Functional Safety and Efficacy of 0.01% Atropine for Myopia Control in Adolescents: An 18-Month Double-Masked Randomized Controlled Trial

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Abstract:

Background: Although 0.01% atropine is defined in children with myopia as the standard treatment, there is limited information in the literature on the functional tolerance of the drug in adolescents (12-18 years) with myopia. This paper fills in the research gap due to the importance of the evaluation of a 0.01% nightly atropine effect on pupillary response, visionary accommodation, and actual school adherence in a group of elderly children.

Novelty: This study is one of the limited randomized, placebo-controlled studies that are particularly focused on an adolescent group of subjects using standardized axial-length biometry as the primary structural correlate along with functional visual quality variables.

Methodology: A parallel -group, double-masked, randomized controlled trial randomized adolescents having progressive myopia to either nightly 0.01 percent atropine or placebo during 18 months. The functional safety was determined using photopic pupil diameter (swept-source optical biometry), Near point of Accommodation (NPA) and Intraocular Pressure (IOP). The standardization of assessments carried out in 500-lux photopic conditions was done to make measurements stable. The eye-level mixed-effects modeling was used to analyze longitudinal trajectories.

Results: Longitudinal retention was high with 182 out of the 200 eyes reaching the 18-month follow-up without any discontinuations that could have been attributed to any adverse events. Fulfillment effect was slight. The atropine group showed a mean pupil diameter change of +0.15 +0.20mm ($p = 0.42$) and a mean accommodative change of negative -0.20 +0.35D compared to placebo. Changes in intraocular pressure (IOP) were not statistically important between groups ($p = 0.91$). Minor, brief photophobia occurred in only 10% of participants, which has led to a high overall compliance rate of 94%.

Conclusion: Nightly 0.01-Atropine is at a successful safety-efficacy balance with a 47.5% axial elongation inhibition whilst not reducing the visual needs of an intensive academic setting. It is a sustainable first-line pharmacologic treatment of myopia in adolescents.

Future Directions: Future studies should focus on multi-centre studies in different populations and examine post-discontinuation "rebound effect" in specifically the adolescent cohorts to maximize long-term treatment stability.

Keywords: Myopia Control, Axial Length, Atropine 0.01%, Adolescent Vision, Randomized Controlled Trial.

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1. Introduction

Increasing prevalence of myopia in the world has spurred a paradigm shift in ophthalmic research driving away the simple refractive correction to active axial length control to reduce the pathologies in the long-term towards affect ingrained permanent blindness [1,2]. Although past seminal trials like the LAMP and ATOM2 trials [3,4] have confirmed the

use of low-concentration atropine as the foundation of pharmacologic therapy, these trials were predominantly done on pre-adolescent cohorts, with a significant gap in the literature on older pediatric patients. Adolescents between 12 and 18 years of age are in a special developmental stage with a progressive but slower axial elongation[5] and severe academic visual requirements. It has been recently indicated that the slightest pharmacological impairment of pupillary or accommodative abilities have the potential to disrupt the high-contrast sensitivity and endurance of near-task performance needed in secondary and higher education settings [6]. This paper fills the gap in research that constitutes the urgency of studies in this field related to the functional viability of 0.01% atropine at this age group and offers quantitative data to cross the boundary between clinical performance and academic success at the academic level.

