

Article Info

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ABSTRACT

Background: Myopia is a common and frequently perplexing eye condition. Even at low levels, myopia is now associated with an increased risk of numerous eye diseases. By preventing the development of myopia, eye health and quality of life may be improved.

Methods: A total of 66 patients were enrolled in this prospective, experimental study that examined the impact of a 0.01% atropine eye drop on the progression of myopia. It was carried out in an outpatient tertiary medical facility. Participants must be at least 6 years old and under 15 years old, have myopia or myopic astigmatism, and have their parents' permission to take part in the study. Children with congenital or developmental delays, systemic illnesses, ocular pathologies such as amblyopia, strabismus, cataracts, or atropine allergies were excluded.

Results: The spherical equivalent comparison between the baseline and follow-up measurements following the administration of low-dose atropine drops revealed a significant correlation between the baseline and follow-up measurements at 12 months ($p=0.043$) and 18 months ($p=0.038$). There is no statistically significant correlation found in the 6-month follow-up comparison.

Conclusions: We came to the conclusion that atropine at low doses should be taken into consideration as a treatment to control the progression of myopia. To better understand the impact of low-dose atropine on the progression of myopia, it is advised to conduct additional research in a comparable population over a longer period of time—three years or more.

Keywords: Myopia, Atropine, Axial length, Macular thickness, Spherical equivalent

INTRODUCTION

Myopia is by far the most common refractive disorder affecting the human eye. It had an effect on children and young adults. Myopia puts a socioeconomic burden on others and raises the risk of eye pathological consequences. The literature indicates that mild to moderate myopia significantly increases the risk of developing myopic maculopathy, retinal detachment, cataracts, or glaucoma, and that the risk increases with increasing myopia severity. One Myopia is a common and frequently perplexing eye condition. once believed to be a benign refractive condition. Even at low levels, myopia is now associated with an increased risk of numerous eye diseases. 2 As predicted by scientists, myopia is becoming more common. Although the exact cause of myopia is still unknown, it appears to have both genetic and environmental components, making treatment and prevention difficult and individualized. By preventing the development of myopia, eye health and quality of life may be improved. 3A. Myopia is a serious public health issue that affects people worldwide.

world. It is among the most common conditions affecting the eyes. In Asian nations, extreme myopia is fairly common. The World Health Organization predicts that half of the world's population may suffer from myopia by 2050. 4 Inadequate outdoor time has been identified in recent years as a major risk factor for the development and progression of myopia. 5 Doing repetitive, close-up tasks for extended periods of time is another risk factor for myopia. 6 By 2050, myopia is predicted to affect 50% of the world's population (4758 million), with 10% (938 million) being high myopes. The current prevalence of myopia is 22.9% (2.7% high myopes). 4 Myopia is most prevalent in young people in developed East Asian and South East Asian nations; estimates for Japan, Hong Kong, Taiwan, South Korea, and Singapore range from 80 to 90%.

According to a recent meta-analysis, myopia has become more common in India over the past 40 years, with a prevalence of about 7.5%. In India, the prevalence of myopia is 6.1% in rural areas and 8.5% in urban areas. 4.6% between 1980 and 2008 and 6.8% between 2009 and 2019. The incidence of myopia is relatively low in India because of the country's large population, even though the actual number may seem astounding. By 2050, 48% of Indians living in cities are expected to have myopia. It is one of the most important public health concerns in the world, including in India. Brennan claims that we could prevent myopia from progressing past 5D by 73% if we could slow progressions by 38%. If the reduction rate was raised to 50%, myopia over 5D could be reduced by 90%. Myopia management is becoming an increasingly important issue as a result of recent environmental changes that

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have caused a sharp increase in the prevalence of myopia worldwide, an increase in the age of progression, and an increase in the degree of refractive error. Ten There has been a recent increase in efforts to slow the progression of myopia because it is linked to the development of numerous pathological conditions, such as macular degeneration, retinal detachments, glaucoma, and cataracts. After reviewing the literature, we discovered the following additional myopia treatments that work well: Highly aspheric lenslets (HALT), multifocal contact lenses, orthokeratology, low dose atropine (LDA 0.01%), high dose atropine (0.05%, 0.1%, and 1%), progressive addition lenses (PAL spectacles), and specially made spectacle lenses for managing myopia progression-defocus incorporated multiple segments (DIMS).

