Original Article

Myopia Controlling using Low Dose Atropine Eye Drop

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Abstract

Purpose: To determine myopic progression, axial length elongation, best-corrected visual acuity (BCVA), pupil dilation, and accommodation amplitude following 24 months of Atropine 0.01% usage among progressive myopic patients.

Methods: Fifty-one progressive myopic patients (age range, 3.5–17 years) were included in the present study. Fifteen patients were excluded due to loss to follow-up (eight patients) and Atropine complications (seven patients) and 36 patients continued therapy. Myopic progression, axial length, far and near BCVA, pupil diameter, and accommodation amplitude were measured at baseline examination and repeated every 6 months up to 2 years. All patients were recommended to instill one drop of Atropine 0.01% in each eye every night. Absolute success of therapy was defined as myopic progression ≤0.50 diopter (D) and axial length growth ≤0.2 mm per year.

Results: Mean myopic progression was 0.16 and 1.28 D and mean axial length change was 0.05 and 0.69 mm at months 12 and 24, respectively. Pupil dilation was 1.26 and 1.84 mm and accommodation reduction was 3.38 and 3.37 D at the same follow-ups, while BCVA was not changed. Absolute success rate for myopic progression control was 56.8% at 12 months and 70.8% at 24 months follow-up. In addition, the success rate in respect to axial length changes was 44.4% and 58.3% at the same time points.

Conclusions: Atropine 0.01% can slow myopic progression and axial length elongation at least in 50% of myopic cases at 12- and 24-month follow-up with no significant complications. Therefore, Atropine therapy is recommended in cases of progressive myopia in children and teenagers.

Keywords: Atropine, Axial length, Low dose, Myopia, Myopic progression control

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Introduction

Myopia is a frequent type of refractive error among the school-age children, especially in the South-eastern Asian countries with a prevalence of 80%–90%.[1] The prevalence of myopia is also increasing in the American population reported from 25% in 1977 to 42% in 1999.[1-3] Regarding the causes of visual impairment reported by the World Health Organization, myopia has been ranked as the sixth cause, which can be associated with a high risk of retinal detachment, chorioretinal degeneration, glaucoma, and age-related macular degeneration.[2,3]

In this regard, there is an increasing rate of publications with the purpose of controlling myopia progression through various strategies such as myopia prevention by recommending more outdoor activity.[4,5] Furthermore,

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different optical modalities including the defocus contact lens, progressive additional lens, and orthokeratology technique, and Atropine eye drop usage have been reported to postpone the myopic progression.[4,6-9]

Although the exact mechanism of Atropine therapy is not clear, it is probable that its preventive effect on the eye globe growth may be the main role.[9]

The present study was conducted to identify the effect of low dose Atropine therapy on myopic progression reported by the changes in refractive error, axial length, and pupil size in 6, 12, 18, and 24-month follow-ups in comparison with the baseline examination values.

Methods

In this interventional case series, a total of 72 myopic eyes from 36 patients in the age range of 3.5–17 years old were participated, only those with a myopia progression >0.50 diopter (D) per year were included in our investigation. All the experimental protocols were approved by the Ethics Committee of the Shahid Beheshti University of Medical Sciences (approval number of IR.SBMU.ORC.REC.1402.013). An informed consent letter was obtained from all the study participants or their parents or legal guardian(s). They were assured that their information was kept confidential.

We excluded patients who had an associated ocular pathology, systemic diseases, inaccurate fixation or media opacity in addition to uncooperative children, and those who did not participate in follow-up visits.

Comprehensive visual and ophthalmic examinations were conducted for all participants including visual acuity assessment using the Snellen E-chart at a distance of 6 m and cycloplegic refraction measurement 30–45 min after installation of cyclopentolate 1% and tropicamide 1% eye drops. Afterward, ocular motility testing was conducted in 9 cardinal gazes and the function of the extraocular muscles was recorded from +4 to −4. Ocular deviation was measured by the alternating prism cover test at distances of far (6 m) and near (33 cm) fixation. The amplitude of accommodation was measured using the monocular push up method, and the pupil measurement was conducted under the day light condition through matching with the standard hemisphere scales printed on the near acuity chart. The patients were asked to fix on a target at a distance of 6 m. The intraocular pressure was measured using the Goldmann tonometer in adults, and it also estimated by tactile method in children who were not cooperative. Anterior and posterior ocular segments were examined using the slit-lamp and indirect ophthalmology through the dilated pupil. The axial length of the patient's eye was measured using A-scan biometry (IOL Master® 500, ZEISS, Ostalbkreis, Germany).

