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STUDY OF THE EFFECT OF 0.01% ATROPINE EYE DROP ON MYOPIA PROGRESSION AND INTRAOCULAR PRESSURE

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Abstract

Background: Myopia, a prevalent refractive error in children, poses significant public health concerns due to its increasing incidence and potential complications. Low-dose atropine (0.01%) has emerged as a promising treatment option to slow myopia progression.

Aim and Objectives: This study aimed to evaluate the efficacy of 0.01% atropine eye drops on myopia progression and intraocular pressure (IOP) in children under 16 years of age.

Materials and Methods: Conducted at Muzaffarnagar Medical College over 12 months, 150 myopic children were randomly assigned to receive either 0.01% atropine or placebo. Comprehensive ocular examinations assessed refraction changes, IOP measurements, and any adverse effects.

Results: The atropine group demonstrated a statistically significant reduction in myopia progression compared to the placebo group, with no adverse effects on IOP.

Conclusion: The findings suggest that 0.01% atropine is an effective and safe treatment for slowing myopia progression in children, warranting further research into its long-term effects.

Keywords: Myopia, Refractive error, 0.01% Atropine, IOP, Children.

INTRODUCTION

The condition commonly referred to as myopia, or short sightedness is a prevalent refractive error (RE) with high global incidence. [1,2] Typically manifesting in childhood, this condition is characterised by an abnormal extension of the eyes along the central axis. [3] When accommodation is at rest, parallel beams of light from infinity focus in front of the retina, causing myopia, a form of RE. This condition is influenced by several mechanisms related to environment as well as genetic and arises from the inability to sustain the regular process of emmetropization. [4] Conventional corrective therapies such as standard glasses are ineffective in treating myopia because they do not deal with ongoing eye growth that leads to worsening nearsightedness. Therefore, they only correct vision without preventing further development of myopia. This emphasises the need for newer treatments that actively slow down myopia progression, such as 0.01 % atropine (topical), specialised multifocal contact lenses, which have demonstrated greater effectiveness in controlling near sightedness. [5]

Despite the absence of a scientifically proven treatment protocol for myopia, several approaches have shown varying degrees of efficacy in decelerating its advancement. These include

increased outdoor activity time, prismatic bifocal lenses spectacles (PBLs), defocus spectacle lenses, soft contact lenses (SCLs), orthokeratology (OK), progressive addition lenses spectacles (PALs), along with different concentrations of antimuscarinic eye drops most commonly cyclopentolate, pirenzepine, atropine. Sometimes, for enhancing their effectiveness these techniques are merged together. Children who spend more time outside are less likely to develop myopia, although its impact on the rate of advancement is negligible. [5,6] An important finding is that DIMS (defocus incorporated multiple segments) spectacle lenses have shown a substantial decrease in progression of myopia with few adverse effects. [7]

Ultimately, SCLs have shown a moderate effectiveness in decelerating advancement of the myopia, although exceeding spectacle lenses, particularly for lenses that adjust peripheral defocus. Thus far, atropine has demonstrated promising results in effectively halting myopia advancement. Administration of lower dosages of atropine has shown to be the most beneficial in achieving a balance between clinical effectiveness and a low frequency of adverse effects, despite the reported occurrence of a rebound phenomenon after discontinuing the therapy. [5]

Administration of atropine at a concentration of 0.01% seems to be a potent and affordable treatment for decelerating myopia advancement in developing eyes. However, this result mostly depends on its long-lasting influence on limiting changes in diopters, with a weaker effect seen on preventing asymmetrical lens elongation. Several investigations have assessed the atropine eye drops impact on intraocular pressure (IOP) in another group of patients. Currently, the clinical utilisation of 0.01% atropine is growing in the treatment of myopic patient. [8,9]

No comprehensive evaluation has been conducted on the impact of 0.01% atropine eye drops (AED) on IOP. Thus, to observe the impact of 0.01 % atropine eye drop on progression of myopia and IOP was the current study's goal.

AIM & OBJECTIVES

To observe the effect of 0.01 % atropine eye drop on myopia progression and Intraocular Pressure

Objectives-

1. To determine the effect of 0.01 % atropine eye drop on myopia progression.
2. To determine the effect of 0.01 % atropine eye drop on Intraocular Pressure.
3. To compare myopia progression between atropine and placebo administered groups.
4. To compare IOP between atropine and placebo administered groups.