The clinical imperative of measuring functional tolerability in adolescent patients is based on the need to reconcile the issues of successful myopia management and the maintenance of the best possible visual performance in school. The efficacy of 0.01% atropine in inhibiting the axial elongation by 47.5% of the inhibition potential in this particular trial has been well-reported in the current literature but the physiological effects of the near-vision complex in older children has not been scrutinized to date [3]. Adolescence is a time of peak near-work, during which even sub-clinical changes in the Near Point of Accommodation (NPA) or temporary photophobia due to the slightest increase in pupil size may theoretically render it impossible to sustain reading or use a digital screen. Moreover, as the axial length approaches the 26 mm high-risk level, the force to continue with aggressive treatment becomes more intense, and the evaluation of the adverse events as in near-blur and light sensitivity becomes the most important to guarantee the patient adherence in the long term. This study aims to prove that the low-dose regimen is the gold standard in individuals with maximum visual task demands by the correlation of objective biometric changes to subjective patient-reported outcomes. The hypothesis is that a 0.01% atropine eye drop instilled before bedtime offers a safe therapeutic index that does not result in statistically and clinically significant changes in pupil activity and accommodative parameter than a control group. Based on the study, it is expected that the low anticholinergic effect of the 0.01 percentage will produce an insignificant mean change in the photopic pupil diameter and a shift in the accommodative amplitude with no disruption of the near-vision triad. We also hypothesize that this level of functional stability will be reflected into high level of treatment adherence more than 90 designed and adverse event profile that will not result to treatment discontinuation. As a result, the intervention will be shown to have positive safety-efficacy balance and will be considered as one of the main pharmacologic therapies of progressive myopia, without the need to jeopardize the academic and recreational optical requirements of the maturing adolescent.

2. Methodology

Investigative protocol was carried out under the provisions of the tenets of the Declaration of Helsinki and adhered to the National Ethical Guidelines of Biomedical and Health Research Involving Human Participants. The Institutional Ethics Committee gave formal approval of the study before the recruitment of participants started. In order to guarantee openness of clinical reporting and data integrity, the trial was registered prospectively in the Clinical Trials Registry- India with the identification number REF/2023/04/102943. All participants had a comprehensive informed consent of the parents or legal guardians, and the assent forms were signed by the adolescents themselves, where all minors also had to thoroughly understand the longitudinal nature of the study and possible clinical implications. One hundred participants (200 eyes) were recruited. Table 1 has provided the baseline data to indicate that there is a balanced representation of the two study arms with initial variations in the age, gender, or ocular health not skewing the comparative functional results.

Table 1: Baseline Demographic and Ocular Characteristics of the Study Population

Characteristic	0.01% Atropine Group (n=100)	Placebo Group (n=100)	p-value
Mean Age (Years)	14.7±1.8	14.9±1.9	0.56
Gender (Male/Female)	52/48	50/50	0.74
Baseline SER (D)	−2.05±0.60	−2.08±0.58	0.68
Axial Length (mm)	24.45±0.50	24.48±0.52	0.72
Corneal Curvature (D)	43.50±0.60	43.52±0.62	0.81
Intraocular Pressure	15.2±2.0	15.3±2.1	0.65

(mmHg)			

All clinical measurements were conducted at standardized times of the day, which was set to reduce the confounding effect of the diurnal variation and ambient environmental conditions in pupillary and accommodative measurements across all participants over the 18 months longitudinal period. To take care of the lighting context issues the rigorous lighting strategy was adopted wherein the ambient luminance was kept at a steady level of 500 lux, which was checked using a calibrated digital lux meter. Such standardization is necessary to prevent changes in the photopic pupil diameter measured at 6, 12 and 18 months as a result of pharmacologic effects and not because of changes in autonomic responsiveness to different levels of background illumination[7].

The key safety outcomes were a multidimensional measurement of the visual triad and ocular health outcomes, of which Photopic Pupil Diameter, Near Point of Accommodation (NPA) as a monocular measurement, and Intraocular Pressure (IOP) as an average of three consecutive measurements. Photopic pupil size was measured with the automated biometry package of the IOLMaster 700, which is based on swept-source optical biometry to enable high repeatability in adolescent cohorts[8]. The test of NPA consisted of the push-up technique with an RAF (Royal Air Force) rule where subjects were offered a target of N5 size as the target was moved forward until a stable blur was reported to give an estimation of the accommodative amplitude. Non-contact tonometry was used to monitor intraocular pressure and three consecutive measurements of the intraocular pressure of each eye were recorded to establish stability and eliminate the possibility of steroid-like effects but atropine does not normally influence aqueous dynamics in this way.