Atropine 0.01% was prepared by adding 0.1 cc from Atropine 1% (Sina Darou, Tehran, Iran) to 10 cc artificial tear drop. All patients were recommended to use the low dose of Atropine (0.01%) daily and participate in visits at 6, 12, 18, and 24 months after the start of treatment. All examinations were repeated in those follow-ups.

All the study participants were interviewed and a questionnaire including information about the family history of myopia, outdoor activity per week, daily activity in near distance, and side effects of Atropine was filled out after at least 6 months of Atropine therapy.

Myopia progression was defined as increase of spherical equivalent (SE) in different follow-up visits of 6, 12, 18, and 24 months.

Success was considered based on the changes of SE as well as axial length and it was classified in different categories of "Absolute success", "Relative success", and "Failure". Regarding the myopic progression control, the absolute success was defined as change in SE ≤0.50 D/years, relative success rate was change in SE of >0.50 and ≤0.75 D/years and failure was considered change in SE of ≥1.00 D/years. Status of success was also defined based on axial length as absolute success (changes of ≤0.2 mm/years), relative success (changes of >0.2 and ≤0.3 mm/years), and failure (change of >0.3 mm/years).[10]

Statistical analysis

To present the data, we used mean, standard deviation, median, and range. To compare the results between the groups, we used *t*-test. To evaluate the changes during the follow-up times, we used paired *t*-tests. All statistical analyses were performed using the SPSS software (Version 25.0. Armonk, NY, USA: IBM Corp.). All tests were two sided and $P < 0.05$ was considered statistically significant.

Results

In the current study, a total of 51 progressive myopic patients (age range, 3.5–17 years) were included. Fifteen patients were excluded due to loss to follow-up (eight patients) and Atropine complications (seven patients, six patients due to blurred near vision, and one patient with induced strabismus). The study was continued on 36 cases (72 eyes).

The baseline characteristics of our cases are presented in Table 1. As shown, the mean age of our cases was 9.73 ± 3.45 years and 44.5% of them were under 10 years of age. Moderate myopia was found in 50% of cases (−2.00 to −5.00 D) and 80.5% reported myopia in their close family. Near work of higher than 3 h per a day was mentioned by 39% of cases, while only 25% of them reported outside activity more than 5–6 h per a week.

Mean myopic progression from baseline to 12 and 24 months was 0.16 D and 1.28 D, respectively, which increased faster and significantly from 18 to 24 months [$P = 0.048$, Figure 1 and Table 2]. On the other hand, 16 (30%) of our cases showed hyperopic shift during the first 6 months of the study from 0.12 to 0.75 D, while only 4% and 16% of cases had hyperopic shift at 1st and 2nd years of follow-ups, respectively.

Mean axial length changed from baseline to 12 and 24 months was 0.05 (axial length was reduced by 0.02 mm up to 6 months follow-up; then axial length was elongated by 0.03 mm from month 6 to month 12; so actual axial length change was equal to 0.05 mm in the 1st year) to 0.69 mm, respectively, as a whole. It also increased significantly from 18 to 24 months [$P = 0.02$, Figure 1 and Table 2].

Mean pupil dilation from baseline to 12 and 24 months was 1.26 and 1.84 mm, respectively, which was statistically significant in all follow-ups when compared to its baseline amount [Table 2] with the most changes from baseline to 6 months (0.83 mm).

The mean reduction of accommodation was 3.38 and 3.37 D at 12- and 24-month follow-ups, respectively, which was significant in all follow-ups compared to baseline amount, with the highest reduction from baseline to 6 months follow-up (2.12 D) [Table 2].

The mean best-corrected visual acuity (BCVA) at far and near distances did not show any significant change at 6, 12, 18, and 24 months follow-ups and it was always somehow better than baseline BCVA according to the Table 2, although no statistically significant difference was observed.