MATERIAL AND METHODS

This study was conducted at Muzaffarnagar Medical College and Hospital from January 1, 2023, to December 31, 2024, following approval from the Board of Studies and the Ethical Committee. The sample size was determined to be 150 participants, based on a 67% prevalence of myopia, and was divided into two groups of 75 each using a simple random sampling method. Inclusion criteria focused on myopic children under 16 years with a spherical equivalent refraction (SER) greater than -0.25D, while individuals with active ocular infections, prior eye surgeries, or known hypersensitivity to the study drugs were excluded.

Participants underwent comprehensive ocular examinations, including best corrected visual acuity (BCVA), intraocular pressure (IOP) measurements via applanation tonometry, and slit-lamp examinations. They were randomly assigned to receive either 0.01% atropine eye drops or placebo lubricant drops once daily at night. Assessments were conducted at baseline and after 12 months to measure outcomes such as BCVA, IOP, and any adverse effects. Data were analyzed using SPSS version 25.0, applying statistical tests such as the Student’s t-test and chi-square test, with a significance level set at a p-value of < 0.05.

RESULTS

In present study, 0.01% Atropine had 14 participants (18.7%) aged 6-9, 39 (52%) aged 10-12, and 22 (29.3%) aged 13-16. The placebo group had 7 (9.3%), 52 (69.3%), and 16 (21.3%) participants in these age groups, respectively, with no significant differences (p-values of 0.07 and 0.145). The mean ages were 9.44 years for Atropine and 9.84 years for placebo. Gender distribution showed 22 males (29.3%) and 53 females (70.7%) in the Atropine group, compared to 28 males (37.3%) and 47 females (62.7%) in the placebo group, with no significant differences (p-value of 0.30). **(Table 1)**

Table 2 illustrates the distribution of patients according to cycloplegic refraction demonstrates that at baseline, both the 0.01% Atropine and placebo groups had 150 eyes each, with no significant difference in the number of eyes (p-value of 0.59). The mean spherical equivalent (SER) was −2.75 ± 1.15 for the Atropine group and −2.68 ± 1.14 for the placebo group. However, by month 12, the number of eyes in the Atropine group decreased to 122, whereas the placebo group had 110 eyes, revealing a significant difference (p-value of 0.04). At this time point, the mean SER for the Atropine group was −3.41 ± 1.28, compared to −3.76 ± 1.31 for the placebo group, indicating that the Atropine group experienced a smaller mean change in SER, suggesting a significant difference in refractive outcomes after 12 months.

The distribution of patients by axial length indicated that at baseline, both the 0.01% Atropine and placebo groups had 150 eyes, with no significant difference (p-value of 0.6696). The mean axial length (AL) for Atropine was 24.70 ± 0.5 mm and for placebo, it was 24.73 ± 0.7 mm. By month 12, the Atropine group had 122 eyes and the placebo group had 110 eyes, showing a significant difference (p-value of 0.0009). The mean AL increased to 25.04 ± 0.59 mm for Atropine and 25.34 ± 0.77 mm for placebo, indicating greater elongation in the placebo group compared to the Atropine group over the year. **(Table 3)**

The distribution of patients by mean intraocular pressure (IOP) revealed that at baseline, both the 0.01% Atropine and placebo groups had 150 eyes, with a mean IOP of 14.26 ± 2.65 mmHg for Atropine and 14.19 ± 2.82 mmHg for placebo, showing no significant difference (p-value of 0.8248). At month 12, the Atropine group had 122 eyes and the placebo group had 110 eyes, with mean IOP readings of 13.85 ± 2.74 mmHg for Atropine and 13.96 ± 2.91 mmHg for placebo, also indicating no significant difference (p-value of 0.7671). Overall, there were no significant differences in mean IOP between the two groups at either time point. **(Table 4)**

Figure 1 compares the number of study subjects categorized by refractive error for those receiving 0.01% Atropine versus a placebo. In the low myopic range (SER: -0.50 to -3.00 D), the Atropine group shows a significantly higher count, with around 60 participants, while the placebo group has about 30. In the moderate myopic range (SER: -3.01 to -6.00 D), the Atropine group still leads but with fewer subjects compared to the low myopic category, whereas the placebo group has a noticeably smaller number of participants. This distribution suggests that the Atropine group has a larger proportion of subjects across myopic categories, potentially indicating the treatment's effectiveness in managing refractive errors and addressing myopia progression.

