Original Article

Effects of 0.01% Atropine Eye Drops on Controlling Myopia Progression in School Age Children in Ophthalmology Department of a Tertiary Care Hospital

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ABSTRACT

Purpose: To determine the effects of 0.01% atropine eye drops in controlling myopia progression in school age children presenting to Ophthalmology Department of a Tertiary Care Hospital.

Study Design: Quasi experimental study.

Place & Duration of Study: Department of ophthalmology Jinnah postgraduate Medical Center, JPMC Karachi and Advanced Eye Clinic Karachi, Pakistan from July 2018 to July 2020.

Methods: One hundred myopic patients (myopia of 0.5D to 13.0D) with age range of 6 – 14 years were recruited. Patients with astigmatism <-2.0D, other ocular or medical disease and history of laser or ocular surgery were excluded. Atropine group was instructed to instill Atropine 0.01% once at night time. Control group did not receive any treatment. Refraction was performed at all examinations with and without Cycloplegia along with fundoscopy and axial length measurements. The follow up frequency was at 3 monthly intervals. Data was analyzed using SPSS 22. To compare quantitative data between groups, t-test was used while for qualitative data Chi-square test was used.

Results: Mean age was 9.21±2.45 years. Out of 100, 57 were males. There was no statistical difference between atropine group vs control group in terms of baseline SER (spherical equivalent refraction), ($p = 0.407$) and baseline axial length ($p = 0.892$). Mean difference in SER from baseline to after completion of study two groups was statistically significant ($p < 0.001$). Mean difference in AL from baseline to end of study between two groups was also statistically significant ($p < 0.001$).

Conclusion: Low concentration atropine 0.01% can be helpful in halting myopia progression.

Key Words: Atropine, Myopia, Astigmatism, Refractive error, Axial length.

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INTRODUCTION

Recently, a rise in myopia severity has been reported worldwide, which is an alarming situation.[1] It poses a degree of risk to vision loss corresponding to the degree of myopia. Severe and irreversible loss of vision can occur, with a myriad of complications like retinal detachment, subretinal neovascularization, early lenticular changes, glaucoma and macular hole.[2,3] This has undoubtedly become a reason of serious concern and to halt progression of myopia have become a topic of prime importance and interest. Progression of myopia halt by outdoor activities, decrease near work, spectacles, contact lenses and use

of atropine eye drops has been reported.[4] Previously, various concentrations of atropine eye drops have been used from 1% to 0.01%. High concentration of atropine caused pupillary dilation, blurred vision and loss of accommodation. The best results have been shown with the use of 0.01% atropine eye drops with a once every night frequency with a lower incidence of side effects.[5,6]

A clinically reliable marker for progressive myopia is the spherical equivalent of refraction. It has been reported that daily use of Atropine 0.01% eye drops helped in lowering yearly increase in mean spherical equivalent refraction.[7,8] Atropine for the treatment of myopia (ATOM1 study) showed atropine 1% eye drops were effective in controlling myopic progression but with visual side effects resulting from cycloplegia and mydriasis.[8] This was followed up by ATOM2 study, which assessed three atropine concentrations of 0.01%, 0.1%, and 0.5%. ATOM 2 demonstrated that the rate of change of SER in atropine treated eyes was significantly lower.[7] With 2years of atropine therapy, the standard progression was −0.30±0.60, −0.38±0.60, and −0.49±0.63 D with the concentrations of 0.5%, 0.1%, and 0.01%, respectively. The ATOM studies concluded the superiority of 0.5% and 0.1% doses over 0.01% dose in terms of effectiveness, but simultaneously had regression of effects after the treatment was halted. To make matters worse, there appeared to be a worsening of myopia in those treated with the higher concentration. On the other hand, with lower concentrations of the drug, we see a little (−0.28D) SER change but on the plus side, the rebound progression was minimal.[9]

Another case–control study in a pediatric ophthalmologic clinic suggested that atropine 0.01% significantly reduced the rate of myopic progression over 1year without much unwanted risks and effects.[10] A small study in German population has suggested that insignificant pupillary dilation and reduction in accommodation 24hours after initiating treatment makes this concentration of 0.01% a favorable choice for treatment.[11]

In our study, we have attempted to see the results of 0.01% atropine treatment in a Pakistani pediatric sample (6 – 14 years). The study was designed with an aim of expanding the results of prior research works.

METHODS

The study was conducted at Jinnah postgraduate Medical Center, JPMC Karachi and Advanced Eye Clinic Karachi from July 2018 to July 2020. WHO sample size calculator was used to calculate sample by taking level of significance at 10%, power 80%, anticipated mean axial length after atropine use as 0.19 ± 0.14mm and anticipated mean axial length in control group as 0.26 ± 0.14mm.[12] Calculated sample size was 100 divided into two groups (50 in Atropine group and 50 in control group). A compounded solution of atropine 0.01% eye drops was used in atropine group as compared to controls that were only kept on a 3 monthly follow up. SER was measured at recruitment and at every three months for 2 years. Data on age, gender, date of birth and occupation was collected. Myopic children with age of 6-14 years were recruited. Myopia of 0.5D to 13.0D in at least one eye, astigmatism (if present, less than or equal to -2.0D), with no medical or ocular disease were included in the study. Cases with a medical history of Marfan syndrome, Stickler syndrome, retinopathy of prematurity, abnormal ocular refractive anatomy (e.g. keratoconus, lenticonus, spherophakia), or previous intraocular or ocular laser surgery were excluded. Informed consent was taken from the parents of child and they were counselled regarding the duration of study and possible outcomes. Only those children were included in the study whose parents had agreed to participate. They were counselled regarding once every night administration of Atropine 0.01% eye drops. The drops were prepared from atropine 1% by dilution. Treatment also included prescribing corrective lenses. Treatment compliance was assessed verbally on each visit. Refraction was performed at all examinations with and without cycloplegia along with fundoscopy and axial length measurements.