Absolute success rate of Atropine 0.01% therapy based on myopic progression control was 56.8% and 70.8% at 12 and 24 months follow-ups, respectively. Regarding the axial length elongation, the absolute success rate was 44.4% and 58.3% at 12- and 24-months follow-ups. The relative success rate based on myopic progression control was 64.9% and 87.8% at months 12 and 24, respectively. The relative success for axial length control was 55.6% and 75% at the same time intervals. Finally, absolute and relative failure based on myopic progression control was 43.2% and 25.7% as well as 22.2% and 12.2% at months 12 and 24, respectively. The failure based on axial length was 44.4% and 25% at the same time intervals.

SE changes according to hours of near work per day are demonstrated in Figure 2. As shown, the SE changes were always slower in cases with less near work and the difference between two groups at all follow-ups were significant (All $P < 0.001$ and $P_{month\ 24} = 0.012$). SE changes according to hours of outdoor activity per week are shown in Figure 3.

Table 1: Baseline characteristics of the study population

Factors	Level	Value, *n* (%)
Sex	Male	14 (39.0)
	Female	22 (61.0)
Age (years)	Mean±SD	9.73±3.45
	Median (range)	10 (3.5–17)
	≤10	16 (44.5)
	>10	20 (55.5)
BCVA (logMAR)	Mean±SD	0.05±0.10
	Median (range)	0.0 (0.0–0.7)
Myopia	Low (SE ≥ −2.00 D)	6 (16.5)
	Moderate (−2.00 D– −5.00 D)	18 (50.0)
	High (SE ≤ −5.00 D)	12 (33.5)
Myopia in family	No	7 (19.5)
	Yes	29 (80.5)
Near activity per a day (h)	1	9 (25.0)
	2	13 (36.0)
	≥3	14 (39.0)
Outdoor activity per a week (h)	1–2	14 (39.0)
	3–4	13 (36)
	5–6	9 (25.0)

BCVA: Best-corrected visual acuity, SE: Spherical equivalent, SD: Standard deviation

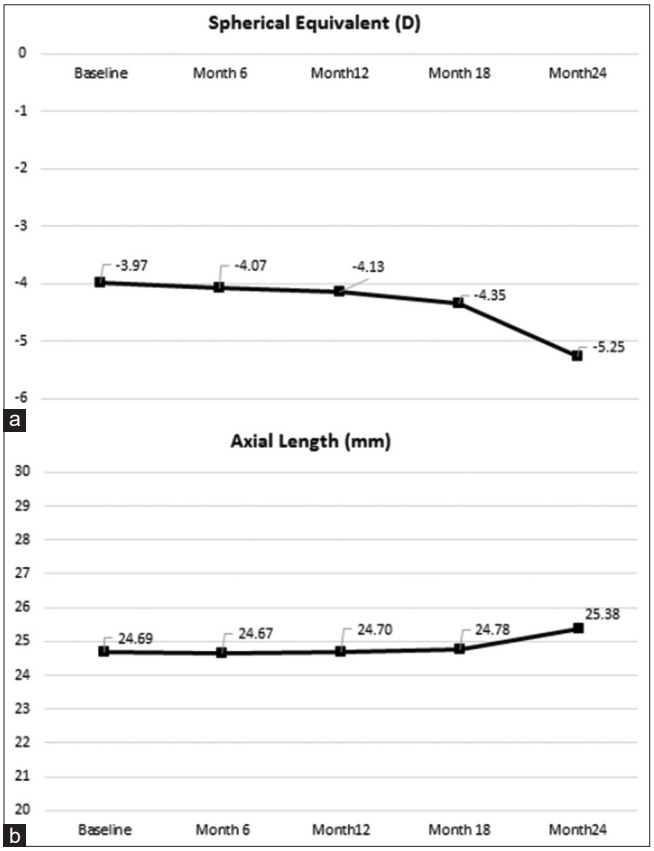

Figure 1: Spherical equivalent (a) and axial length (b) in different follow-ups

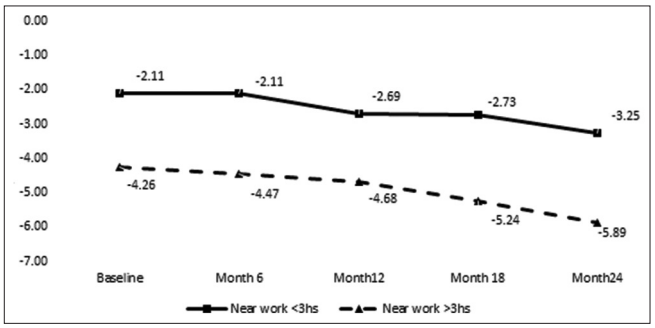

Figure 2: Spherical equivalent of children with low (<3 h) and high (>3 h) near activity in different follow-ups

