±0.50	-2.87±0.55	-3.04±0.60	0.50 D	**0.039***
	Control	-2.47±0.43	-2.72±0.48	-2.97±0.53	-3.22±0.57	0.75 D	
Left	Case	-2.52±0.60	-2.69±0.60	-2.86±0.60	-3.03±0.60	0.51 D	**0.044***
	Control	-2.30±0.76	-2.55±0.75	-2.80±0.74	-3.05±0.74	0.75 D	

*: statistically significant

Keratometric measurements remained stable throughout the 18-month follow-up in both groups, indicating that the intervention had no significant effect on corneal curvature compared with the control group (table 5).

Table 5: Change in keratometry

Eye	Group	Baseline	6 Months	12 Months	18 Months	Mean Change (Baseline–18 Months)	p value
Right	Case	44.09±0.19	44.11±0.18	44.18±0.12	44.30±0.09	0.21	0.64
	Control	44.14±0.18	44.19±0.14	44.20±0.17	44.26±0.10	0.12	
Left	Case	44.10±0.18	44.18±0.16	44.20±0.11	44.27±0.16	0.17	0.82
	Control	44.17±0.19	44.20±0.18	44.23±0.19	44.31±0.13	0.14	

Seven (15.6%) children in the atropine group reported mild adverse effects. Photophobia was the most frequent complaint, followed by headache and dry or irritated eyes. None of the participants discontinued treatment during the study. Minimum adverse effects and no serious ocular or systemic complications were observed (table 6).

Table 6. Adverse effects among atropine-treated children (n = 45)

Adverse effect	N	%
Photophobia	4	8.9
Headache	2	4.4
Dry/irritated eye	1	2.2
Total experiencing adverse effects	**7**	**15.6**

DISCUSSION

There are published literatures using atropine drops, but the concentrations used were high and there are limited studies using 0.01% strength. Considering the existing paucity in the literature from the Indian-sub-continent, the present study was conducted to analyse the benefits of low dose atropine (0.01%) concentration in slowing down the progression of myopia. In this study; females were comparatively more as compared to males in case well as control group. Equal distribution of male and female was revealed by Neena R et al [18] in their study. Shifei Wei et al [19] in their study revealed more males as compared to females. This might be due to difference in study area and design. Maximum subjects were from age group of 12-14 years in both and control group. Similar age distribution was revealed by Shifei Wei et al [19] in their study. In a study by Neena R et al [18], the mean age was 8.31 years.

At baseline, maximum subjects had UCVA of 6/36 in both the study groups. UCVA was found to be comparable in case and control group as $p>0.05$. UCVA had not much changes upto 1year followup. BCVA was maintained from baseline to after one year in both interventional and control groups as mentioned by Seema Rajvanshi et al [20] in their study. Increase in SER was found to be more in control group as compared to case group with statistically significant difference as $p<0.05$. In a retrospective case-control study in European children, the atropine, 0.01%, group had as lower myopia progression of a mean (SD) of 0.54 (0.26) than that of the control group at −1.09 (0.64) [20]. In 2019, the LAMP study first provided placebo-compared evidence of low-concentration atropine eyedrops in myopia control. After 1 year, the mean (SD) myopic progression was−0.27 (0.61) D, −0.46 (0.45) D, −0.59 (0.61) D, and −0.81(0.53) D, in the atropine, 0.05%, 0.025%, and 0.01%, groups and placebo groups, respectively [12]. According to Shifei Wei et al [19], the mean (SD) myopia progression values for the atropine, 0.01%, group and the placebo group were −0.49 (0.42) D and −0.76 (0.50) D (mean difference, 0.26 D; 95% CI, 0.12-0.41 D; $P < .001$). These findings are similar to our study. Similarly, Seema Rajvanshi et al. [20] reported that the control group had a significantly lower proportion of eyes demonstrating reduced myopia progression

compared with the atropine-treated groups. Chua WH et al [13] in their study showed that after 2 years of follow-up, the mean rate of progression of myopia was significantly lower in the 1% atropine group (−0.28±0.92 D) compared with the placebo group (−1.20±0.69D).

