STUDY OF ATROPINE (1%) IN MYOPIA PROGRESSION AT THE AGE OF 6 TO 14 YEARS SCHOOL CHILDREN

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Abstract:

Background: Atropine is the most studied and used antimuscarinic agent for myopia management. It is believed that its fundamental action is produced by blocking the muscarinic receptors of the retina and of the scleral fibroblasts, acting as an ocular growth inhibition factor. Therefore, the objective of the present study was to study the effect of 0.01% atropine (eye drop) in prevention of myopia progression in children.

Material and Methods: The present study was conducted among children aged 6 to 14 years. All included patients were treated with 0.01% atropine sulfate one nightly eyedrop in each eye for 12 months. The main outcome of this study was myopia progression in terms of SE and AL changes over one year. The descriptive analysis of the variables was also performed. The software used for the analysis was IBM SPSS Statistics 20. P value< 0.05 was considered statistically significant.

Results: The total of 100 patients was included in the study in which 50% were females and 50% were males. After the first year of treatment, there was mean increase in the SE was and AL. All parameters underwent significantly changes except for best corrected visual acuity at distance and near.

Conclusion: The present study concluded that Atropine 0.01% is effective and safe for myopia progression control as Spherical Equivalent, Axial length increased after using atropine.

Introduction: In 1611, Kepler proposed his hypothesis of near work as the cause of myopia, suggesting that reading and performing visual tasks at short distances in childhood accustomed the eye to near objects.[3] Due to Kepler's work, accommodation was linked to myopia. Several mechanisms related to accommodation and/or convergence were proposed during the next two centuries.[4,5]Myopia has been considered the sixth major cause of vision loss.[6]In 2000 the global

prevalence of myopia was 23% and of high myopia 3%. However, by 2050 these proportions will raise respectively to 50% (5 billion) and 10% (1 billion) of the world population.[7] In India, its prevalence was found to be 21.1% in children aged 5 to 15 years.[8] The progression of myopia in children and adolescents is gradual. Furthermore, earlyonset myopia can be associated with the development of high myopia[9], which could lead to several pathological complications, such as choroidal thinning, posterior scleral staphyloma, cataracts, peripheral retinal tears, myopic choroidal neovascularization, glaucoma, macular degeneration, and even blindness.[10,11] By the mid-1800s, atropine was frequently used in ophthalmology for pupillary dilation to examine the posterior segment of the eye and as a temporary treatment to improve vision in cases of cataracts. It was also used to induce mydriasis during cataract surgery and to prevent or break the posterior synechia in cases of uveitis. At that time, it was not used in myopia treatment.[12-14] Atropine was first used to prevent myopia in 1920s.[15] Atropine at low concentration has been shown to be safe and effective in slowing myopia progression in children of Chinese ethnicity.[16-20] Therefore, the objective of the present study was to study the effect of 0.01% atropine (eye drop) in prevention of myopia progression in children.

Material and Methods: The present study was conducted among children aged 6 to 14 years with refractive error from − 2.00 to − 6.00 D, astigmatism less than 1.50 D, and documented myopic progression of at least − 0.50 D under cycloplegic examination. Before the initiation of the study ethical approval was taken from the Ethical Committee of the institute and informed consent was taken from the parent/guardian after explaining the study. Patients with ocular or systemic diseases that could affect vision or refractive error, contraindicated use of atropine due to any reason, amblyopia or strabismus history, previous use of atropine or pirenzepine, orthokeratology lens for myopia control or any other circumstances that could impede protocol adhesion, including the refusal to stop using contact lenses during the duration of the study, were excluded. All included patients were treated with 0.01% atropine sulfate one nightly eyedrop in each eye for 12 months. The eyedrops were compounded and dispensed in accordance with an identical procedure. The 0.01% atropine ophthalmic solution was prepared in a sterile manner (Atropine Sulfate 1 mg, Sodium Chloride ClNa 0.9%, Glacial Acetic Acid q.s., Sodium Acetate q.s. to pH 5.0–6.0; Active Pharmaceutical Ingredient API 10 ml), and was stored in Low Density Poliethylene LDPE multi-dose bottles. Demographic data and iris color were recorded in every patient. At each visit, best-corrected distance and near visual acuity was assessed according to logMAR scale, using Early Treatment Diabetic Retinopaty Study (ETDRS) charts. Ocular AL and anterior chamber (AC) depth were measured on an IOL Master (Carl Zeiss Meditec, Inc, Dublin, CA), with six readings of average. Automatized measures of pupil diameter (IOL Master, Zeiss) were made with the same ambient light conditions. Cycloplegic autorefraction (Nidek ARK-510, Nidek) was performed at least thirty minutes afer the third 1% cyclopentolate eyedrop, and three to fve readings of the spherical and cylinder components that had to be less than< 0.25 D apart were obtained. Spherical equivalent (SE) was calculated as spherical power plus half of the cylinder power. When necessary, cycloplegic subjective refraction was done for glasses prescription. All the patients underwent the same follow-up protocol: after the initial visit, a telephone consultation was provided two weeks