As seen, although the SE change was slower in cases with more outdoor activity, the difference was not significant in all follow-ups ($P_{month\ 6}=0.221$, $P_{month\ 12}=0.235$, $P_{month\ 18}=0.829$, and $P_{month\ 24}=0.974$).

Figure 4 presents the changes of SE in high and moderate myopic cases. As seen, the mean SE among moderate myopic cases decreased (myopic shift) ($P_{month\ 6}=0.929$, $P_{month\ 12}<0.001$, $P_{month\ 18}<0.001$, and $P_{month\ 24}=0.001$), while SE among high myopic cases increased (hyperopic shift) ($P_{month\ 6}=0.073$, $P_{month\ 12}=0.001$, $P_{month\ 18}=0.003$, and $P_{month\ 24}=0.004$).

Figure 5 shows higher myopic shift in cases aged older than 10 years compared to younger ones, especially after follow-up of 1 year, which was only statistically significant at 24 months' follow-up ($P_{month\ 6}=0.789$, $P_{month\ 12}=0.693$, $P_{month\ 18}=0.187$, and $P_{month\ 24}=0.003$).

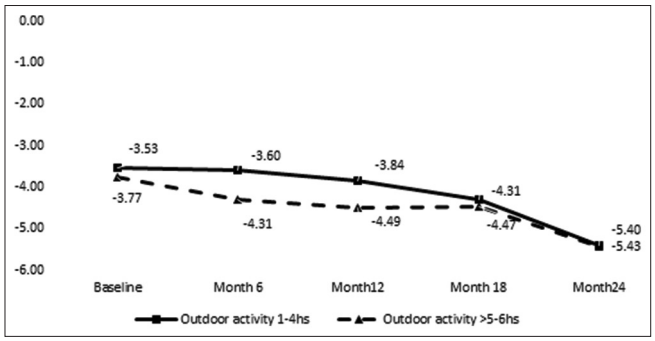

Figure 3: Spherical equivalent in children who had lower (1–4 h) and higher (5–6 h) outdoor activity in different follow-ups

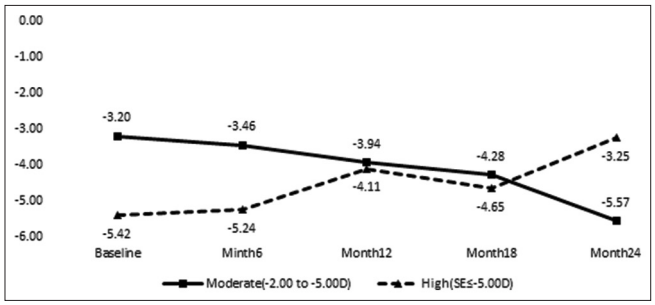

Figure 4: Spherical equivalent of low-moderate and high myopia in different follow-ups

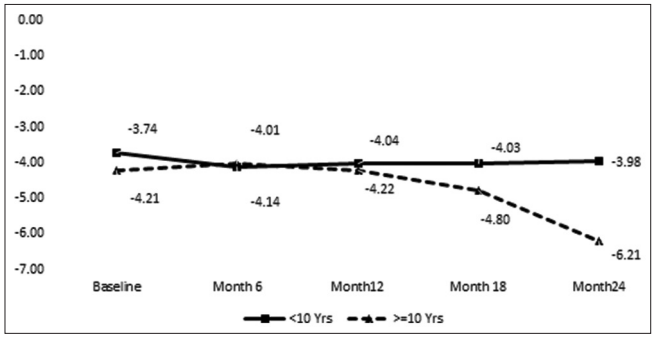

Figure 5: Spherical equivalent based on different age groups in different follow-ups

Discussion

In the present study, the mean myopic progression was −0.16 ± 0.76 D and −1.28 ± 0.78 D at 12 and 24 months, respectively. Myopic progression occurred slower during the 1st year while it changed faster during the 2nd year of Atropine therapy, especially after 18 months.

