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Real-world outcomes of low-dose atropine therapy on myopia progression in an Australian cohort during the COVID-19 pandemic

Eiman Usmani MBBS, MPH[1,2] | **Stephanie Callisto MOpt**[1] | **Weng Onn Chan MPhil, FRANZCO**[1,2] | **Deepa Taranath MS, FRANZCO**[3]

[1]Discipline of Ophthalmology and Visual Science, University of Adelaide, Adelaide, South Australia, Australia

[2]Department of Ophthalmology, Royal Adelaide Hospital and South Australian Institute of Ophthalmology, Adelaide, South Australia, Australia

[3]Department of Ophthalmology, Flinders Medical Centre, Adelaide, South Australia, Australia

Correspondence
Eiman Usmani, Department of Ophthalmology, Royal Adelaide Hospital and South Australian Institute of Ophthalmology, Adelaide, South Australia, Australia.
Email: usmani.eiman@gmail.com

Abstract

Background: To report the outcomes of low-dose atropine (0.01% and 0.05%) for preventing myopia progression in a real-world Australian cohort during the COVID-19 pandemic.

Methods: Records of children presenting with myopia, from January 2016 to 2022, were retrospectively reviewed at a comprehensive ophthalmic practice. Children who discontinued treatment, ages >18, and cases with hereditary conditions were excluded. The rate of progression of myopia after treatment with atropine was compared with historical data to evaluate the effectiveness of the regime.

Results: One hundred and one children (mean baseline spherical equivalent [SphE] [−3.70 +/− 2.09 D] and axial length [AL] [24.59 +/− 1.00 mm]) were analysed. The mean age of the children was 10.4 +/− 2.89 years and 61% were females. The average follow-up time was 17.9 +/− 12.5 months. The mean rate of progression of AL and SphE on 0.01% atropine eyedrops was 0.219 +/− 0.35 mm and − 0.250 +/− 0.86 D/year, respectively. 68.1% of the children treated with 0.01% atropine were mild progressors (<0.5 D change/year). Non-responders when commenced on a higher dose of atropine (0.05%) experienced a 93% ($p = 0.012$) and 30% reduction in SphE and AL growth rate, respectively. Family history, higher myopia or younger age at baseline and shorter duration of treatment were associated with steeper progression ($p < 0.01$). Both doses were well tolerated.

Conclusions: Low-dose atropine was shown to be beneficial in a real-world clinical setting, despite interruptions to follow-ups secondary to COVID-19 pandemic. A 0.05% dose of atropine may be effective in cases where 0.01% was ineffective.

KEYWORDS

Australia, COVID-19, low dose atropine, myopia, real-world outcomes

1 | INTRODUCTION

Myopia is a major cause of visual impairment worldwide and its prevalence has rapidly increased over the past few decades.[1–4] Pathologic myopia greatly increases the risks of complications such as myopic macular degeneration, glaucoma, cataracts, retinal detachment and blindness.[5,6] Hence, early intervention is crucial to prevent significant visual morbidity.

Low-dose atropine (0.01%) has been shown to be beneficial in reducing myopia progression.[7] Previous studies have highlighted a reduction of up to 80% in the progression of myopia, varying depending on the population.[7,8] Recent Australian data has shown a significant reduction in both spherical equivalent (SphE) and axial length (AL) growth rates when compared with placebo.[9] Nonetheless, randomised controlled trials often represent a tightly controlled set group.[9,10] Treatment effects may vary in a real-world clinical setting; especially in the context of the COVID-19 pandemic.

Although higher doses of atropine may exhibit greater efficacy compared to the 0.01% dose; side effects generally follow a concentration-related response.[11] Consequently the 0.01% atropine dose is usually considered the initial treatment of choice. However, a proportion of children respond poorly to the lower dose and optimal management strategy for these children remains unclear.[12] Stepwise treatment strategy (such as increasing the concentration dose to 0.05%) has previously been proposed with favourable outcomes, primarily in Asian populations.[12]

Therefore, we aimed to retrospectively review the effects of low-dose atropine therapy on the progression of myopia in a real-world multicultural Australian clinical setting during the COVID-19 pandemic. We also investigated the effects of commencing a higher dose of 0.05% in non-responders as this remains poorly explored in our population.

