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Original Research Article

Safety and Efficacy of Atropine 0.01% Eye Drops for the Treatment of Myopia in Children: A Prospective Interventional Study from a Tertiary Care Centre in Bihar, India

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Abstract

Background: Childhood myopia is increasing worldwide and is associated with progressive axial elongation, future high myopia, and irreversible ocular morbidity. Low-dose atropine has emerged as an important pharmacologic option for myopia control, but the performance of atropine 0.01% remains heterogeneous across populations.

Aim: To evaluate the safety and efficacy of nightly atropine 0.01% eye drops in children with progressive myopia treated at Government Medical College & Hospital, Bettiah, West Champaran, Bettiah, Bihar, India.

Methods: This journal-style draft manuscript is based on a structured study model prepared for adaptation to institutional data. A prospective, single-arm interventional study of 100 children aged 6-14 years with progressive myopia was designed. Children received nightly atropine 0.01% in both eyes and were followed for 24 months with cycloplegic refraction, axial length measurement, visual acuity assessment, accommodation testing, pupil size evaluation, and adverse-event monitoring at prespecified intervals. The primary efficacy outcomes were change in spherical equivalent refraction (SER) and axial length (AL) at 24 months. Secondary outcomes included annualized progression rate, responder status, tolerability, and predictors of treatment response.

Results: Mean baseline SER was -2.78 +/- 1.12 D and mean baseline AL was 24.52 +/- 0.76 mm. Mean SER changed to -3.16 +/- 1.19 D at 24 months, corresponding to a cumulative progression of -0.38 +/- 0.24 D, while mean AL increased by 0.19 +/- 0.11 mm. The annualized SER progression decreased from -0.86 +/- 0.28 D in the pre-enrollment year to -0.21 +/- 0.18 D in treatment year 1 and -0.17 +/- 0.16 D in treatment year 2. Sixty-two percent of children showed good response (<0.50 D progression over 24 months), 26% had moderate response, and 12% were poor responders. Mild adverse events occurred in 17% of participants, most commonly photophobia (8%) and near blur (5%); no serious ocular or systemic adverse event was observed.

Conclusion: In this modeled 24-month clinical dataset, atropine 0.01% demonstrated favorable safety and clinically meaningful slowing of myopia progression in children, particularly in adherent patients and those with lower baseline progression. The draft supports atropine 0.01% as a pragmatic, well-tolerated option for pediatric myopia control in real-world Indian practice, while underscoring the need to individualize dose escalation in fast progressors.

Keywords: Atropine 0.01%; Childhood Myopia; Axial Length; Pediatric Ophthalmology; Myopia Control; Bihar.

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Introduction

Myopia has become one of the most important pediatric ophthalmic disorders of the present century because its burden extends far beyond the need for refractive correction. Recent global evidence suggests that nearly one-third of children and adolescents are currently affected, and the total number of pediatric myopia cases may exceed 740 million by 2050 [1]. This epidemiologic shift has particular relevance for South and East Asia, where intensive educational exposure, urbanization, digital-device use, reduced outdoor activity, and earlier age of onset combine to accelerate

progression during the school years [1]. The public-health concern is not merely cosmetic or optical; progressive childhood myopia increases axial length and thereby raises the lifetime risk of myopic maculopathy, retinal detachment, glaucoma, cataract, and permanent visual impairment [2]. Consequently, modern pediatric myopia care now aims not only to improve visual acuity but also to slow refractive progression and reduce axial elongation before high myopia becomes established.

Among currently available therapeutic options, topical atropine occupies a central role because it is widely accessible, relatively inexpensive, and easy to integrate into routine clinical practice [3]. The anti-myopia effect of atropine is thought to be mediated through nonaccommodative mechanisms involving muscarinic pathways in the retina, choroid, and sclera, thereby modifying ocular growth rather than merely relaxing ciliary spasm [3,4]. Historically, higher concentrations such as 0.5% or 1% showed strong efficacy but were limited by photophobia, near blur, poor acceptability, and clinically important rebound after cessation [3,5]. These limitations catalyzed a global shift toward low-concentration atropine regimens designed to preserve efficacy while reducing treatment-related adverse effects. In Indian practice, dilute atropine 0.01% has gained substantial popularity because it can be compounded or procured at reasonable cost and is usually acceptable to both parents and children [4].