The mean myopic progression of −0.14 ± 0.23 D among 200 children in an age range between 9 and 12 years was reported by Diaz-Llopis and Pinazo-Durán[11] after a 5-years follow-up. This is the least myopic progression reported in a meta-analysis study by Zhao *et al*.[12] in 2019. Myopic progression in the 1st year of our study was 0.16 D, which was similar to Diaz-Llopis and Pinazo-Durán[11] study during their 5 years' follow-up.

Chia *et al*.[10] in their study on 75 children with a mean age of 8.6 ± 1.1 years reported the myopic progression of − 0.77 ± 0.49 D after 2.5 years of treatment with Atropine 0.01% drop. While myopic progression with placebo was 1.40 D in the same period. It means that Atropine 0.01% therapy could slow myopic progression in about 50%.

Yam *et al*.,[13] in their low concentration Atropine myopic progression, study on 97 children with the mean age of 8.23 ± 1.85 years also reported myopic progression of −0.59 ± 61 D at 12 months of follow-up.

The outcomes of other authors in this regard were from +0.24 D hyperopic shift to −0.50 D myopic progression, which our myopic progression in the 1st year (−0.16) was among them.

The differences among these studies could be due to discrepancies in age, amount of baseline myopia, and length of their follow-ups.

The mean axial length change in our study was 0.05 and 0.69 mm from baseline to 12 and 24 months follow-ups. In other studies, it has been reported from 0.11 mm to 0.42 mm. Cui *et al*.,[14] Chia *et al*.,[10] Yam *et al*.,[13] and Zhang *et al*.[15] reported the axial elongations of 0.42 mm, 0.41 mm, 0.36 mm, and 0.26 mm, respectively. Our result was the least at 12 months and the most at 24 months follow-ups among these studies. The reasons could be related to the more responses and hyperopic shift of our cases at the 1st months of starting Atropine drop and getting used to it after a while. Age, race, baseline myopia, and follow-up differences could be the other reasons among them.

The mean pupil diameter of 5.05 mm and photopic dilation of 1.26 mm at 12 months was observed in our study. In Chia *et al*.'s[10] study, it was 5.18 mm in photopic condition with 1.25 mm dilation from baseline. Our findings were in line with these reported results.

In the present study, the baseline accommodation amplitude was 11.44 ± 3.07 D and the mean reduction of accommodation was −3.38 ± 4.04 D and −3.37 ± 2.21 D at 12 and 24 months after Atropine 0.01% therapy, respectively. The mean reduction of accommodation reported by Yam *et al*.[13] and Chia *et al*.[10] was