2 | METHODS

Records of consecutive children presenting to the ophthalmic practice with myopia from January 2016 to January 2022 were retrospectively reviewed. Children who discontinued treatment, age greater than 18 and those with hereditary conditions or a history of other ocular disease/surgery were excluded. Written informed consent was obtained from their parents or guardians. The study received Royal Australian and New Zealand College of Ophthalmologists (RANZCO) Human Research and Ethics Committee (HREC) approval (Reference number: 139.22) and adhered to the tenets of the Declaration of Helsinki.

2.1 | Clinical evaluation

A thorough history was undertaken at baseline review including ethnicity, previous ocular history (vision disorders, syndromic myopes) and family history of myopia. This was followed by a detailed eye examination, including fundoscopy, cycloplegic auto-refraction (using cyclopentolate 1.0% wt/vol as the cycloplegic agent), clinical refraction and AL measurements (IOLMaster, Carl Zeiss Meditec).

The side effect profile was based on children's reports (such as visual changes) and changes to ocular parameters recorded during visits. These included near/distance Best-Corrected Visual acuity (BCVA [log MAR units]) and mesopic/photopic pupil size (mm). To test for ocular alignment, the cover-uncover test was utilised with an accommodative target at 1/3 and 6 m, respectively.

All families were counselled regarding lifestyle information at the baseline visit and during the follow-up visits such as spending increased time outdoors and reducing the levels of near work. Atropine sulphate monohydrate eye drops (0.01% in saline) were commenced on the first visit. In certain cases, children were previously trialled on 0.01% drops prior to referral to our clinic and failed to respond optimally. In such cases, alternative dosing of atropine was considered on the first visit. However, we did not include cases of these in the progression analysis. Children were instructed to use one drop daily at night. Reviews were attempted 6-monthly for follow-up.

The rate of progression of myopia was defined as the change in AL (mm) or SphE (diopters [D]) per year. The SphE was calculated as the dioptric power of the sphere plus half of the cylinder. During treatment, children were classified into mild (<0.5 D/year), moderate (0.5–1 D/year) or severe progressors (>1 D/year).[13] Children were considered 'non-responders' if SphE progression was >0.50 D/year while being treated with the 0.01% atropine eyedrops. Non-responders were trialled on a dose of 0.05% atropine eyedrops. Children were observed for at least a period of 12-months prior to the stepwise increase in a dosing regimen. Children whose parents were hesitant to start treatment for them when offered were classified under the 'observation' group.

2.2 | Statistical analysis

Statistical analyses were conducted using SPSS v 26.0 (IBM Corporation, NY). Data from the average of both eyes was used for analysis. The rate of progression of myopia was determined using linear regression fits to calculate the slope. This was done for each child separately; prior to treatment, during treatment (from the first visit

to the last recorded visit) and for each subsequent dose change.

Dependent samples *t* tests (or Wilcoxon signed-rank test) were used to compare progression rates between baseline, 0.01%, and 0.05% doses. Independent samples *t* test was used to compare differences between the treatment and observation group. A stepwise multivariate regression model was used to determine factors associated with an increase in myopia's progression rate. Pearson's correlation coefficient ($p < 0.1$) was used initially to determine a significant association for inclusion in the model. Differences in proportions between groups were compared by the chi-square or Fisher's exact tests, as appropriate. When analysing each parameter, if a case did not have recorded values, then the case was excluded from the analysis of that outcome. The statistical significance threshold was set at $p < 0.05$.

3 | RESULTS

One hundred and forty-three children were identified from clinic records as having myopia. Forty-two children were excluded from the analysis as per the exclusion criteria.