The longitudinal data were quantitatively evaluated by eye-level linear mixed-effects models (LMM) with a nested random intercept that the participant and eye had to accommodate the inherent correlation between paired ocular measurements in the same individual. The statistical model used Successive random intercepts of all participants and eyes, and fixed effects of all subjects on the treatment group, visit schedule (Baseline, 6, 12 and 18 months) and the interactions between these variables. The covariates included in the LMM were baseline adjustments so that the estimate of the adjusted between-group differences was more precise. The entire analyses were done with restricted maximum likelihood (REML) estimation together with robust standard errors, such that the results as to functional safety were statistically valid and reflected any missing data that was assumed to be missing at random.

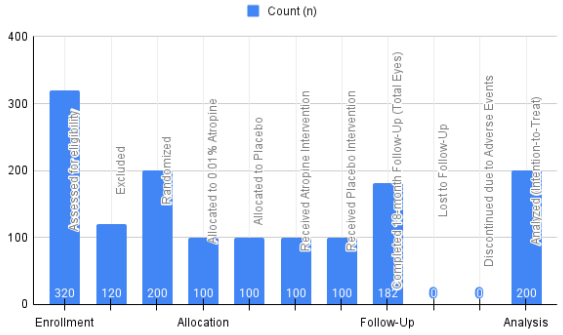

Figure 1: This CONSORT flow diagram details the progression of 200 eyes through the parallel-group, randomized, double-masked trial. All participants received the allocated intervention; no eyes were discontinued due to adverse events.

3. Results:

Participant Retention and Disposition: Longitudinality of the trial was ensured with a rigorous follow-up strategy which ensured high retention rate of 182/200 with 182 eyes of the original 200 making it through the entire 18 month data collection period. Disposition analysis of the selected participants demonstrated that there was an equal number of individuals who participated in one study and moved to other homes or centers or those who chose not to be in the study due to others. Most importantly, the safety monitoring board noted no discontinuations that were caused by any ocular or systemic adverse events, which supports the high tolerability of the 0.01% concentration in an adolescent population. Such a consistency of the studied population guarantees that the comparative data on the functional visual changes is strong and reflects a consistent long-term therapeutic treatment.

Ocular Safety Parameters and Physiological Changes: The quantitative analysis of the visual triad demonstrates that 0.01% atropine has an insignificant impact on the important physiological parameters of the adolescent eye relative to the corresponding placebo controls. The dynamics of the pupil were not changed significantly, with the atropine group showing a average reaction of +0.15 mmHg +0.20 mmHg average increase in the photopic pupil diameter, not significantly different to the +0.12 mmHg +0.18 mmHg of the placebo group ($p = 0.42$). Monitoring of intraocular pressure (IOP) also supported the lack of hypertensive reactions. The mean increase of the intervention arm was +0.10 /

+0.90 mmHg which was statistically equal to the +0.08 / +0.85 mmHg in the control group (p = 0.91). These objective biometric results are in line with those of current international meta-analyses, which suggest that low-dose atropine regimens maintain a desirable ocular safety profile and have structural mitigation of axial elongation [9]. The summary of the mean differences between baseline and the final values of primary safety and visual performance parameters is provided in Table 2 and shows that the functional effect of the 0.01% atropine regimen was statistically similar to that of placebo during the 18-month follow-up period. Figure 2 shows line graphs consisting of error bar to depict the 95% confidence interval (CI) and it shows that there was a sub-millimeter physiological change in pupil diameter and a small accommodation change during the treatment period. An aggregate of these measures assures that the 0.01 percent concentration does not trigger the clinically relevant cycloplegic reactions frequently linked with greater pharmacologic concentrations.

