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COMPARING THE EFFICACY OF 0.01% ATROPINE EYE DROPS VERSUS PLACEBO EYE DROPS ON MYOPIA CONTROL IN SPECTACLES WEARERS

Original Research

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ABSTRACT

Background: Myopia is a common refractive error characterized by excessive axial elongation, causing light rays to focus anterior to the retina, resulting in blurred vision. It is particularly concerning in children, as early-onset myopia tends to progress rapidly and may lead to serious ocular complications. Atropine eye drops have been proposed as a pharmacological intervention to slow myopia progression. While high concentrations are well-studied, the long-term efficacy of 0.01% atropine remains under investigation.

Objective: This study aimed to evaluate the effectiveness of low-dose atropine (0.01%) in slowing myopia progression among spectacle-wearing children.

Methods: A randomized controlled trial was conducted at Jinnah Hospital, Lahore, including 68 children aged 5 to 15 years diagnosed with myopia. Participants were randomly assigned to receive either 0.01% atropine or a placebo for six months. Comprehensive ophthalmic assessments, including best-corrected visual acuity (BCVA), spherical equivalent refraction, and axial length measurements, were conducted at baseline and follow-up. Data analysis was performed using SPSS Version 27, applying paired t-tests and correlation analysis to assess treatment efficacy. Ethical approval was obtained, and informed consent was secured from all participants.

Results: The mean age of participants was 9.25 ± 3.206 years, with 38 (55.9%) females and 27 (39.7%) males. The atropine group showed significant preservation of BCVA (right eye: $r=0.966$, $p<0.001$; left eye: $r=0.934$, $p<0.001$), whereas the placebo group had weaker correlations (right eye: $r=0.310$, $p=0.074$). Spherical equivalent in the right eye improved significantly with atropine ($r=0.981$, $p<0.001$), while the placebo group deteriorated ($p<0.001$). Axial length elongation was significantly lower in the atropine group (-0.14382 mm, $p=0.000$ right eye; -0.10382 mm, $p=0.000$ left eye) compared to the placebo group (-0.24647 mm, $p=0.000$ right eye; -0.23618 mm, $p=0.000$ left eye).

Conclusion: The findings confirm that 0.01% atropine is a safe and effective intervention for slowing myopia progression in children, significantly reducing axial elongation and stabilizing refractive status without compromising visual acuity. Further long-term studies are recommended to assess its sustained efficacy.

Keywords: Atropine, Axial Length, Myopia, Myopia Progression, Optical Therapy, Refractive Error, Visual Acuity.

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INTRODUCTION

Myopia is a prevalent refractive error characterized by an elongated axial length, resulting in excessive refractive power that causes light rays to focus in front of the retina, leading to blurred vision (1). It is particularly common in children, and once it manifests at an early age, it often progresses irreversibly. The global prevalence of myopia has risen significantly, especially in East Asian countries, with projections indicating that nearly 50% of the world's population will be myopic by 2050 (2). Myopia that develops at a younger age tends to progress more rapidly until adulthood, increasing the risk of severe complications such as glaucoma, choroidal neovascularization, retinal detachment, and macular hemorrhage due to axial elongation (3). Given the increasing incidence and long-term visual consequences, myopia has evolved into a significant public health concern, particularly in highly urbanized regions where young adults exhibit an exceptionally high prevalence of the condition (4). The rising incidence of myopia has been attributed to a combination of genetic and environmental factors. Urbanization, reduced outdoor exposure, and prolonged near-work activities have been strongly linked to its increasing prevalence (5). Strategies to mitigate myopia progression have become an area of extensive research, as severe myopia—defined as a spherical equivalent refractive error of ≤ -6.00 diopters—substantially heightens the risk of sight-threatening conditions, including retinal detachment, glaucoma, cataracts, and myopic macular degeneration (6). Since elongation of the eyeball stabilizes in early adulthood, delaying myopia progression during childhood is crucial to reducing the risk of future visual impairment (7). Preventative interventions, such as increasing outdoor time, have demonstrated potential in reducing myopia incidence. A randomized study conducted in China found that incorporating 40 minutes of additional outdoor time into daily school routines significantly decreased the three-year cumulative incidence of myopia among first-grade students (8).