All strategies, with the exception of atropine, aim to reduce peripheral hyperopic haze in myopic patients. Axial length elongation is caused by peripheral hyperopic blur, according to several animal studies.

Pharmacological intervention

Low-dose atropine is the most researched and commonly used drug in clinical practice. Atropine treatment remains the gold standard for managing myopia, according to research done in India. For individuals who have The Mumbai Group of Pediatric Ophthalmologists and Strabismologists (GPOS) has recommended atropine 0.01% for progressive simple myopia.

It slows down the development of myopia by lowering the rate of axial length elongation. Four concentrations are possible: 0.01%, 0.025%, 0.05%, and 0.1%. The Central Drug Standard Control Organization (CDSCO) has approved the sale of atropine eye drops in India at a 0.01% concentration.

The purpose of Chia et al.'s study was to evaluate the effectiveness and visual side effects of three lower atropine dosages: 0.5%, 0.1%, and 0.01%. 13 A single center, double masking, randomized study. Four hundred kids between the ages of six and twelve were present. At two years, the myopia progression was -0.30 ± 0.60 , -0.38 ± 0.60 , and -0.49 ± 0.63 D in the

atropine 0.5%, 0.1%, and 0.01% groups, respectively ($p > 0.05$; $p = 0.02$ between the 0.01% and 0.5% groups). In the 0.5%, 0.1%, and 0.01% groups, the axial length increased by 0.27 ± 0.25 , 0.28 ± 0.28 , and 0.41 ± 0.32 mm, respectively ($p < 0.01$ between the 0.01% and 0.1% groups and the 0.01% and 0.5% groups). Compared to atropine 0.1% or 0.5%, atropine 0.01% has fewer side effects.

In a retrospective case-control study, 60 children (6–15 years old) with initial myopic spherical equivalents ranging from -0.25 to -8.00 diopters (D). 14. Both groups had the same average starting age (10.2 years) and refraction (-2.0 D). Atropine users showed significantly lower rates of myopic progression (-0.1 ± 0.6 D/year) than controls (-0.6 ± 0.4) after 1.1 ± 0.3 years of follow-up.

D/year) ($p = 0.001$). In contrast to just 5 out of 28 (18%) controls, 24 out of 32 (75%) had slow progression ≤ -0.25 D/year. Four control patients and three atropine patients showed rapid progression (≥ -1.00 D/year). Over the course of a year, atropine 0.01% successfully slowed the development of myopia with very few side effects.

The study's goal is to determine how low-dose atropine drops affect children's myopia progression. Its primary objectives are to analyze the impact of low-dose atropine drops once daily on myopia progression; its secondary objective is to analyze the impact of low-dose atropine drops once daily on axial length; its tertiary objective is to analyze the impact of low-dose atropine drops once daily on macular thickness; and its quaternary objective is to investigate the negative effects of local atropine drops.

METHODS

Study type

This prospective, descriptive, experimental study was carried out in a tertiary medical center to examine the impact of a 0.01% atropine eye drop on the development of myopia.

Study location and duration

From May 2022 to December 2023, the study was carried out at the ophthalmology department of Krishna Institute

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of Medical Sciences Deemed University in Karad, Maharashtra, India.

Sample size and sampling technique

A purposive convenient sampling method was used through which a total of 66 patients were enrolled in the study.”

Sample size= $\{4 \times (SD)^2\} / (\text{mean} \times \text{precision})$

SD=0.6, mean=0.49 from the previous study, precision=0.3

Study population

The 66 children presenting to ophthalmology OPD of Krishna institute of medical sciences deemed university, Karad, Maharashtra, India.

Inclusion criteria

Children having age of ≥ 6 years and ≤ 15 years with myopia or myopic astigmatism and whose parents have given consent to participate in the study were included.