Data was analyzed using SPSS 22. Quantitative data was presented using mean +/- standard deviation. Qualitative data was presented as frequency and percentages. To compare quantitative data between groups, Student t-test was used while for qualitative data we used Chi-square test. A p-value of < 0.05 was considered statistically significant.

RESULTS

A total of 100 children were enrolled, which were equally divided into two groups by convenient sampling. Mean age was 9.21 ± 2.45 years. There were

Table 1: *Comparison of Baseline Characteristics in both groups.*

Parameter	Atropine Group(n = 50)		Control group(n = 50)		p-value
Mean age	8.80 ± 2.39 years		9.62 ± 2.45 years		0.094
Gender	**Male**	**Female**	**Male**	**Female**	0.545
	30 (60.00%)	20 (40.00%)	27 (54.00%)	23 (46.00%)	
Mean SER	-1.59 ± 0.05D		-1.60 ± 0.05D		0.407
Mean AL	24.88 ± 1.56mm		24.84 ± 1.37mm		0.892

Table 2: *Post-treatment Comparison between Atropine and Control groups.*

Parameter	Atropine Group(n = 50)	Control Group(n = 50)	p-value
Mean SER	-1.89 ± 0.03D	-2.67 ± 3.51D	0.118
Mean difference of SER from baseline	-0.29 ± 0.06D	-0.57 ± 0.06D	0.000
Mean AL	25.16 ± 1.54mm	25.62 ± 1.38mm	0.114
Mean difference of AL from baseline	0.27 ± 0.46mm	0.78 ± 0.40mm	0.000

69% in 6 – 10 years age group and 31% in 11 – 14 years age group. There were 57%males. Details of both groups are shown in Table 1.

Mean difference in SER from baseline to after completion of study period in atropine group was -0.29 ± 0.06D while in control group it was -0.57 ± 0.06D, (p = 0.000). Mean difference in AL from baseline to after completion of study period in atropine group was 0.27 ± 0.46mm while in control group it was 0.78 ± 0.40mm, (p = 0.000). The details are shown in Table 2.

DISCUSSION

Our results showed that children receiving atropine 0.01% had halt in myopia progression as evident by the mean axial length and SER from baseline. This was consistent with previous studies on the same concentration of drug.[13]

There was a mean differences of -0.4 between 0.01% atropine treated and those given only usual eye care, after 1 years of treatment. Both the groups were followed at 3 monthly interval. The ones pharmacologically treated, were reported to have a slowdown of myopia progression. New prescription glasses were needed earlier in conventionally managed group.

Higher concentration of atropine has also proved to slow down progression of myopia but higher concentration use has been limited due to side effects such as photophobia, glare, and blurring of vision.[14-16]

The mechanism of action of atropine in halting down the progression of myopia is not exactly known. It has been shown that atropine increases choroidal thickness, by modulating release of dopamine which has been thought to reduce the rate of growth of eyeball.[17-18] Now it is also thought that atropine inhibits the growth of eye by inhibiting the growth of sclera and retina by modulating the function of scleral fibroblast.[19–21] After using atropine eye drop, little increase in refractive error and axial length proved that growth of eyeball is responding to inhibitory effects of atropine. Final myopia level and chances of developing complication like retinal detachment, glaucoma, choroidal neovascularization, and macular hole secondary to high myopia would be less after use of atropine drop so treatment should be continued during growing phase of eye ball.[22]

There were certain limitations in our study including only two years follow up. Longer duration of study is recommended to see the progression of myopia after stoppage of atropine 0.01% eye drop yielding more inclusive results as it is also reported by other studies that progression of myopia increased after stopping atropine eye drop.[23]

CONCLUSION

Low concentration atropine 0.01% can be a good option for halting down progression of myopia making it a real world favorable choice for intervention. The results of this study are consistent with previous studies in various populations, thus making atropine in low concentration of 0.01% a promising pharmacological intervention.

Conflict of Interest: Authors declared no conflict of interest.

Ethical Approval: The study was approved by the Institutional review board/Ethical review board **(F.2-81/2018-GENL/8009/JPMC).**

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Authors' Designation and Contribution

Rabia Khawar Chaudhry; Consultant Ophthalmologist: *Concepts, Manuscript Preparation.*

Tariq Aziz; Consultant Ophthalmologist: *Design, Manuscript Review.*

M. Nasar Qamar Khan; Consultant Ophthalmologist: *Data Acquisition, Data Analysis.*

Mahwash Khan; Consultant Ophthalmologist: *Literature Search.*

Mehboob Dad; Postgraduate Trainee: *Statistical Analysis, Manuscript Editing.*