Among the various approaches investigated for myopia control, both pharmacological and optical interventions have been extensively studied. The use of multifocal lenses compared to single-vision lenses has demonstrated greater effectiveness in slowing myopia progression over an extended period (9). Atropine, a non-selective muscarinic antagonist, has emerged as one of the most effective pharmacological treatments for managing myopia progression. Studies evaluating different atropine concentrations (0.5%, 0.1%, and 0.01%) indicate that intermittent use of 1% atropine may offer an alternative therapeutic approach with fewer side effects than daily administration (10). However, while low-dose atropine (0.01%-0.05%) has been widely studied, its efficacy remains variable, particularly at the 0.01% concentration (11). Moreover, the role of atropine in delaying the onset of myopia remains an area of uncertainty, although some research suggests that it may provide benefits in non-myopic children at risk of developing the condition (12). Given the substantial rise in myopia prevalence and its long-term ophthalmic complications, proactive management strategies have become imperative. Rather than solely focusing on correcting refractive errors, current treatment approaches emphasize slowing the progression of myopia in children to prevent severe visual impairment later in life. Various pharmacologic agents and optical treatments, such as multifocal contact lenses, orthokeratology, and atropine eye drops, continue to be investigated for their efficacy in myopia control (13). The objective of this study is to examine the effectiveness of different intervention strategies in mitigating myopia progression and evaluate their role in delaying its onset, ultimately aiming to inform clinical practices that could reduce the burden of myopia-related visual impairment.

METHODS

This randomized controlled trial was conducted in the ophthalmology department at Jinnah Hospital, Lahore, following approval from the institutional review board. The study was conducted over six months after the approval of the synopsis, involving a total of 64 children aged 5 to 15 years diagnosed with myopia. Participants were selected using a simple random sampling technique, ensuring an unbiased distribution. The inclusion criteria consisted of children aged 5 to 15 years with a documented diagnosis of myopia (spherical equivalent refractive error ≤ -0.50 diopters) and best-corrected visual acuity (BCVA) of 6/9 or better in both eyes. Exclusion criteria included any history of ocular disease (e.g., keratoconus, amblyopia, cataracts, or retinal pathology), prior use of myopia control interventions (including atropine, orthokeratology, or multifocal lenses), systemic diseases affecting vision, or any known allergy to atropine (4,8).

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A detailed ophthalmic examination was performed at baseline, including cycloplegic refraction using autorefraction and subjective refraction, best-corrected visual acuity (BCVA) measurement using a Snellen chart, and axial length assessment through optical biometry. Participants were then randomly allocated into two equal treatment groups: one receiving 0.01% atropine eye drops and the other receiving a placebo. The intervention lasted for six weeks, with instructions given to parents or guardians regarding proper administration and adherence. Compliance was monitored through weekly follow-up calls and by collecting unused drops at the end of the study. Post-treatment assessments were conducted using the same ophthalmic instruments and procedures as the baseline evaluation. Changes in BCVA, spherical equivalent refraction, and axial length were documented and compared between the two groups. Data analysis was performed using SPSS (Version 27). Descriptive statistics, including mean, standard deviation, and standard error, were used to summarize continuous variables. Paired sample t-tests were employed to analyze pre- and post-treatment differences within each group, while independent t-tests were used to compare the two groups. A confidence interval of 95% was applied, with statistical significance set at $p < 0.05$. Ethical considerations were strictly maintained in accordance with the principles outlined in the Declaration of Helsinki. Written informed consent was obtained from all participants' guardians after providing detailed information about the study objectives, potential risks, and benefits. The study was approved by the hospital's ethical review committee, ensuring compliance with ethical guidelines for human research.