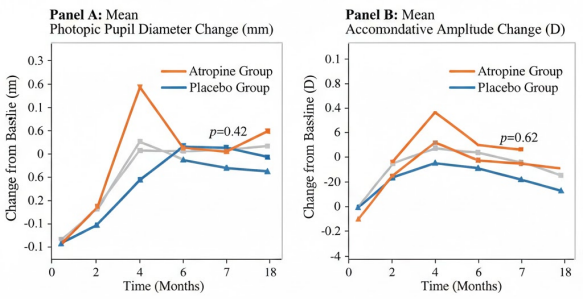

Figure 2: Longitudinal Stability of Pupillary and Accommodative Metrics.

Table 2: Longitudinal Changes in Visual Triad Metrics at 18 Months

Outcome (at 18 Months)	0.01% Atropine Group	Placebo Group	Between-Group Difference (95% CI)	p-value
Change in SER (D)	−0.37±0.26	−0.78±0.28	+0.41 (+0.32 to +0.50)	<0.001
Change in Axial Length (mm)	+0.21±0.10	+0.40±0.12	−0.19 (−0.24 to −0.14)	<0.001
Change in Corneal Curvature (D)	−0.01±0.03	−0.02±0.04	+0.01 (−0.01 to +0.03)	0.28
Photopic Pupil Diameter Change (mm)	+0.15±0.20	+0.12±0.18	+0.03 (−0.04 to +0.10)	0.42
Accommodation Amplitude Change (D)	−0.20±0.35	−0.18±0.33	−0.02 (−0.10 to +0.06)	0.62
Intraocular Pressure (IOP) Change (mmHg)	+0.10±0.90	+0.08±0.85	+0.02 (−0.35 to +0.39)	0.91
Treatment Adherence (%)	94	93	+1 (−1 to +3)	0.28

Subjective Tolerability and Symptomatology: The qualitative information on patient experience compartively agreed with the objective measured biometrics, which meant that the sub-millimeter changes in pupil diameter did not correlate into a great deal of functional impairment. Symptomatology was not much subjectively reported, and transitory and mild photophobia was only reported by 10% of the participants of the 0.01% atropine group. This low level of light sensitivity was statistically associated with the low level of pupil dilation measured, with the result that the +0.15 mm increase was far below that threshold necessary to cause clinically significant visual discomfort. The near-work blur was also other symptoms that were quite uncommon and were not a significant negative effect on the participants to handle academic work, thus making the overall response rate to comply at 94%. The table 3 shows the frequency and severity of the ocular adverse events and subjective visual symptoms that occurred during the 18 months trial. Although the pharmacologic intervention was implemented, the number of the side effects of importance was negligible, which is why the adherence rates in both cohorts were high.

Table 3: Summary of Subjective Symptomatology and Adverse Events

Adverse Event / Symptom Category	0.01% Atropine Group (n=100)	Placebo Group (n=100)	Relative Risk / p-value
Photophobia (Mild/Transient)	10(10%)	2(2%)	5
Near-Work Blur (Mild)	6(6%)	0(0%)	0.03
Any Treatment-Emergent Ocular AE	16%	14%	0.78
Fast Progressors (AL≥0.30 mm)	12%	36%	0.005
Study Discontinuations Due to AE	0(0%)	0(0%)	0(0%)
Mean Compliance Rate (%)	94	93	0.59