In the present study, Keratometric readings remained stable throughout the 18-month follow-up in both the intervention and control groups. Although minor fluctuations were observed over time, there was no statistically significant difference between the groups in either the right eye (p=0.64) or the left eye (p=0.82). These findings indicate that low-dose atropine therapy does not impact clinically in corneal curvature, suggesting that its myopia control effect is independent of alterations in corneal biomechanics. These findings are in agreement with the Low-Concentration Atropine for Myopia Progression (LAMP) Study conducted by Yam JC and colleagues [12], who demonstrated that 0.05%, 0.025%, and 0.01% atropine effectively reduced myopia progression while producing no significant changes in keratometric parameters during follow-up. The authors concluded that the therapeutic effect of atropine primarily acts through inhibition of axial elongation rather than changes in corneal curvature. Similarly, Chia A et al [14], in the Atropine for the Treatment of Myopia (ATOM2) Study, reported that long-term administration of low-dose atropine was not associated with significant changes in corneal curvature or corneal refractive power. Their results support the hypothesis that atropine exerts its effect mainly through modulation of scleral remodeling and growth in the axial length of the eyeball instead of altering anterior segment parameters. Comparable observations were reported by Seema Rajvanshi et al [20], who found that while low-dose atropine significantly reduced myopia progression, keratometric values remained essentially unchanged during the study period. They concluded that corneal curvature remained stable despite prolonged atropine use, reinforcing the safety profile of low-concentration atropine therapy. The stability of keratometric measurements observed in the present study is clinically important because it indicates that low-dose atropine does not induce corneal steepening or flattening that could influence refractive outcomes. Instead, the beneficial effect of atropine appears to result predominantly from suppression of axial elongation, consistent with current understanding of its mechanism of action.

In the present study, seven (15.6%) children in the atropine group reported mild adverse effects. Photophobia was the most frequent complaint, followed by headache and dry or irritated eyes. No participant discontinued treatment because of adverse effects, and no serious ocular or systemic complications were observed. Shifei Wei et al [19] too in their study stated that no serious adverse events related to atropine were reported. Five children (4.5%) reported photophobia in the atropine, 0.01%, group compared with 1 child (0.9%) in the control group. Allergic reactions were uncommon, with 4 children experiencing allergic conjunctivitis. Similar to our experience, Yam et al [12] observed 2 participants (2.1%) had photophobia and 7 participants (6.4%) had allergic conjunctivitis in the atropine (0.01%) group. In a comparative study of various topical atropine concentrations in adolescents, Cooper et al. [21] identified 0.02% atropine as the threshold dose that does not cause clinically significant accommodation paresis or pupillary dilation. It would may be a reasonable strategy for those children with myopia to be treated initially with atropine, 0.01%; if myopia progression was still faster, then change to a higher concentration. Seema Rajvanshi et al. [20] reported that the use of low-dose atropine (0.01%) was associated with significantly better patient tolerability, thereby supporting its long-term use in the management of myopia progression.

The strengths of this study included its randomized controlled trial design and the standardized measurement of refractive errors using cycloplegia. However, there are several shortcomings in our study. First, we could not avoid the potential for unmasking of the participants attributable to the atropine-induced photophobia and cycloplegia as well as other atropine eye drops studies. In addition, this study only evaluated the efficacy of low concentration atropine eyedrops at the level of 0.01%. Thus, further studies should be carried out to compare the efficacy of other different doses of atropine.

Limitations

- Sample size is small, and further studies are required to confirm these results.
- Short follow-up period for each subject.
- Pre data baseline of myopia should have been evaluated
- Age matching was not done in our study
- Pupillary size changes should have been evaluated.

CONCLUSION

Low-dose (0.01%) topical atropine eye drops treatment was a safe and effective method for slowing down the progression of myopia SER. Long-term follow-up is, however needed for extrapolation into the general population.

Atropine treatment has now been incorporated into clinical practice in India and shows real promise as a treatment for controlling myopia, however, future studies are required to investigate the mechanism of action of the low-dose atropine.

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