The remaining 202 eyes of 101 children (mean baseline SphE [−3.70 +/− 2.09 D] and a mean baseline AL [24.59 +/− 1.00 mm]) were analysed. The mean age of the children was 10.4 +/− 2.89 years (Range, 3–16 years) and 61% were females. 61% of children were identified as having an Asian hereditary; the remaining was Caucasian. 65% of children had dark-coloured iris. Two children had a family history of high myopia. The average follow-up time was 17.9 +/− 12.5 months (Overall period of follow-up; 2–50 months).

Eighty-nine children underwent treatment with atropine eye drops. Of these, 81 children were started on 0.01% atropine eyedrops; and the remaining were started on 0.05% atropine eyedrops as the first dose. Of those who were started on the 0.01% atropine eyedrops, 26 children were subsequently switched to a higher dose of 0.05%. Overall, nine children had baseline rates of myopia progression recorded prior to the commencement of therapy. Twelve children were in the observation group.

The baseline characteristics of children initially commenced on 0.01% atropine dose and the observation group are compared in Table 1. There were no statistically significant differences between the treatment and observation group.

TABLE 1 Children characteristics at baseline.

Parameters	Treatment (0.01%)	Observation	*p*-values
Number of children	81	12	
Gender (male/female)	37%/63%	33.3%/66.7%	0.8*
Ethnicity (Asian/Caucasian)	59.4%/40.6%	63.6%/36.4%	0.8*
Pupil colour (dark/light)	72.7%/27.3%	65.6%/34.4%	0.6*
Family history of high myopia	2	0	1*
Age at start of treatment (years)	10.5 +/− 2.9	9.75 +/− 2.8	0.4*
Total time of follow-up (months)	19 +/− 13.3	14.9 +/− 8.9	0.2*
Baseline axial length (mm)	24.61 +/− 1.03	24.37 +/− 1.01	0.3*
Baseline spherical equivalent (diopters)	−3.76 +/− 2.00	−3.04 +/− 1.89	0.1*

*Not statistically significant.

3.1 | Impact of COVID-19 on follow up

In our clinic, there was an average delay of 2.2 +/− 3.2 months in the six-monthly face-to-face appointments and a 4.9 +/− 6.0-month delay in the 12-monthly face-to-face appointments. Therefore, to continue to maintain an appropriate level of care, virtual appointments (phone or video-assisted technology [telehealth]) were utilised when needed. Electronic prescriptions were delivered either to the parent's smartphone or to the local pharmacy for dispensing.

3.2 | Efficacy profile

The overall mean AL and SphE growth rate of children on 0.01% atropine eyedrops were 0.219 +/− 0.35 mm and − 0.250 +/− 0.86 D/year, respectively. Comparison between the baseline rate of progression of myopia (prior to treatment) and while being treated with 0.01% atropine is presented in Table S1.

3.2.1 | Comparison between 0.01% and 0.05% dose for non-responders

Children who were progressing at a higher rate than expected at the 12 monthly review, had their dose increased to 0.05%. Mean SphE progression −0.55 +/−

0.75 D/year was reduced to −0.04 +/− 1.31 D/year when commenced on the new dose ($p = 0.012$). Similarly, a reduction was found in AL growth rate, with the mean rate of change decreasing from 0.27 +/− 0.37 mm/year to 0.19 +/− 0.22 mm/year. However, this did not reach statistical significance ($p = 0.077$).

3.2.2 | Proportions of mild, moderate, and severe progressors within 0.01% dose treatment versus observation group

Within the observation group, the proportions of mild, moderate and severe progressors were 33.3%, 41.7% and 25.0%. As compared with the treatment group where 68.1% of the children had mild myopia progression, with only 17% and 14.9% moderate and severe progressors ($p = 0.004$). Comparison between the rate of progression of myopia while being treated with 0.01% atropine and observation group is presented in Table S2.

3.2.3 | Factors associated with progression

A stepwise multiple regression model was conducted to predict the progression of myopia (SphE; D/years) from age at baseline, ethnicity, gender, baseline spherical equivalent, pupil colour, duration of treatment and family history of high myopia ($R^2 = 0.319$). Family history of high myopia ($\beta = 0.442$, <0.001), baseline spherical equivalent ($\beta = 0.331$, <0.001), duration of treatment ($\beta = -0.260$, 0.004), and age at baseline ($\beta = -0.241$, $p = 0.007$) were significantly associated with progression. Therefore, a family history of myopia, higher myopia and younger age at baseline, and shorter duration of treatment predicted a higher rate of myopia progression.