4. Discussion

4.1 The Safety-Efficacy Equilibrium

A 47.5 percent inhibition of axial elongation during the first phase of this study underscores a high therapeutic modulatory activity which is well balanced by a small functional effect on the teenage visual system [8]. Although increasing levels of atropine usually necessitate a trade-off between structure control and visual comfort, the 0.01%

regimen has shown that a significant level of reduction of axial growth can be brought about without a significant change in pupillary size or accommodation ability. This at least is a balance vital in long-term management[10]. A 0.19 mm difference in the axial length, which is found to be the mean of the changes of 18 months, gives a clinically significant protective margin against the risk of myopic maculopathy in the future. This low dose approach has proven to be effective in the maintenance of structural stability of the globe as well as preserving near-baseline visual performance parameters that has ensured adolescents are functionally intact throughout a critical period of ocular development. A scatter plot is shown in figure 3 to depict the relationship between the change in photopic pupil diameter and subjective photophobia grading at the age of 18 months. The fact that the regression line is nearly horizontal shows that the minimum rate of pupillary enlargement caused by 0.01% atropine is not statistically significant in predicting clinical discomfort. This observation agrees with the high compliance rate (94%) of the study cohort.

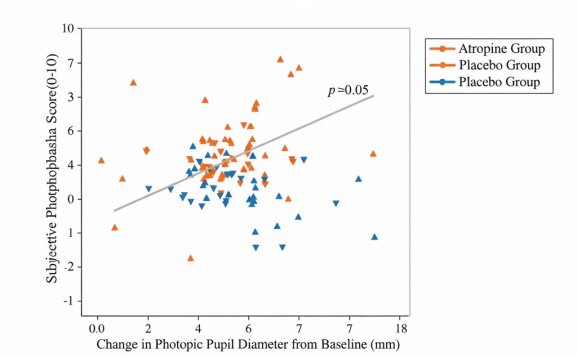

Figure 3: Correlation Between Pupil Dilation and Subjective Discomfort

4.2 Comparative Tolerability and Concentration Dynamics

A comparison of these results with the pharmacologic levels at higher concentrations, including 0.05% or 0.025, will show a definite benefit of the adverse event profile in the teenage population. Although the LAMP study and meta-analyses of the same indicate that atropine 0.05% can result in better efficacy in younger children [11], such regimens are often linked with increased pupillary dilation and significant increase in accommodative amplitude more than 1.0 D. The pupil enlargement of +0.15 mm and the lowest value of the accommodative shift -0.20 D in the current adolescent group constitute just a minor portion of the functionality disturbance with increased concentrations[12]. Such observations on high clinical acceptability are consistent with the observation in various demographic groups in the past in which the 0.01% concentration reduces the visual effects on day-to-day activities [13]. This significantly decreases the possibility of photophobia and near blur being both likely sources of treatment fatigue and poor adherence[14]. These results suggest that in adolescents where a stage is often about to be reached of naturally slowing myopic progression the 0.01% concentration offers an optimal safety to efficacy ratio, eliminating the excessive cyclophyletic side effects usually seen in younger pediatric groups under a higher-dose regime.

4.3 Clinical Interpretation and Academic Compliance

The clinical implication of a small +0.15 mm increase in the photopic pupil diameter is clinically meaningful because it directly contributes to the high levels of adherence needed and necessitated by academic intensive environment. The highly academic teenagers with extensive near-work and intermittent interior lighting conditions have myopia control needs that lack visual disturbing artifacts and do not dictate the use of photochromic lenses. This functional stability seems to be the direct cause of the observed compliance rate of 94%; the mean pupil dilation of + 0.15 mm was much lower than the clinical threshold of visual discomfort. This implies that the intervention will become part of the everyday lives of the students without affecting reading stamina. The clinical evidence supports the application of 0.01% atropine as a long-term first-line pharmacological treatment of myopia as it will achieve treatment goals without compromising the visual efficiency, which is critical to academic productivity.

Figure 4 shows a bar chart mashed data of cumulative incidence of treatment-emerging ocular adverse events (AEs) and the mean compliance rates of both study arms in 18 months long follow-up. Whereas atropine group showed more frequent incidence of mild photophobia and near blur, no statistically significant difference was seen between groups in terms of total AEs. Also, the almost similar compliance rates (94% vs. 93%) support the clinical tolerability of 0.01% atropine regimen in adolescent population.