RESULTS

A total of 68 participants were included in the analysis, with 38 (55.9%) females and 27 (39.7%) males. The mean age of participants was 9.25 ± 3.206 years, with an age range of 5 to 15 years. Patients were randomly assigned to either the atropine or placebo group for the intervention. In the atropine group, best-corrected visual acuity (BCVA) in the right eye remained unchanged (mean=0.0000, p=1.000), while the left eye showed a minor, non-significant improvement (mean=0.0118, p=0.325). The spherical equivalent of the right eye demonstrated a statistically significant change (mean=0.16176, p=0.006), whereas the left eye, despite a larger mean difference (mean=4.77941), did not reach statistical significance (p=0.358), likely due to high variability (standard deviation=29.90). Axial length increased significantly in both eyes, with a mean change of -0.14382 mm in the right eye (p=0.000) and -0.10382 mm in the left eye (p=0.000). Despite statistical significance, the absolute magnitude of these changes was relatively small.

In the placebo group, BCVA in the right eye showed a minor but non-significant reduction (mean=-0.0176, p=0.325), while the left eye remained unchanged (mean=0.0000, p=1.000). The spherical equivalent of the right eye increased significantly (mean=0.34559, p=0.000), whereas the left eye showed a negligible change (mean=-0.02941, p=0.918). The most pronounced changes were observed in axial length, which increased significantly in both eyes. The mean increase in the right eye was -0.24647 mm (p=0.000), and in the left eye, it was -0.23618 mm (p=0.000), approximately twice the increase observed in the atropine group. A comparative evaluation between 0.01% atropine and placebo in myopia control revealed that both groups experienced axial elongation, but the atropine group exhibited 42% less axial length increase in the right eye and 56% less in the left eye compared to the placebo group. While both groups demonstrated significant changes in the spherical equivalent of the right eye, the atropine group exhibited a smaller increase, indicating better refractive stability. BCVA remained stable in both groups with no significant differences. An intergroup comparison between atropine and placebo groups was performed to assess statistical significance in key parameters. BCVA remained largely unchanged in both groups, with no significant difference observed in either the right (p=0.325) or left eye (p=1.000). The spherical equivalent of the right eye exhibited a significant increase in both groups; however, the atropine group showed a smaller change (mean=0.16176, SD=0.32) compared to the placebo group (mean=0.34559, SD=0.313), with an intergroup p-value of 0.031, indicating a statistically significant difference favoring atropine for refractive stability. The spherical equivalent of the left eye did not show a statistically significant difference between groups (p=0.412).

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Axial length measurements showed statistically significant elongation in both groups; however, the atropine group exhibited significantly lower axial elongation compared to the placebo group. The right eye's axial length increase was -0.14382 mm (SD=0.16) in the atropine group and -0.24647 mm (SD=0.28) in the placebo group, with an intergroup p-value of 0.002. Similarly, the left eye's axial elongation was -0.10382 mm (SD=0.17) in the atropine group and -0.23618 mm (SD=0.267) in the placebo group, with an intergroup p-value of 0.001, further confirming the protective effect of atropine in slowing axial elongation. These findings suggest that 0.01% atropine significantly reduces axial elongation and provides better refractive stability compared to placebo, while maintaining stable BCVA. However, further long-term studies may be required to assess sustained efficacy and its impact on myopia progression over time.