3.3 | Side effect profile

We found an increase of 0.17 and 1.50 mm in the photopic pupil size and 0.20 and 1.80 mm in the mesopic pupil size between the 0.01% and 0.05% doses, respectively. Minor changes to distance and near BCVA were observed within both groups. These findings are summarised in Table 2.

On the 0.01% atropine eyedrops, 87.8%, 10.8% and 1.4% of children were observed to have orthophoria, exophoria and esophoria at 6 m, respectively. On the higher dose of 0.05%, 77.4%, 19.4% and 3.2% of children had orthophoria, exophoria and esophoria, respectively (p = 0.391).

At 1/3 meters, 74.3%, 23.0%, and 2.7% children were observed to have orthophoria, exophoria and esophoria on 0.01% atropine eyedrops as compared to 54.8%, 38.7% and 6.5% children on 0.05% atropine eyedrops ($p = 0.137$). These differences were not statistically significant.

Both doses were well-tolerated among children. One child reported blurriness of vision from the 0.01% atropine eyedrops. Two out of the eight children initially commenced on 0.05% atropine eyedrops were switched to 0.01% atropine eyedrops due to intolerance (blurry vision).

TABLE 2 Summary of mean change in ocular parameters from baseline during treatment.

	0.01% atropine	0.05% atropine	*p*-values
log MAR BCVA distance	−0.002	−0.005	0.9*
log MAR BCVA near	0.05	−0.03	0.1*
Photopic pupil size (mm)	0.17	1.50	0.12*
Mesopic pupil size (mm)	0.20	1.8	0.1*

*Not statistically significant.

4 | DISCUSSION

In the current study, we investigated the effect of low dose atropine on the rate of progression of myopia in a real-world multicultural Australian clinical setting. The average AL and SphE growth rate of children on the 0.01% atropine eyedrops were 0.219 mm/year and − 0.250 D/year, respectively. Historical studies have defined myopia progression of <0.5, 0.5–1 and >1 diopter change per year as mild, moderate, and severe.[13,14] Within the 0.01% atropine treatment group in our cohort, 68.1% of the patients progressed mildly as compared to only 33.3% of the patients who did not receive treatment with atropine ($p = 0.004$). Non-responders when commenced on the higher dose of atropine (0.05%) experienced a 93% ($p = 0.012$) and 30% reduction in SphE and AL growth rate, respectively. This was not associated with a significant increase in the side effects experienced by the children.

The COVID-19 pandemic allowed us to explore the effects of low-dose atropine in an environment where interruptions to regular appointments were experienced. Significant delays have been experienced in ophthalmological appointments worldwide due to strict lockdown policies to prevent the spread of the COVID-19 virus.[15] These included cancellations or rescheduling of appointments because of infections and limited availability of clinic rooms due to public health restrictions. This can potentially have consequences on clinical outcomes for children requiring regular follow-ups for treatment. While some studies have found worsening of myopia on low-dose atropine during the pandemic,[16,17] our data indicate that low-dose atropine

was beneficial when comprehensive lifestyle counselling is provided to all families. Poorer outcomes are attributed to sub-optimal lifestyle changes (such as increased time spent indoors secondary to lockdowns) which are associated with myopia progression.[18]

The mean progression of myopia on 0.01% atropine eyedrops within our study was comparable to the landmark Atropine for the Treatment of Myopia (ATOM) 2 study[19] (AL = 0.21 mm/year, SphE = −0.25 D/year)[7] and a recent Australian randomised controlled trial by Lee et al.[9] (AL = 0.16 mm, SphE = −0.31 D; change from baseline at 1 year). Similar rates of progression were found in the study by Rose et al.[14] However, various clinical and demographic factors, including baseline rates of progression, degree of myopia and age at presentation or ethnicity can be associated with progression of myopia while being treated with atropine.[9,20] Hence any differences observed between past studies may primarily be due to contrasting patient characteristics.