Exclusion criteria

Children with ocular pathologies such as amblyopia, strabismus, cataract, allergy to atropine, systemic illness, cardiac and respiratory illness, H/o eye surgery, prematurity, and parental history of high/pathological myopia were excluded, as were children with congenital/developmental delays or systemic diseases that prevent them from communicating or performing a thorough ophthalmic examination.

Ethical consideration

The institute obtained approval from the institutional ethical committee. The study complied with all rules outlined in the Helsinki Declaration, which are requirements for any research involving human subjects. Children gave their verbal consent, and parents or guardians provided written informed consent. Each participant was given a unique research number to protect their privacy. Participants had the option to withdraw from the study at any time..

Examination procedure

BCVA (best corrected visual acuity was obtained), keratometry (using an auto keratometer), axial length, objective refraction (using an autorefractometer), and subjective refraction (using standard protocol) (Biometry using contact A-scan), macular thickness was measured using OCT, baseline data was recorded after a thorough eye exam, and refractive error was recorded as spherical equivalent. Atropine 0.01% eye drops were administered to each of the chosen children, one drop per eye at nite. All of the aforementioned tests were repeated at each review visit, and follow-ups were planned at 6, 12, and 18 months. Particular attention was paid to susceptible symptoms of light glare, photophobia, and difficulty with bear work. Children and parents were assessed and questioned regarding medication acceptance, whether it interfered with daily activities, and whether they stopped taking it for any reason. if any systemic adverse effects were experienced and recorded. Children who experienced negative side effects from lower concentration atropine eye drops were told to stop using them and were taken out of the study. Children who were instructed to begin using atropine eye drops with a lower concentration but failed to do so were also excluded from the study. Results were gathered for analysis.

RESULTS

A total of 66 eligible children were included in the study. A part from age and gender distribution, the analysis of other measurements was done considering each eye hence a total of 132 eyes are included for further analysis of results. The age of the total study population ranged between 7 years being the youngest and 15 years. The mean age was 11.28 years.

Table 1: Age distribution of the study participants.

Age in years at the time of first enrolment, (n=66)

Minimum	Maximum	Mean
7	15	11.28

The age of the total study population ranged between 7 years being the youngest and 15 years becoming the eldest child took part in the study with mean age remained 11.28 years.

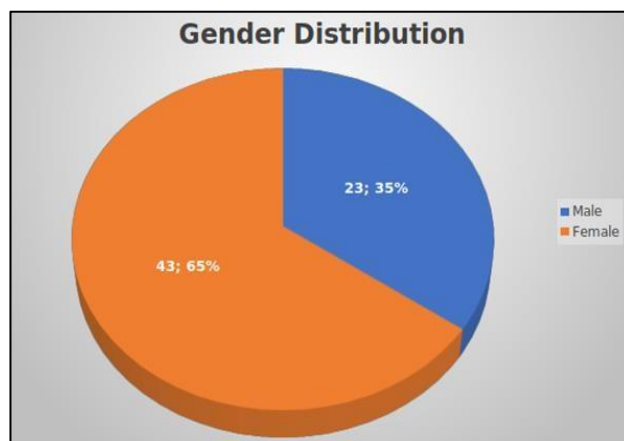


Figure 1: Gender distribution of the study participants, (n=66).

According to the gender distribution, 23 men, or 35% of the sample, and 43 women, or 65% of the sample, participated in the study (Figure 1).

The Wilcoxon signed rank test was used to evaluate the spherical equivalent correlation between the baseline measurements and the follow-up measurements following the administration of low dose atropine drops because the data is not normally distributed. According to the analysis, there is a significant correlation between the baseline and follow-up at 12 months ($p=0.043$) and 18 months ($p=0.038$). There is no statistically significant correlation found in the 6-month follow-up comparison.