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later concerning to the treatment tolerance and compliance; then the patients had office controls at 4, 8 and 12 months from the baseline visit. Compliance and treatment side effects were evaluated verbally with the parents by telephone call two weeks after baseline visit, and with both, parents and children, during the next visits. A main outcome of this study was myopia progression in terms of SE and AL changes over one year. The SE progression was categorized as≤− 0.50 D; − 0.50<X− 0.50 D were also analyzed.

Statistical analysis: A descriptive analysis of the variables was also performed. The software used for the analysis was IBM SPSS Statistics 20. P value< 0.05 was considered statistically significant.

Results: The total of 100 patients was included in the study in which 50% were females and 50% were males. After the first year of treatment, there was mean increase in the SE was and AL. All parameters underwent significantly changes except for best corrected visual acuity at distance and near.

Table 1: Distribution according to demographic variables

Variables	**N(%)**
Patients	**100(100%)**
Male	**50(50%)**
Female	**50(50%)**
Iris color (pigmentation)	
Dark	**80(80%)**
Medium	**15(15%)**
Light	**5(5%)**

Table 2: Changes in ophthalmic parameters after one-year atropine 0.01% treatment

Variable	Baseline visit	12 month visit	p-value*
SE (mean±SD, D)	− 3.54±1.11	− 4.02±1.13	0.0000
AL (mean±SD, mm)	23.87±0.67	25.02±0.72	0.0000
AC (mean±SD, mm)	3.84±0.30	3.88±0.27	0.0085
Pupil size (mean±SD, mm)	5.69±1.32	6.39±1.13	0.0000

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Near VA (mean±SD, logMAR)	0.00±0.03	0.00±0.02	0.8539
Distance VA (mean±SD, logMAR)	0.00±0.04	− 0.01±0.03	0.3583

SE-Spherical Equivalent, AL- Axial length, AC-Anterior chamber, VA-Visual acuity, logMAR-logarithm of minimum angle resolution.

Discussion: Myopia typically starts to develop in childhood, and although the vision can be corrected with glasses, contact lenses or surgery, myopic eyes have an increased risk of developing comorbidities such as glaucoma, cataract, retinal detachment and choroidal neovascularization at the macula.[21-23] Importantly, the risks of associated comorbidity and visual loss are associated with the degree of myopia and cannot be reduced with optical correction alone. Myopia is more prevalent in East Asia. Recent epidemiological studies show increasing rates among adolescents in European populations and suggest myopia is occurring at an earlier age than in previous generations.[24-26]

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As lower concentrations of atropine have been shown to be effective, and considering that the effect can last for up to 2 weeks.[27]

Polling et al. (2016) studied 77 myopic children of diverse ethnicity (European, Asian, and African) who received 0.5% atropine eye drops every day. Sixty children received the treatment for 12 months. The most common adverse events were photophobia (72%), reading difficulties (38%), and headache (22%). Myopia progression before treatment was −1.0 D/year ± 0.7, and drastically diminished during the treatment period to −0.1 D/year ± 0.7. Those children who stopped the therapy had a progression of −0.5 D/year ± 0.6.[28]

Jethani J (2022) did a study to understand the role of LCA in premyopic children in preventing progression. The mean age in the LCA group was 7.7 ± 2.1 years (5–12 years), and in the control group, it was 7.2 ± 1.9 years (4–12 years). The mean baseline progression per year in the LCA group (before starting the eye drops) was − 0.72 ± 0.3 D, and in the control group, it was − 0.69 ± 0.4 D. At the end of the first year, the mean progression in the LCA group was − 0.31 ± 0.3 D versus − 0.76 ± 0.4 D, and the axial length increase was 0.12 ± 0.1 mm in the LCA group and 0.21 ± 0.2 mm in the control group. At the end of the second year, the mean progression compared with

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the baseline in the LCA group was − 0.6 ± 0.3 D versus − 1.75 ± 0.4 D, and the axial length showed an increase from baseline in the LCA group by 0.21 ± 0.2 mm, and in the control group, the increase was 0.48 ± 0.2 mm in 2 years. The study concluded that Low-concentration eye drops (0.01%) work in preventing the progression of axial myopia in premyopic children.[29]

Conclusion: The present study concluded that Atropine 0.01% is effective and safe for myopia progression control as Spherical Equivalent, Axial length increased after using atropine.

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