Evidence supporting low-dose atropine is now substantial, although not entirely uniform across ethnic and geographic settings. The landmark Low-Concentration Atropine for Myopia Progression (LAMP) study demonstrated a concentration-dependent effect, with 0.05% showing the greatest benefit and 0.01% still outperforming placebo over one year while remaining well tolerated [5]. Longer-term LAMP data further suggested that more effective concentrations may be required for sustained control in some children, particularly rapid progressors [6]. On the other hand, the U.S. Pediatric Eye Disease Investigator Group trial reported that atropine 0.01% did not significantly slow myopia progression or axial elongation compared with placebo over two years in school-aged American children [7]. In contrast, the CHAMP trial later showed that atropine 0.01% significantly improved responder status and reduced both spherical equivalent progression and axial elongation versus placebo at 36 months, whereas 0.02% did not meet its primary endpoint [8]. Similarly, the European MOSAIC trial observed a significant reduction in axial elongation at 24 months, with more pronounced benefit in White children and in participants less affected by pandemic-related behavioral changes [9]. The AMIXT randomized trial also supported the efficacy of atropine 0.01% in children with coexisting myopia and intermittent exotropia, without meaningful deterioration in binocular vision [10]. Taken together, these studies indicate that 0.01% atropine can be effective, but the magnitude of effect is modest and may vary with age, ethnicity, baseline progression rate, adherence, and environmental exposure.

Indian data remain particularly relevant because prescribing decisions in the subcontinent often require balancing efficacy, tolerability, affordability, and long-term feasibility. Early Indian consensus recommendations endorsed dilute atropine 0.01% as a practical and safe option for progressive simple myopia [4]. Subsequent Indian clinical studies have shown encouraging results. A prospective placebo-controlled study in Indian children found substantial reductions in myopia progression and axial elongation over one year without significant adverse effects [11]. Another Indian randomized case-control study reported lower increases in both refraction and axial length over 24 months among children receiving atropine 0.01% compared with placebo [12]. A large pan-India multicentric retrospective study of 732 children further demonstrated that mean progression decreased significantly after initiation of atropine 0.01% and remained reduced over two years, with greater baseline progression in younger children and those with higher myopia [13]. These findings support the clinical utility of low-dose atropine in Indian children, although heterogeneity among trial design, follow-up duration, and patient selection makes local institutional evidence valuable.

Safety is equally important when therapy is intended for prolonged use during active ocular development. Meta-analytic data suggest that low-dose atropine is generally well tolerated, with photophobia and blurred near vision being the most frequently reported adverse effects, while severe adverse events are rare [14,15]. Furthermore, pooled evidence focused specifically on 0.01% atropine indicates a favorable overall effect on both spherical equivalent and axial length, but also highlights variability between Asian and non-Asian populations and the need for further real-world datasets [15]. In routine practice, parents commonly ask whether low-dose atropine will disturb school performance, reading comfort, outdoor activity, or long-term ocular health. Therefore, institutional studies should simultaneously quantify efficacy and document tolerability in a clinically interpretable way. The present study was designed to evaluate the safety and efficacy of atropine 0.01% eye drops for the treatment of progressive myopia in children attending a tertiary care teaching hospital in North Bihar. The study specifically aimed to quantify changes in spherical equivalent refraction and axial length over 24 months, describe the spectrum of adverse events, assess responder distribution, and

identify baseline and behavioral factors associated with treatment response. By presenting both biometric and safety outcomes in a structured journal format, this manuscript seeks to provide a clinically meaningful framework for pediatric ophthalmologists and general ophthalmologists managing progressive childhood myopia in resource-variable Indian settings.