Table 2: The changes of the visual and ocular parameters in different follow-ups

Factors	Levels	Mean±SD	Median (range)	*P*
Myopic progression (D)	Pre	−3.97±2.51	−3.50 (−15.75–1.25)	-
	Month 6	−4.07±2.39	−3.69 (−13.13–1.00)	-
	Month 12	−4.13±2.00	−3.44 (−9.75–0.75)	-
	Month 18	−4.35±1.99	−3.88 (−8.25–0.50)	-
	Month 24	−5.25±1.94	−5.38 (−8.75– −2.00)	
	Change (pre–month 6)	−0.10±0.82	−0.13 (−2.50–4.75)	0.161
	Change (pre–month 12)	−0.16±0.76	−0.50 (−3.13–0.75)	0.765
	Change (pre–month 18)	−0.38±0.66	−0.63 (−2.25–0.38)	0.479
	Change (pre–month 24)	−1.28±0.78	−0.69 (−2.63–0.38)	0.018
	Change (month 6–12)	−0.06±0.55	−0.25 (−2.13–1.50)	0.908
	Change (month 6–18)	−0.28±0.53	−0.50 (−1.75–0.63)	0.591
	Change (month 12–18)	−0.22±0.44	−0.13 (−1.13–1.00)	0.641
	Change (month 18–24)	−0.90±0.29	−0.19 (−0.88–0.38)	0.048
Axial length (mm)	Pre	24.69±1.23	24.68 (22.00–27.75)	-
	Month 6	24.67±1.27	24.58 (22.08–27.81)	-
	Month 12	24.70±1.11	24.74 (22.12–27.09)	-
	Month 18	24.78±1.13	24.79 (22.22–27.11)	-
	Month 24	25.38±1.08	25.58 (23.64–27.19)	-
	Change (pre–month 6)	0.02±0.48	0.17 (−1.31–2.29)	>0.999
	Change (pre–month 12)	−0.01±0.37	0.23 (−1.82–1.11)	0.913
	Change (pre–month 18)	−0.09±0.27	0.41 (−1.82–1.11)	0.693
	Change (pre–month 24)	−0.69±0.33	0.38 (−0.07–1.37)	0.013
	Change (month 6–12)	−0.03±0.60	0.10 (−2.22–1.46)	0.513
	Change (month 6–18)	−0.11±0.67	0.15 (−2.18–1.64)	0.176
	Change (month 12–18)	−0.08±0.38	0.13 (−0.83–2.02)	0.763
	Change (month 18–24)	−0.6±0.15	0.11 (−0.13–0.45)	0.020
BCVA (logMAR)	Pre	0.05±0.10	0.0 (0–0.7)	-
	Month 6	0.05±0.11	0.0 (0.0–0.7)	-
	Month 12	0.02±0.05	0.0 (0.0–0.3)	-
	Month 18	0.03±0.06	0.0 (0.0–0.30)	-
	Month 24	0.02±0.03	0.0 (0.0–0.10)	-
	Change (pre–month 6)	0.0±0.03	0.0 (−0.1–0.22)	0.831
	Change (pre–month 12)	−0.03±0.04	0.0 (−0.22–0.10)	0.050
	Change (pre–month 18)	−0.02±0.04	0.0 (−0.17–0.10)	0.391
	Change (pre–month 24)	−0.03±0.04	0.0 (−0.17–0.05)	0.204
	Change (month 6–12)	−0.03±0.04	0.0 (−0.22–0.05)	0.158
	Change (month 6–18)	−0.02±0.5	0.0 (−0.22–0.10)	0.976
	Change (month 12–18)	0.01±0.05	0.0 (−0.10–0.30)	0.074
	Change (month 18–24)	−0.01±0.01	0.0 (−0.05–0.0)	0.162
Pupil size (mm)	Pre	5.05±1.13	5.0 (2.5–7.0)	-
	Month 6	5.88±1.45	6.0 (3.0–9.0)	-
	Month 12	6.31±1.30	6.55 (3.5–9.0)	-
	Month 18	6.98±1.02	7.0 (5.0–9.0)	-
	Month 24	6.89±1.13	7.0 (5.0–9.0)	-
	Change (pre–month 6)	0.83±1.90	2.0 (−2.7–5.5)	0.008
	Change (pre–month 12)	1.26±1.58	1.4 (−1.3–4.5)	<0.001
	Change (pre–month 18)	1.93±1.26	2.25 (0.2–4.4)	<0.001
	Change (pre–month 24)	1.84±1.98	2.0 (−2.7–5.5)	<0.001
	Change (month 6–12)	0.43±1.57	0.7 (−2.00–5.25)	0.189
	Change (month 6–18)	1.10±2.09	1.88 (−2.0–4.0)	0.0004
	Change (month 12–18)	0.67±1.18	0.65 (−1.00–3.75)	0.017
	Change (month 18–24)	−0.09±0.62	0.0 (−1.50–0.0)	0.090

Contd...

Table 2: Contd...