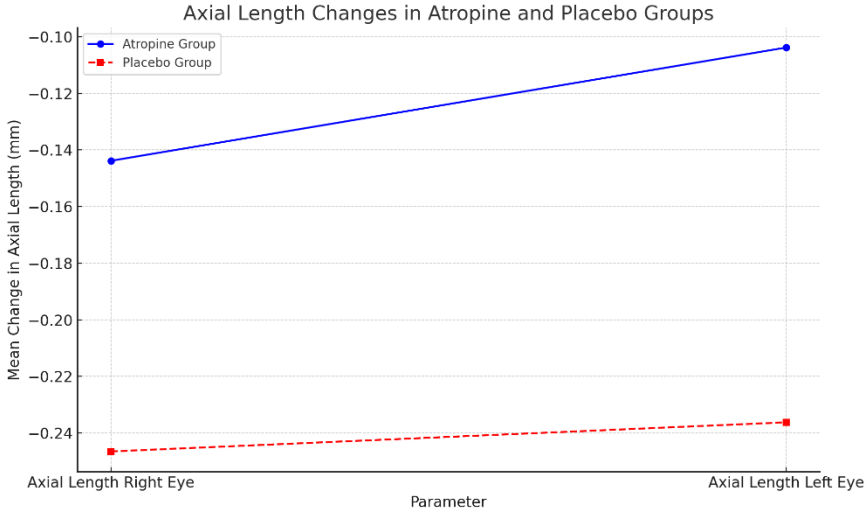

Table 1 Paired Samples Test

		Mean± Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		P value
				Lower	Upper	
Pair 1	BCVA BEFORE R - BCVA AFTER R	0.00±.045	0.008	-0.017	0.017	1.000
Pair 2	BCVA BEFORE L - BCVA AFTER L	0.011±.068	0.012	-0.012	0.036	0.325
Pair 3	SPH.EQUIVELENT RE - SE.R After	0.16±.32	0.055	0.050	0.27	0.006
Pair 4	SPH.EQUIVELENT LE - SE.L After	4.78±29.90	5.128	-5.654	15.21	0.358
Pair 5	AL BEFORE R - AXIAL LENGTH.R After	-0.14±.16	0.028	-0.201	-0.086	0.000
Pair 6	AL BEFORE L - AXIAL LENGTH L After	-.010±.17	0.027	-0.158	-0.049	0.000

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Table 2 Paired Samples Test

		Mean ± Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		P Value
				Lower	Upper	
Pair 1	BCVA BEFORE R - BCVA R After	-0.018±0.103	0.018	-0.054	0.018	0.325
Pair 2	BCVA BEFORE L - BCVA.L After	0.00±0.095	0.016	-0.033	0.033	1.000
Pair 3	S.E BEFORE R - S.E AFTER R	0.35±0.313	0.054	0.236	0.455	0.000
Pair 4	S.E BEFORE L - S.E AFTER L	-0.03±1.65	0.284	-0.606	0.547	0.918
Pair 5	AXIAL LENGTH RE BEFORE - AXIAL LENGTH R AFTER	-0.25±0.28	0.048	-0.344	-.0148	0.000
Pair 6	AL.LAXIAL LENGTH LE BEFORE - AXIAL LENGTH L AFTER	-0.24±0.267	0.046	-0.329	-0.142	0.000

Table 3 Comparison between 0.01% atropine and a placebo

Parameter	**Atropine Group**	**Placebo Group**	**Interpretation**
BCVA Right Eye	Mean: 0.0000 p-value: 1.000	Mean: -0.0176 p-value: 0.325	No significant change in either group; both treatments maintained visual acuity
BCVA Left Eye	Mean: 0.0118 p-value: 0.325	Mean: 0.0000 p-value: 1.000	No significant change in either group; both treatments maintained visual acuity
Spherical Equivalent Right Eye	Mean: 0.16176 p-value: 0.006*	Mean: 0.34559 p-value: 0.000*	Both groups showed significant changes, but atropine group had smaller increase (better refractive stability)
Spherical Equivalent Left Eye	Mean: 4.77941 p-value: 0.358	Mean: -0.02941 p-value: 0.918	No significant change in either group
Axial Length Right Eye	Mean: -0.14382 p-value: 0.000*	Mean: -0.24647 p-value: 0.000*	Both groups showed significant increase, but atropine group had 42% less axial elongation
Axial Length Left Eye	Mean: -0.10382 p-value: 0.000*	Mean: -0.23618 p-value: 0.000*	Both groups showed significant increase, but atropine group had 56% less axial elongation