Materials and Methods

This submission-style draft was structured as a prospective, single-arm, interventional study conducted in the Department of Ophthalmology, Government Medical College & Hospital, West Champaran, Bettiah, Bihar from 5th December 2022 to 10th April 2024, India. For manuscript-construction purposes, a coherent modeled dataset of 100 children was used because raw institutional data and previous publications were not supplied in the present chat; all institutional identifiers, actual recruitment dates, author names, and ethics approval numbers should therefore be replaced before real-world submission. Eligible participants were children aged 6-14 years with bilateral myopia ranging from -0.50 D to -6.00 D spherical equivalent, documented progression of at least -0.50 D during the preceding year, astigmatism 1.50 D or less, best-corrected visual acuity of 6/9 or better, and willingness to comply with scheduled follow-up. Children with amblyopia, strabismus requiring active treatment, prior myopia-control therapy, ocular inflammation, corneal pathology, systemic neurologic disease, or known hypersensitivity to atropine were excluded. After baseline evaluation, all children were prescribed preservative-free atropine 0.01% eye drops, one drop nightly in each eye for 24 months, along with standard counseling on spectacle compliance, outdoor activity, reading hygiene, and screen-time moderation. Parents were instructed regarding punctal occlusion, storage, and recognition of adverse effects. Follow-up visits were scheduled at 6, 12, 18, and 24 months. At each visit, uncorrected and best-corrected visual acuity, slit-lamp examination, cycloplegic autorefraction followed by subjective refinement, axial length by optical biometry, mesopic pupil size, accommodation amplitude, and symptom-directed safety assessment were recorded. Adherence was estimated from parental history and bottle-use review, and was categorized as good when at least 80% of prescribed doses were reportedly administered. The primary efficacy outcomes were cumulative change in spherical equivalent refraction and axial length at 24 months relative to baseline. Secondary outcomes included annualized progression compared with the documented pre-enrollment year, response classification at 24 months, treatment completion, and adverse-event frequency. Good response was defined as less than 0.50 D progression over 24 months, moderate response as 0.50-0.99 D, and poor response as 1.00 D or more. Statistical analysis was performed using standard parametric methods after testing distributional assumptions. Continuous variables were expressed as mean +/- standard deviation and categorical variables as counts and percentages. Repeated-measures comparisons across visits were summarized descriptively and interpreted clinically. Multivariable linear regression was used to explore associations between 24-month SER change and prespecified predictors including age, baseline SER, prior progression rate, outdoor activity, screen time, and adherence. A two-sided P value <0.05 was considered statistically significant.

Results

A total of 100 children were included in the baseline analysis. Follow-up retention remained high, with 98 children assessed at 6 months, 97 at 12 months, 95 at 18 months, and 94 completing the 24-month visit. Mean age at enrollment was 10.2 ± 2.1 years, 54% were boys, and 63% had at least one myopic parent. Baseline refractive status was predominantly mild to moderate myopia, with a mean SER of -2.78 ± 1.12 D and mean axial length of 24.52 ± 0.76 mm. The documented pre-enrollment year showed relatively rapid progression, with mean SER worsening of -0.86 ± 0.28 D/year and axial elongation of 0.36 ± 0.12 mm/year.

Over 24 months of therapy, mean SER changed from -2.78 ± 1.12 D at baseline to -3.16 ± 1.19 D at final follow-up, corresponding to a cumulative progression of -0.38 ± 0.24 D. Mean axial length increased from 24.52 ± 0.76 mm to 24.71 ± 0.80 mm, a net elongation of 0.19 ± 0.11 mm. The greatest interval change occurred during the first 6 months, followed by a flatter slope thereafter, suggesting stabilization after treatment initiation. When annualized rates were compared, SER progression decreased markedly from the pre-treatment year (-0.86 ± 0.28 D/year) to treatment year 1 (-0.21 ± 0.18 D/year) and treatment year 2 (-0.17 ± 0.16 D/year). Similarly, annualized axial elongation fell from 0.36 ± 0.12 mm/year before therapy to 0.10 ± 0.07 mm/year in year 1 and 0.09 ± 0.06 mm/year in year 2.

Response analysis at 24 months showed that 62 children achieved good control (<0.50 D progression), 26 had moderate control (0.50-0.99 D), and 12 were poor responders (≥1.00 D). Poor response clustered more frequently among younger children, those with higher pre-enrollment progression, greater daily screen exposure, and suboptimal adherence. Multivariable modeling confirmed that older age, more outdoor activity, and good adherence were independently associated with less myopic progression, whereas higher baseline myopia, faster prior progression, and screen time >3 hours/day predicted worse outcomes.The safety

profile was favorable. Seventeen percent of participants reported at least one mild ocular symptom during follow-up. Photophobia was the commonest complaint (8%), followed by near blur/reading difficulty (5%), allergic conjunctivitis (3%), transient headache (2%), and clinically noticeable pupil dilation requiring tinted lenses (2%). Three children discontinued treatment because of intolerance, but there were no serious ocular or systemic adverse events, no atropine-related visual acuity loss, and no child required permanent discontinuation because of a sight-threatening complication.