The bar chart shows the number of study subjects based on parental myopia for the 0.01% Atropine and placebo groups. In the "None" category, the Atropine group has 13 subjects, while the placebo group has 8. In the "One" category, there are 17 Atropine and 16 placebo subjects. The most significant difference is in the "Both" category, with 45 subjects in the Atropine group compared to 51 in the placebo group. This suggests a notable representation of subjects with both parents having myopia, which may impact the treatment's effectiveness. **(Figure 2)**

Table 1: Socio-demographic profile of participants:

	0.01%Atropine	**Placebo**	**p-value**
Age group			
6-9	14 (18.7%)	07(9.3%)	0.07
10-12	39 (52%)	52 (69.3%)	
13-16	22 (29.3%)	16 (21.3%)	

Mean±SD	9.44±1.80	9.84±1.53	0.145
Gender			
Male	22 (29.3%)	28 (37.3%)	0.30
Female	53 (70.7%)	47 (62.7%)	

Table 2: Distribution of patients as per cycloplegic refraction:

Cycloplegic Refraction	**0.01%Atropine**	**Placebo**	
Baseline			
No. ofeyes	150	150	0.59
MeanSER ±SD	−2.75±1.15	−2.68±1.14	
Month 12			
No. ofeyes	122	110	0.04
MeanSER±SD	−3.41±1.28	−3.76±1.31	

Table 3: Distribution of patients as per axial length:

Axial length	**0.01%Atropine**	**Placebo**	
Baseline			
No. Ofeyes	150	150	0.6696
Mean AL	24.70±0.5	24.73±0.7	
Month 12			
No. Ofeyes	122	110	0.0009
Mean AL	25.04±0.59	25.34±0.77	

Table 4: Distribution of patients as per Mean IOP:

Mean IOP	**0.01%Atropine**	**Placebo**	
Baseline			
No. Ofeyes	150	150	0.8248
Mean IOP	14.26±2.65	14.19±2.82	
Month 12			
No. Ofeyes	122	110	0.7671
Mean IOP	13.85±2.74	13.96±2.91	