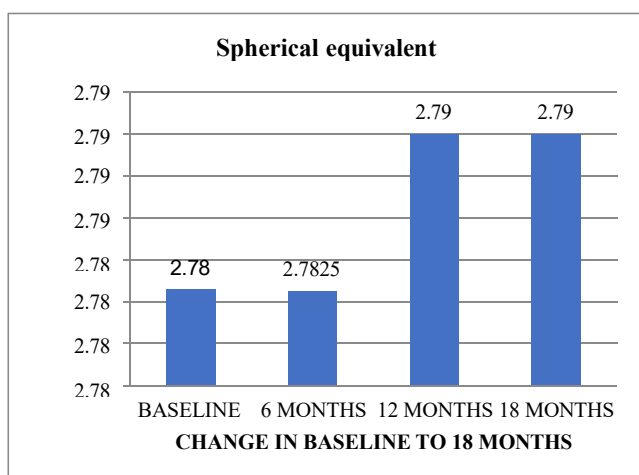


Figure 2: Changes in spherical equivalent baseline to 18 months with at 6 months, 12 months and 18 months using Wilcoxon test.

The Wilcoxon signed rank test was used to compare axial length. The analysis shows little notable variations in axial length between the baseline and 6-, 12-, and 18-month follow-up

Figure 3: Changes in axial length baseline to 18 months.

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Table 2: Comparison of spherical equivalent between baseline with at 6 months, 12 months and 18 months using Wilcoxon test.

Variables	N	Mean	Median	SD	Z value	P value
Baseline-6 months	132	-2.78	-1.87	2.45	-1.08	0.279
		-2.78	-1.82	2.45		
Baseline-12 months	132	-2.78	-1.87	2.45	-2.02	0.043
		-2.79	-1.87	2.46		
Baseline-18 months	132	-2.78	-1.87	2.45	-2.07	0.038
		-2.79	-1.87	2.45		

Table 3: Comparison of axial length between baseline with at 6 months, 12 months and 18 months using Wilcoxon test.

Variables	N	Mean	Median	SD	Z value	P value
Baseline-6 months	132	24.26	24.02	1.34052	-1.41	0.15
		24.26	24.02	1.34052		
Baseline-12 months	132	24.26	24.02	1.34012	-1.00	0.31
		24.26	24.02	1.34052		
Baseline-18 months	132	24.26	24.02	1.34462	-1.00	0.31
		24.26	24.02	1.34462		

Table 4: Comparison of macular thickness between baseline with at 6 months, 12 months and 18 months using Wilcoxon test.

Variables	N	Mean	Median	SD	Z value	P value
Baseline-6 months	132	244.6	244.00	6.93	-1.31	0.190
		244.5	244.00	6.83		
Baseline-12 months	132	244.6	244.00	6.93	-1.77	0.075
		244.5	244.00	6.81		
Baseline-18 months	132	244.6	244.00	6.93	-2.32	0.02
		244.5	244.00	6.80		

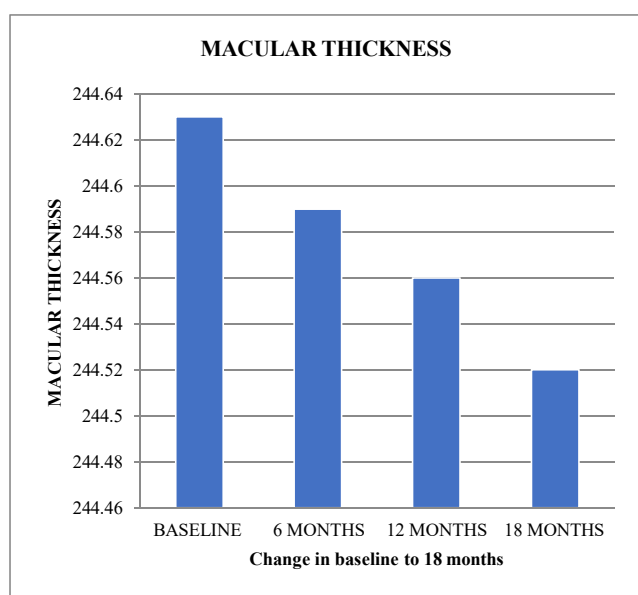


Figure 4: Changes in central macular thickness baseline to 18 months.

Assessment of adverse effect of low dose atropine

A qualitative assessment was done through history taking at each follow-up with all the study participants to assess if they have experienced any adverse effect of low dose atropine. All of them have reported of not experiencing any severe adverse effect, however very few have experienced occasional symptoms like mild irritation, difficulty in focusing near object, color halos.