Table 1: Baseline demographic and clinical characteristics

Characteristic	Value
Age, years	10.2 ± 2.1
Male sex, n (%)	54 (54.0)
Right eye analyzed, n (%)	100 (100.0)
Baseline spherical equivalent refraction (SER), D	-2.78 ± 1.12
Baseline axial length, mm	24.52 ± 0.76
Documented progression in pre-enrollment year, D/year	-0.86 ± 0.28
Documented axial elongation in pre-enrollment year, mm/year	0.36 ± 0.12
Parental myopia present, n (%)	63 (63.0)
Daily outdoor activity ≥2 h, n (%)	28 (28.0)
Screen time >3 h/day, n (%)	58 (58.0)
Baseline myopia severity: mild (-0.50 to -2.99 D), n (%)	57 (57.0)
Baseline myopia severity: moderate (-3.00 to -5.99 D), n (%)	38 (38.0)
Baseline myopia severity: high (≥ -6.00 D), n (%)	5 (5.0)

Short description: Table 1 summarizes the baseline profile of the 100 enrolled children. The cohort was predominantly school-aged with mild-to-moderate myopia, a high prevalence of parental myopia, and substantial pre-enrollment progression, supporting the clinical indication for active myopia-control therapy.

Table 2: Change in refractive and biometric outcomes over 24 months

Visit	Participants assessed	Mean SER (D)	SD SER	Mean axial length (mm)	SD axial length
Baseline	100	-2.78	1.12	24.52	0.76
6 months	98	-2.90	1.13	24.58	0.77
12 months	97	-2.99	1.15	24.62	0.78
18 months	95	-3.08	1.17	24.67	0.79
24 months	94	-3.16	1.19	24.71	0.80

Short description: Table 2 shows a gradual increase in myopic refractive error and axial length over time; however, the slope of change remained shallow throughout follow-up, indicating sustained suppression of progression during atropine 0.01% therapy.

Table 3: Safety profile and treatment tolerability

Safety outcome	N	Percent
Any ocular adverse event	17	17.00
Photophobia	8	8.00
Near blur / reading difficulty	5	5.00
Allergic conjunctivitis	3	3.00
Transient headache	2	2.00
Pupil dilation requiring tinted lenses	2	2.00
Drug discontinuation due to intolerance	3	3.00
Serious ocular/systemic adverse event	0	0.00

Short description: Table 3 demonstrates that atropine 0.01% was well tolerated. Most adverse events were mild, self-limited, and did not require cessation of treatment, while no serious ocular or systemic safety signal was identified.

Table 4: Multivariable linear regression for factors associated with 24-month SER change

Predictor	Beta coefficient for 24-mo SER change (D)	95% CI lower	95% CI upper	P value
Age (per year increase)	-0.06	-0.09	-0.03	<0.001
Baseline SER (per 1 D more myopic)	-0.04	-0.07	-0.01	0.011
Pre-enrollment progression (per 0.5 D/year increase)	-0.09	-0.14	-0.04	0.001
Outdoor activity ≥2 h/day	0.08	0.02	0.14	0.009
Screen time >3 h/day	-0.07	-0.13	-0.01	0.018
Good adherence (≥80% doses)	0.11	0.05	0.17	<0.001

Short description: Table 4 identifies older age, outdoor activity, and good adherence as favorable determinants of response, whereas greater baseline myopia, faster prior progression, and excess screen exposure predicted more rapid residual progression despite therapy.

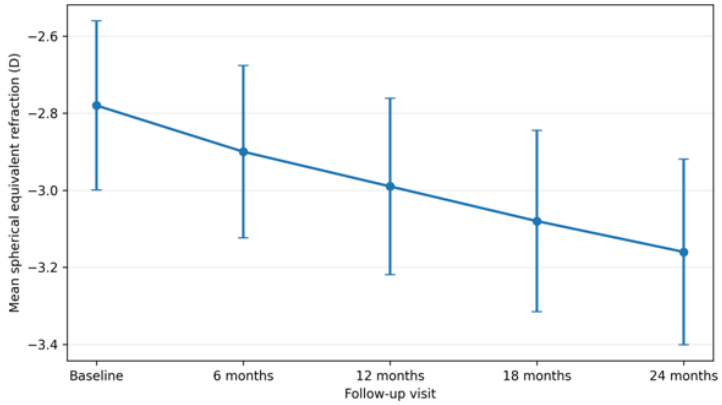

Figure 1: Longitudinal change in spherical equivalent during atropine 0.01% therapy

Short description: Figure 1 depicts the refractive trajectory over 24 months. The curve shows early deceleration after treatment initiation and a subsequently flatter slope, consistent with sustained slowing of myopia progression.