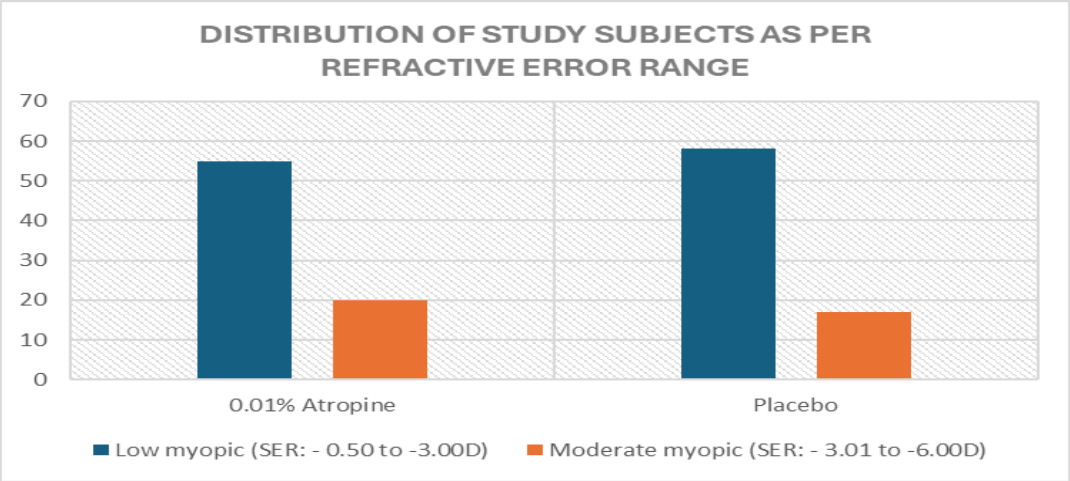

Figure1: Distributionofstudysubjectsasperrefractiveerror range

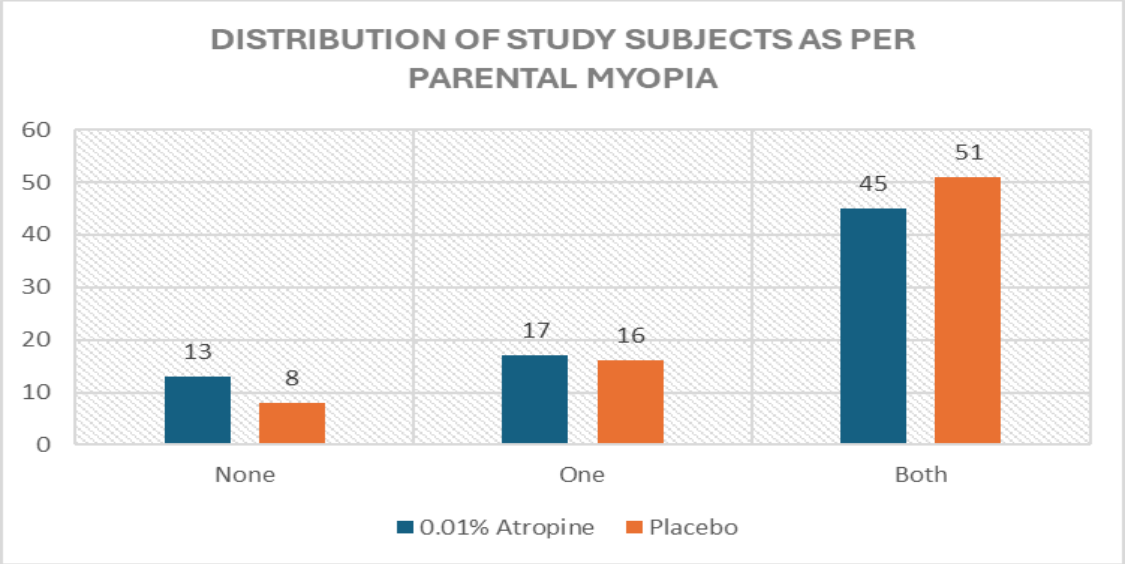

Figure 2: DistributionofStudySubjectsasperParental Myopia

DISCUSSION

In this research examining the efficacy of 0.01% atropine on myopia progression, participants mean age was 9.44years in atropine group whereas 9.84 years in placebo group. 10–12years age group had the highest representation in each group. Between the mean ages of 2 groups, no significant difference was there (p=0.145), suggesting comparable age distributions at baseline.

In our study, females constituted the majority in both the atropine (70.7%) and placebo (62.7%) groups, with no statistically significant difference between them (p=0.3003), indicating a balanced gender distribution across the groups.

In our study, the majority of individuals in both atropine along with placebo groups presented with low myopia (−0.50D to −3.00D), accounting for 73.3% and 77.3% of each group, respectively. Moderate myopia (−3.01D to −6.00D) was observed in 26.7% —of the atropine group and 22.7% of placebo group. Variation between the groups had not been statistically significant (p=0.5712), indicating a comparable baseline distribution of refractive errors.

In our study, the mean SER at baseline was −2.75D in atropine group whereas −2.68D in placebo group, with no statistically significant difference between 2 groups (p = 0.5969). This indicates that the initial severity of myopia was comparable across both groups.

After 12 months, our study found that the mean SER was −3.41D in atropine group whereas −3.76D in placebo group, with the statistically significant variation (p=0.0408). This implies that the atropine group witnessed a slower rate of myopia progression, indicating that 0.01% atropine is an effective way to slow down the progression of myopia.

In our study, mean AL was 24.70mm in atropine group as well as 24.73mm in placebo group, with no statistically significant difference between 2 groups (p=0.6696). This indicates that both groups had comparable baseline AL.

In our study, parental myopia‘s distribution among individuals was as subsequent: 60% of atropine group along with 68% of placebo group had both parents with myopia; approximately 22% in both groups had one parent with myopia; and 17.3% of atropine group as well as 10.7% of placebo group had no parental history of myopia. The variation had not been statistically significant (p=0.450), indicating a comparable genetic predisposition across both groups.

CONCLUSION

The study concluded that 0.01% atropine eye drops effectively slowed myopia progression in children, with a significant difference in mean spherical equivalent refraction compared to the placebo group after 12 months. Additionally, the treatment did not adversely affect intraocular pressure, suggesting it is a safe and promising option for managing myopia.

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