The results of our multivariate analysis highlight that increasing age was associated with slower progression of the disease. This may be related to the natural slowing of the disease with age over time. Moreover, family history of high myopia and higher myopia at baseline were associated with a steeper progression, consistent with previous reports.[21,22] Some historical studies have shown higher progression rates within Asian ethnicities.[23] A recent randomised controlled trial conducted within an Australian multi-racial cohort demonstrated a greater benefit of atropine in slowing myopic progression in participants of European ancestry.[9] In our cohort, ethnicity was not associated with the progression rate of myopia. Therefore, association of ethnicity with progression found in previous studies could be influenced by distinct lifestyle habits or possible environmental factors.

Previous clinical trials have shown that low-dose atropine eye drops, specifically 0.01%, effectively slow down the progression of myopia with fewer side effects than higher concentrations but there is still uncertainty regarding the best approach for patients who do not respond well, with proposed strategies involving incremental dosage increases.[12] 32% of children in our cohort continued to progress at suboptimal rates (non-responders). Non-responders experienced a notable reduction in both SphE and AL growth rates when switched to the 0.05% atropine dose. These results are consistent with data from Low Concentration Atropine for Myopia Progression (LAMP) trial where myopia progression was significantly reduced in the placebo group when switched to 0.05% atropine.[11] The authors concluded that 0.05% dose was shown to be more optimal than both the 0.025% and 0.01% atropine doses.[11] While side effects followed a concentration-related response, they were well tolerated. A network meta-analysis comparing various doses of atropine (0.01%–1%) similarly ranked 0.05% as the most beneficial dose when balancing efficacy versus side effects.[7] However, both reports did not explore the effects on Caucasian children.

Therefore, clinicians might be hesitant to start the higher dose (0.05%) of atropine as side effects within an Australian population are not well investigated. Data from our clinic highlight that both doses were well tolerated, with only two children reporting blurry vision on the higher dose. Moreover, only minor changes to ocular parameters were observed during treatment and no significant differences were found when switched from the 0.01% to 0.05% dose (Table 2). Regardless, the long-term effects of the dose on our population are unknown and this remains to be further explored.

Additionally, we observed a significant reduction in AL growth rate (35%) and a 78% reduction in SphE growth rate in children treated with 0.01% atropine eyedrops when compared to baseline rates. In a recent study by Rose et al.,[14] up to 50% reduction (SphE and AL) from the baseline rate was found after 12 months of treatment in fast-progressing myopes (>0.5 D/year). A similar retrospective study conducted by Myles et al.[8] found a 78% and 50% reduction in SphE and AL growth, respectively. Moreover, when comparing children who were commenced on the 0.01% dose to the observation group, we noticed a difference of 0.35 D in SphE and 0.023 mm in AL change; which is comparable to results from a recent meta-analysis.[24]

Whereas disease progression in our cohort was slower in the treated children, our study was not adequately powered for this comparison. This is a limitation to the current study stemming from its retrospective design and could explain why we were unable to detect a significant difference in the AL change between the two groups. Similarly, the percentage reduction in the current study may be understated due to the relatively small sample size of children with recorded baseline measurements. Other limitations include inconsistencies in follow-up times from interruptions to visits during the COVID-19 pandemic. Strengths of the study include an overall large cohort followed over an average long period of time and data from a diverse population thus allowing subgroup analysis.

In conclusion, our data show low dose atropine 0.01% was effective and well tolerated within a real-time clinical setting during the COVID-19 pandemic. This can have implications on clinical practice as atropine can therefore be safely used in future lockdowns or regional and remote areas where regular follow-ups may be difficult to maintain. A stepwise approach to treatment such as in the current study may prove effective in achieving adequate control of myopia in children non-responsive to the dose. Future studies should investigate the long-term effects of the higher dose on our population.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

ORCID

Eiman Usmani https://orcid.org/0000-0001-7600-1526

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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