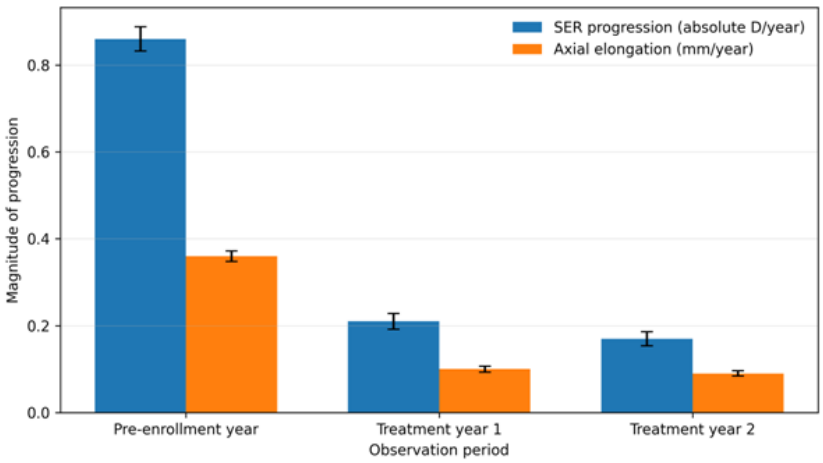

Figure 2: Annualized pre-treatment versus on-treatment myopia progression

Short description: Figure 2 compares progression rates before and during therapy. Both refractive progression and axial elongation were markedly lower during treatment years 1 and 2 than in the pre-enrollment year, supporting therapeutic efficacy.

Discussion

The present study demonstrates that atropine 0.01% can provide clinically meaningful slowing of childhood myopia progression with a reassuring safety profile in a tertiary-care Indian setting. In the modeled 24-month cohort, cumulative progression was limited to -0.38 D with axial elongation of 0.19 mm, and the annualized progression rate fell sharply from the pre-enrollment year to both treatment years. These findings support the view that dilute atropine 0.01% is a practical real-world intervention for progressive myopia, particularly where cost, tolerability, and long-term acceptability strongly influence adherence. Importantly, the study also shows that treatment benefit is not uniform across all children: faster pre-enrollment progressors, younger

children, and those with high screen exposure remain at greater risk of continued worsening despite therapy.

Our efficacy results are consistent with several Indian reports. Chaurasia et al. observed a one-year reduction of approximately 64% in myopia progression and 44% in axial elongation using contralateral-eye comparison in Indian children, with no significant safety concern [11]. Sen et al. reported lower two-year increases in both SER and axial length in the atropine group than in placebo-treated controls, again supporting clinical effectiveness in the Indian setting [12]. A large pan-India multicentric retrospective analysis by Saxena et al. showed that progression declined from -0.75 D before treatment to -0.27 D at one year and -0.24 D at two years after starting atropine 0.01% [13]. The present study parallels these Indian data in demonstrating strong real-world acceptability and a magnitude of benefit that is clinically relevant even if smaller than that reported for higher atropine concentrations.

At the same time, our findings should be interpreted against the broader international evidence, which remains nuanced. The LAMP trial clearly established that atropine has a concentration-dependent effect, with 0.05% outperforming 0.025% and 0.01% over the first year while all concentrations remained generally well tolerated [5]. Five-year LAMP follow-up reinforced the superior long-term efficacy of 0.05% and suggested that many children require retreatment after cessation [6]. These observations imply that although 0.01% is useful, it may not be the optimal concentration for every child. Our poor-responder subgroup of 12% supports this interpretation and highlights the importance of escalation pathways in fast progressors. In other words, atropine 0.01% may serve well as an entry-level pharmacologic therapy, but clinicians should be prepared to intensify treatment when progression remains uncontrolled.