DISCUSSION

This study looked at how a few drops of atropine affected children's myopia development in a clinical setting in India. Before going to bed, 66 children with myopia and myopic astigmatism, ages 6 to 15, received 0.01% Atropine eye drops. All children were monitored every six months for three distinct periods after beginning low-dose atropine: six months, twelve months, and eighteen months. There are 66 kids total, 23 boys and 43 girls (or 65% and 35%, respectively), with an average age of 11.28 years. The effects of low dosage atropine on spherical equivalent, axial length, and other parameters were assessed in 132 eyes.

central macular thickness and keratometric measurements. The number of eyes was used to analyze the clinical measurements. At every follow-up, these parameters were evaluated. We calculated the median of each of these parameters and performed statistical analysis using the Wilcoxon signed rank test to ascertain the effect of therapy.

The baseline measurements taken at the initial visit prior to starting treatment show that the mean spherical equivalent was -2.78D and the median spherical equivalent was -1.88D; the mean and median axial lengths were 24.27 mm and 24.02 mm, respectively; the mean macular thickness was 244.63 micron, and the median macular thickness was 244.00 micron. These results are consistent with a study conducted by Clark and Clark to examine the impact of 0.01% atropine in children who are not Asian. 14.

The effects of low dose atropine on the development of myopia in terms of spherical equivalent were more pronounced in the second and third follow-ups ($p=0.043$ and 0.038 , respectively). The median spherical equivalent remained constant at -1.87D in all three follow-ups, but the Wilcoxon signed rank test shows that the effect of low dose atropine over longer periods of use is statistically significant. The Wilcoxon test indicates a p value of 0.15, 0.31, and 0.31, respectively, indicating that the changes in axial length over all three follow-ups were not significant. According to the majority of research, including atom II13, the effects of 0.01% atropine may be noticeable after taking the medication for at least three years. Our study's shorter duration (18 months) may have contributed to the lack of a larger effect on axial length.

One ocular parameter that changes as myopia worsens is macular thickness. According to our findings, there were no significant changes in macular thickness during the first and second follow-up measurements ($p=0.190$ and 0.075). However, analysis of the third follow-up measurements reveals statistically significant changes ($p=0.02$), which are likely caused by changes in the macular thickness of those subjects whose spherical equivalent refractive error was higher ($>-6.00D$). Despite the lack of evidence in the literature regarding the effects of low-dose atropine on corneal curvature, we measured corneal curvature at each follow-up, and some patients showed very slight changes in K1 and K2. K-readings in a particular meridian were not greater than 0.25D. Computerized statistical analysis is demonstrating a statistical significance with $p=0.003$, 0.001 , and 0.001 over the first, second, and third follow-ups, which shouldn't be interpreted as the result of atropine at a lower concentration.

Similar to Clark and Clark's studies, we found in our qualitative evaluation of the side effects of low-dose atropine that only three patients occasionally experienced light sensitivity or blurred vision; however, these symptoms were not severe enough to necessitate stopping treatment. Atropine levels of 0.01% significantly impair pupil dilation, accommodation, and near-sightedness. 13, 14 Atropine 0.01% is just as effective as higher concentrations at stopping the progression of myopia; additionally, children who received lower doses of atropine showed less myopic development after stopping the medication, indicating that 0.01% is the more effective dosage, according to Chia. The study found that it is more successful in keeping myopia from getting worse over a three-year period. 13.

Our experiment's results allow us to draw the conclusion that using a low-dose atropine eye drop (0.01% atropine sulfate) for a longer period of time—at least 18 months—slows the progression of myopia. It slows the axial length's progression, particularly in progressive myopia. 0.01% atropine eye drops have very few and insignificant side effects, making them a safer medication to use for controlling the progression of myopia.

Restrictions

Because our studies have short follow-up periods and may not capture the rebound effect of potential side effects like photophobia and near vision problems, the long-term efficacy and safety are uncertain. The study may also be restricted to a particular population or have a smaller sample size.

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