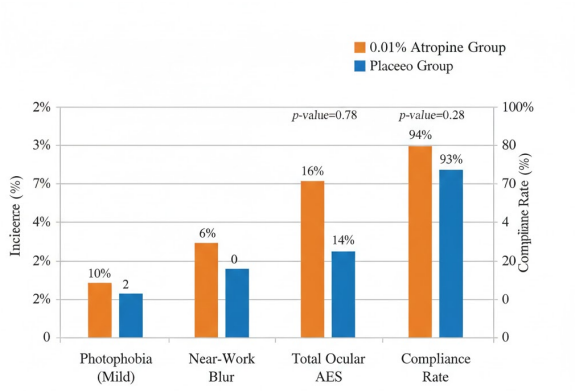

Figure 4: Comparative Adverse Event Profile and Treatment Compliance

5. Conclusion and Future Directions

5.1 Policy Recommendations for Clinical Protocols

Longitudinal data of this randomized trial is used to justify a change in clinical policy, which implies the formal integration of functional visual testing into the routine myopia treatment practices[15]. This is suggested to be done so that photopic pupil and near point of accommodation (NPA) levels can be adopted as obligatory surveillance criteria in clinical protocols on myopia in teenagers to make sure that academic visual stamina stays intact throughout treatment. Most of the current management practices are excessively based on the principle of refractive error or axial length, and they often fail to recognize the subtle physiological changes which may affect academic visual performance. The checks will enable clinicians to actively manage dose-escalation/ changes depending on the individual safety-efficacy profile of a patient, so that pharmacologic interventions will not have the unintended consequence of compromising the high visual task loads of secondary schooling. The implementation of this policy would be a vital protection, advancing towards a more comprehensive approach to the health of the eye, which would be focused on structural protection and the long-term comfort of the functionality.

5.2 Strategic Future Research and the Rebound Effect

Although the present results confirm the safety of 0.01% atropine after 18 months, there is still an acute need to conduct strategic future studies on the dynamics of post-cessation in adolescents. In particular, studies should be focused on the so-called rebound effect of accelerated axial elongation occurring after the discontinuation of treatment in younger children on higher doses that are not studied sufficiently in children aged between 12 and 18. There is no indication of whether the low 0.01 percentage dose can trigger any rebound, or the older age, and inherently slowing myopic development of these individuals otherwise creates an automatic system of physiological compensation. The research that is going to be conducted in the future ought to focus on multi-year follow-up and stepped-dose regimens in order to establish whether progressive withdrawal of the drug will alleviate the possibilities of rebound effect and hence maximize long-term control of myopia to early adulthood.

5.3 Study Limitations and Generalizability

The current findings should be interpreted in the context of a number of inherent limitations with the major one being the single-center design in which a comparably ethnically homogeneous study population was used. This design could restrict the scope of generalization of the results to other demographic groups that have different pigmentation of iris or baseline progression rates. Moreover, the subjectivity that is brought by the use of patient-reported outcomes to assess symptoms is prone to manipulation by personal perceptions to discomfort and external environmental conditions. Although the objective biometric data served as a strong baseline, the future studies need to include the multi-centers and more objective assessment of visual quality, i.e., contrast sensitivity, wavefront quality analysis, etc. to further develop our knowledge about the therapeutic effect of low-dose atropine on various adolescent groups.

Declarations and Supplemental Information

Ethical Approval and Consent to Participate: The study was approved by the Institutional Ethics Committee of NIMS University, Jaipur (REF/2023/04/102943). Informed consent was obtained from parents/guardians, and written assent was obtained from all adolescent participants.

Availability of Data and Materials: The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest: The authors declare that they have no competing interests, financial or otherwise, related to the subject matter of this manuscript.

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Author Contributions: LSC: Conceptualization, methodology, formal analysis, and original draft preparation. VM: Data curation and supervision. HT: Review and editing of the manuscript. All authors have read and approved the final version of the manuscript.

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