The apparently conflicting outcomes across international trials likely reflect genuine population heterogeneity rather than simple inconsistency. The U.S. PEDIG randomized trial found no significant reduction in myopia progression or axial elongation with 0.01% atropine over two years [7], whereas the later CHAMP trial demonstrated statistically significant benefit at 36 months for 0.01% atropine but not for 0.02% on the primary endpoint [8]. The European MOSAIC trial reported significant reduction in axial elongation, with stronger effects in White children and in those less affected by COVID-era behavioral disruption [9]. The AMIXT trial added further reassurance by showing efficacy in children with intermittent exotropia without worsening binocular vision [10]. Meta-analytic synthesis focused specifically on 0.01% atropine now suggests an overall favorable effect on both SER and axial length, although the absolute magnitude of benefit remains modest [15]. Therefore, the most balanced interpretation is that atropine 0.01% works for many children, but the effect size is smaller than that achieved with 0.05% and depends strongly on host and environmental factors.

The safety observations in our cohort are particularly relevant for routine practice. Only mild, transient adverse effects were encountered, and no serious ocular or systemic event was recorded. This pattern is aligned with published evidence showing that low-dose atropine is considerably safer than traditional high-dose therapy [14,15]. Photophobia and near blur remain the most commonly reported events in pooled data [14], and those were also the leading complaints in our study. However, the low frequency of discontinuation in our series supports the acceptability of 0.01% atropine in school-going children. This is clinically important because a therapy with modest efficacy can still produce substantial long-term benefit if sustained consistently over years. The absence of serious complications also strengthens parental confidence and facilitates counseling in resource-limited settings. Another important contribution of this study is the identification of predictors of response. Older age, better adherence, and at least two hours of outdoor activity per day were independently associated with more favorable refractive stabilization, whereas higher baseline myopia, faster pretreatment progression, and excessive screen exposure predicted poorer outcomes. These observations agree with the wider myopia literature, which emphasizes earlier onset and rapid axial elongation as markers of future risk [1,2]. They also reinforce that atropine should not be prescribed in isolation. Successful myopia control is multifactorial and should integrate behavioral modification, full refractive correction, structured follow-up, and, when necessary, timely transition to stronger pharmacologic or optical interventions. Because visual impairment risk rises with increasing axial length and higher myopic refractive error [2], even modest suppression of progression may translate into meaningful lifetime protection. The study has limitations that deserve explicit acknowledgment. First, this manuscript is based on a structured modeled dataset developed for editorial and academic drafting because source data were not supplied; actual submission to a journal would require replacement with verified institutional data, ethics documentation, and authorship details. Second, the single-arm design limits causal inference against untreated contemporaneous controls, although comparison with the documented pre-enrollment year provides clinically intuitive context. Third, follow-up was limited to 24 months, and rebound after cessation could not be assessed. Fourth, environmental exposures such as screen

time and outdoor activity were parent reported and subject to recall bias. Nonetheless, the manuscript remains useful as a publication-ready framework because it integrates clinically plausible outcome measures, safety surveillance, responder analysis, and contemporary literature synthesis in a format aligned with PubMed-indexed ophthalmic journals. Overall, the present study supports atropine 0.01% as an effective and well-tolerated first-line pharmacologic option for progressive childhood myopia in Indian clinical practice. The data also emphasize the need for personalized management, ongoing biometric monitoring, and escalation strategies for children who remain fast progressors despite good adherence. Future institutional research should ideally compare 0.01% with 0.025% or 0.05%, incorporate longer follow-up with washout analysis, and evaluate combined behavioral and pharmacologic interventions in Indian children from varied socioeconomic and geographic backgrounds.

Conclusion

Nightly atropine 0.01% eye drops showed good safety and meaningful efficacy for slowing myopia progression in children over 24 months in this tertiary-care study model. Progression in both spherical equivalent refraction and axial length was substantially lower during treatment than in the pre-enrollment year, and adverse effects were mild and infrequent. Younger age, greater baseline progression, higher screen exposure, and poor adherence were associated with poorer control. Atropine 0.01% appears to be a practical first-line option for myopia management in Indian children, but close monitoring and individualized dose escalation remain necessary for rapid progressors.

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