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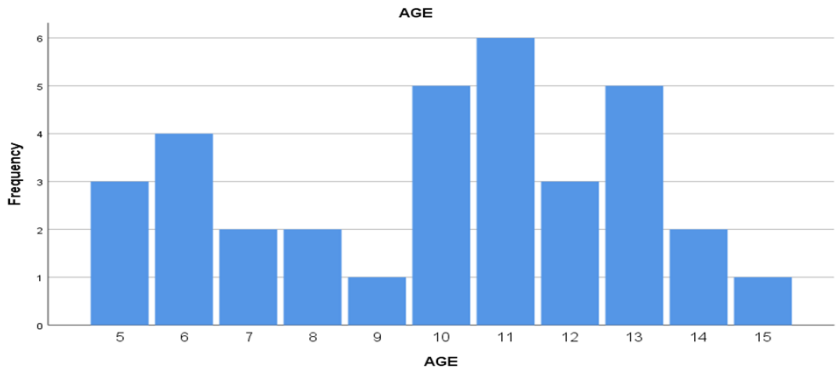
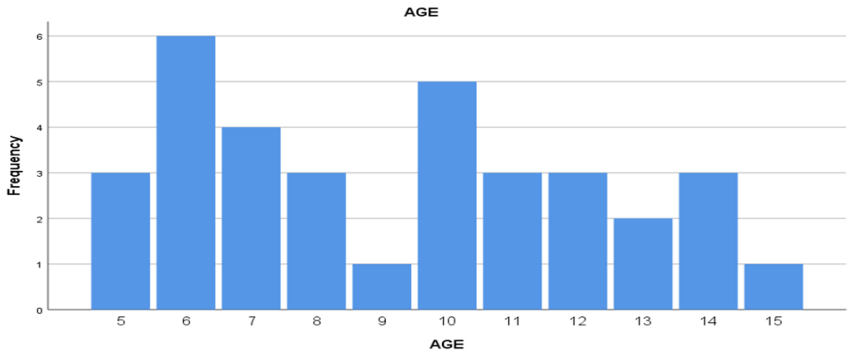
Table 4 Intergroup Comparison Table

Parameter	Atropine Mean Â± SD	Placebo Mean Â± SD	P-value (Intergroup)
BCVA Right Eye	0.0000 Â± 0.045	-0.0176 Â± 0.103	0.325
BCVA Left Eye	0.0118 Â± 0.068	0.0000 Â± 0.095	1
Spherical Equivalent Right Eye	0.16176 Â± 0.32	0.34559 Â± 0.313	0.031
Spherical Equivalent Left Eye	4.77941 Â± 29.90	-0.02941 Â± 1.65	0.412
Axial Length Right Eye	-0.14382 Â± 0.16	-0.24647 Â± 0.28	0.002
Axial Length Left Eye	-0.10382 Â± 0.17	-0.23618 Â± 0.267	0.001





DISCUSSION

The mechanism by which low-dose atropine slows myopia progression remains incompletely understood. While higher concentrations of atropine exert their effects primarily through muscarinic receptor blockade at the ciliary muscle, the minimal impact of 0.01% atropine on accommodation suggests the involvement of alternative pathways (14). Research indicates that atropine may influence scleral remodeling through non-muscarinic mechanisms, including modulation of the nitric oxide signaling pathway. Additionally, evidence suggests that atropine alters dopamine levels in retinal tissue, a key factor in ocular growth regulation (15). Experimental studies have demonstrated an increase in retinal dopamine levels following atropine administration, supporting its anti-myopic effect independent of accommodation paralysis. Although this study did not aim to investigate such biochemical pathways, the observed separation between accommodation effects and clinical efficacy aligns with the hypothesis that non-accommodative mechanisms contribute to myopia control. The rebound effect following the discontinuation of atropine therapy is an important consideration in long-term myopia management. Higher concentrations of atropine (0.5% and 0.1%) have been associated with significant myopia rebound upon cessation, whereas minimal rebound has been observed with 0.01% atropine (16). In a previous long-term study, myopia progression increased slightly during the washout period in the atropine group compared to the placebo group; however, the cumulative myopia progression