Factors	Levels	Mean±SD	Median (range)	*P*
Accommodation (D)	Pre	11.44±3.07	11.0 (5.9–20.0)	-
	Month 6	9.32±3.62	9.9 (0.5–20.0)	-
	Month 12	8.06±2.19	7.65 (4.0–12.5)	-
	Month 18	7.96±2.95	7.0 (4.0–17.0)	-
	Month 24	8.07±2.37	8.0 (4.0–11.0)	-
	Change (pre–month 6)	−2.12±3.75	−3.15 (−12.0–2.7)	0.009
	Change (pre–month 12)	−3.38±4.04	−3.3 (−12.5–3.7)	<0.001
	Change (pre–month 18)	−3.48±3.71	−2.3 (−12.5–3.7)	<0.001
	Change (pre–month 24)	−3.37±2.21	−1.7 (−4.5–1.4)	<0.001
	Change (month 6–12)	−1.26±4.04	−0.67 (−14.5–9.5)	0.082
	Change (month 6–18)	−1.36±4.12	−0.8 (−14.0–7.0)	0.120
	Change (month 12–18)	−0.1±2.32	0.0 (−2.50–6.4)	0.551
	Change (month 18–24)	0.11±1.14	0.0 (−0.50–3.0)	0.771

BCVA: Best-corrected visual acuity, SD: Standard deviation, D: Diopter

10.88 D and 6.21 D after 24 months of follow-up, respectively. The mean baseline accommodation in their studies was about 12 D. Although our baseline accommodation amplitude was nearly equal to those studies, their accommodative reductions were higher than our findings. This could be related to age and high sensitivity to Atropine in some cases, especially in blond children.

The mean BCVA in far and near distances did not show a significant change during our study up to 24 months of follow-up. It should be due to prescription of total myopia every 6 months according to cycloplegic refraction for cases. The BCVA in Chia *et al*.[10] and Yam *et al*.[13] studies showed a similar pattern.

Patient with less near work (<3 h/day) showed a lower myopic progression at all follow-up visits indicating a significant difference in our study. Yam *et al*.[13] reported no significant difference with placebo cases. Near work of more than 3 h per day was reported at least in 30% of our cases, especially during the recent 2 years because of the coronavirus pandemic.

Twenty-five percentage of our cases reported outdoor activity of more than 5–6 h per week that was much less than optimal timing that is 15 h per week, but myopic progression was not different between them (<1–4 vs. >5–6 h) similar to Yam *et al*. study.[13] Similarly, Németh *et al*.[16] also have reported that more outdoor activity can prevent the onset of myopia as well as slowing the shift to myopia in nonmyopic eyes but cannot slow the myopic progression in myopic children.

The mean age of our cases was 9.73 ± 3.45 years that was close to Chia *et al*.[10] (8.6 ± 1.1) and Yam *et al*.[13] (8.23 ± 1.83) studies. Young age, existence of myopia in close family, higher amount of baseline myopia, and less outdoor activity could indicate a higher chance of myopia progression in future. These risk factors are the strong predictors of high myopia, as reported in the literature.[16] In the present study, myopic progression was more noticeable in cases older than 10 years, as myopic natural course. Other studies did not report myopic progression control according to our age classification.

Absolute success rates in our study according to myopia progression of ≤0.50 D/Y were 56.8% and 70.8% at after 12 and 24 months of follow-up and absolute success rates regarding the axial length elongation (≤0.2 mm/year) were 44.4% and 58.3% at the same follow-up periods. As seen, our absolute success was higher in controlling myopic progression compared to axial length elongation. It means that despite axial length elongation, myopic progression was not increased as well.

To the best of our knowledge, this is the first study determining the effect of Atropine therapy on myopia progression among Iranian myopic patients. These patients might have a different response to this kind of treatment due to their race. Furthermore, in the present study, follow-ups were performed every 6 months with re-examination of many variables; such as cycloplegic refraction, axial length, BCVA, accommodation, pupil size, near work and outdoor activity hours; while in the most other studies, only cycloplegic refraction and axial length were evaluated. In addition, some comparisons of SE between patients with high and moderate myopia, patients under and over 10 years old, and patients with less or more near work and outdoor activities were performed.

Our study had some limitations. The first limitation is the lack of a control group since patients did not accept to perform ocular visits as well as axial length and cycloplegic refraction measurements every 6 months with no therapy. The second limitation is the loss to follow-up of 29% of our cases due to the coronavirus pandemic conditions and some side effects of Atropine drop like photophobia and blurred near vision.

In conclusion, Atropine 0.01% can slow myopic progression and axial length elongation at least in 50% of myopic cases at 12- and 24-month follow-ups with no significant complications. Therefore, Atropine therapy is recommended in cases of progressive myopia in children and teenagers.

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Conflicts of interest

There are no conflicts of interest.

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