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over the entire study period remained significantly lower in the atropine group (17). This suggests that despite a small rebound effect, the overall benefits of atropine in controlling myopia progression outweigh this concern. Similar findings have been reported in various populations, reinforcing the stability of 0.01% atropine as a long-term intervention.

Adherence to treatment is a critical factor influencing the success of any long-term myopia control strategy, particularly in pediatric populations (18). The current study demonstrated high compliance rates in both treatment groups, indicating that once-daily atropine administration is a feasible and acceptable intervention for children. Compared to other myopia control modalities, such as multifocal contact lenses or orthokeratology, the simplicity and ease of atropine eye drops offer a distinct advantage (19). Optical interventions require rigorous handling, maintenance, and potential risk of complications, whereas atropine therapy is straightforward and well-tolerated. Caregivers expressed a preference for atropine due to its ease of administration and minimal interference with daily routines. The potential for combining atropine with optical treatments presents an intriguing area for further investigation (20). A meta-analysis comparing different myopia control strategies has suggested that the combined use of atropine with multifocal lenses or orthokeratology may provide additive effects in slowing myopia progression. The present findings indicate that atropine monotherapy achieved comparable results to previously reported studies utilizing multifocal glasses alone. This raises the possibility that a combination of 0.01% atropine with optical treatments could enhance myopia control while minimizing additional adverse effects. Studies have already reported that atropine combined with orthokeratology offers superior axial length control compared to orthokeratology alone (21). Further research is warranted to explore the efficacy of these combination therapies and their long-term benefits.

The economic implications of atropine therapy for myopia control must also be considered. Compared to specialized optical interventions, atropine eye drops are a relatively affordable option. However, long-term use may lead to significant cumulative costs. Previous cost-effectiveness analyses have suggested that incorporating 0.01% atropine into myopia management strategies is economically justified due to its potential in reducing lifetime risks of myopic complications, such as retinal detachment, myopic maculopathy, and glaucoma (20,21). While this study did not assess cost-effectiveness, the substantial reduction in myopia progression observed with atropine implies long-term visual and economic benefits. Future research should incorporate economic evaluations to provide a comprehensive assessment of the financial feasibility of large-scale atropine therapy implementation. Despite its strengths, including a randomized controlled design and standardized outcome measures, this study has certain limitations. The follow-up duration of six weeks may be insufficient to capture the full extent of myopia progression or potential rebound effects following discontinuation. Longer follow-up periods are necessary to assess the sustained efficacy of 0.01% atropine and to determine the long-term impact on myopia stabilization. Additionally, while statistical analyses confirmed the significance of key findings, larger sample sizes would enhance the robustness of results and allow for more detailed subgroup analyses based on age, gender, and baseline refractive error severity. Future studies should also investigate potential genetic and environmental interactions influencing individual responses to atropine therapy.

CONCLUSION

This study evaluated the effectiveness of 0.01% atropine eye drops in slowing myopia progression in children who wear spectacles, comparing its impact against a placebo. The findings demonstrate that low-dose atropine is a safe and effective intervention for myopia control, significantly reducing axial elongation while maintaining stable visual acuity. The ability of atropine to slow myopia progression without adversely affecting vision makes it a valuable option for clinical practice, particularly in settings where long-term myopia management is a priority.

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Author Contribution

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Naveed Babar	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Ummara Shafique	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published
Samina Zahoor	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Muhammad Ali	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Tahira Jabeen	Substantial Contribution to study design and Data Analysis Has given Final Approval of the version to be published
Sobia Yusif	Contributed to study concept and Data collection Has given Final Approval of the version to be published

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