Original Article

Evaluation of Reasons for Discontinuation of Atropine 0.01% in Myopia Management: A Single-Center Retrospective Study from Türkiye

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Abstract

Objectives: This study aimed to identify the key factors contributing to non-adherence in patients using 0.01% atropine for progressive myopia control in a specific single-center Turkish population and to propose strategies to enhance adherence.

Materials and Methods: This retrospective study included 30 patients (mean age: 10.67±3.47 years; age range: 5-16 years; 14 males and 16 females) diagnosed with progressive myopia and prescribed 0.01% atropine treatment in our clinic between January and June 2021. All participants had discontinued 0.01% atropine treatment before completion. The reasons for discontinuation were analyzed using patient records and categorized into factors such as light sensitivity, difficulties with near vision, ocular or systemic side effects, the need for monthly eye drop renewal, and the long treatment duration. Data on patients' age, sex, treatment adherence, and reasons for discontinuation were collected. Statistical analyses were performed using IBM SPSS Statistics software.

Results: The treatment discontinuation rate in our patient population was 14.92% (95% confidence interval: 10.23-19.61). The most common reasons for discontinuation were the need for monthly drop renewal (80%), long treatment duration (70%), and light sensitivity (60%). Discontinuation rates did not significantly differ by age group ($p>0.05$). The need for monthly renewal was more frequently reported as a barrier among female patients. Informed consent procedures had highlighted the long treatment duration and the need for monthly renewal, but these still represented barriers to adherence for some families.

Conclusion: To improve adherence to 0.01% atropine treatment for progressive myopia in our patient population, patient education and enhanced support systems are essential. Implementing strategies to address challenges related to monthly renewal and providing better information about the long-term benefits of treatment could help increase adherence rates.

Keywords: Atropine 0.01%, treatment adherence, myopia management, atropine therapy in Türkiye

Introduction

The incidence of myopia is increasing worldwide.[1] Complications resulting from myopia are linked to economic and social burdens. Therefore, efficacious strategies should be implemented for myopia management.[2] These strategies may include preventing myopia onset and slowing myopia progression among school-age children. As evidence increases, many treatment strategies have been developed for clinicians to provide effective myopia management. However, this does not discredit the use of atropine eye drops, one of the earliest methods of myopia management. Atropine has been used against myopia since the mid-19th century.[3] Although its use is off-label and the mechanism of slowing axial elongation is not fully understood, topical atropine is still frequently used alone or in combination with other treatment options such as multifocal soft contact lenses, myopia control spectacles, or orthokeratology.[4,5,6] Atropine is a non-specific muscarinic antagonist that has biochemical effects on the sclera, influencing its remodeling.[7] Another theory suggests that increased ultraviolet exposure (secondary to pupil dilation) may increase collagen cross-linking within the sclera, thereby limiting scleral growth.[8] A study conducted in Türkiye demonstrated that different doses of atropine (0.01%, 0.025%, and 0.05%) were effective in slowing myopia progression in a Turkish population.[9]

In the literature, patient discontinuation of atropine eye drop treatment has been reported at varying percentages due to ocular or systemic side effects. The ocular side effects of atropine eye drops include photophobia, blurred near vision,

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local allergic reactions, and ocular discomfort. Systemic side effects are uncommon with the ocular use of atropine but can include dry mouth, facial flushing, headache, increased blood pressure, constipation, and central nervous system disturbances.[10] A recent meta-analysis conducted by Gong et al.[11] reviewed the effectiveness and side effects of atropine treatment in childhood myopia and found that higher doses of atropine were associated with several adverse effects. The most common side effects of low-dose atropine were photophobia (6.3%), poor near visual acuity (2.3%), and others (4.8%), with no reported ocular or systemic allergic reactions.

In our clinical practice, we prefer using atropine 0.01% due to its reduced side effects and potentially lower rebound effect. However, treatment cessation remains an issue. This study aimed to investigate the reasons for the discontinuation of 0.01% atropine treatment in a specific single-center Turkish population and develop strategies to improve adherence based on these findings.

Materials and Methods

This retrospective cross-sectional study was conducted at the Department of Clinical Ophthalmology, Acıbadem Hospital, Ankara, from March 1 to July 31, 2024. The study was reviewed and approved by the Acıbadem Mehmet Ali Aydınlar University Medical Research Evaluation Board Ethics Committee (approval no: 2024-2/93, date: 15.02.2024). The study included 30 patients with progressive myopia who discontinued atropine 0.01% treatment for myopia management. The patients had a mean age of 10.67±3.47 years (age range: 5-16 years), and the cohort consisted of 14 males and 16 females. Informed consent was obtained from all parents or guardians, including detailed information about the expected treatment duration and the need to renew the eye drops monthly.

Inclusion criteria were children aged 5-16 years with progressive myopia (≥0.75 diopters annually) treated with 0.01% atropine eye drops. Exclusion criteria included the presence of other eye diseases (e.g., glaucoma, cataracts, keratoconus, or any form of strabismus), genetic syndromes, or the use of other myopia control treatments.

Atropine eye drops are not commercially available in Türkiye and were therefore prepared by pharmacies. Atropine sulfate 1 mg/1 mL ampoule (Atropin®, Türk Tıpsan, Ankara, Türkiye) was diluted with sodium hyaluronate 1.5 mg/1 mL (Eyestil®, SIFI Pharmaceuticals, Catania, Italy) to achieve a 0.01% atropine solution.[12] Due to the limited shelf life of the solution, parents must obtain a new supply from the pharmacy every month.

Treatment discontinuation was defined as the complete cessation of prescribed medical therapy without the attending doctor's recommendation. The reasons for treatment discontinuation were analyzed retrospectively based on patient and guardian reports and documented in a structured format. These reasons were categorized into factors such as light sensitivity, near-vision difficulties, ocular or systemic side effects, the need for monthly eye drop renewal, long treatment duration, and inadequate information about the treatment. Patients and their parents/guardians were interviewed to identify the most significant factor contributing to the discontinuation of atropine treatment. While participants had the option to select multiple factors influencing their decision, they were specifically asked to identify the primary reason in order to highlight the dominant barrier to treatment.

Statistical Analysis

The sample size was calculated using Python 3.10 and the statsmodels library (version 0.13.2). For the statistical analysis, IBM SPSS Statistics V29 (Released 2023; IBM Corp. Armonk, New York, USA) was utilized. The results were presented in tables, with categorical variables (light sensitivity, near-vision difficulties, ocular or systemic side effects, sex, need for monthly eye drop renewal, and long treatment duration) reported as frequencies and percentages. Numerical variables, such as age, were expressed as mean ± standard deviation. To explore potential effect modifiers, treatment discontinuation and its leading causes were stratified by age and sex. Mann-Whitney U test was used to compare continuous variables between groups, whereas categorical variables were compared using the chi-square test. Statistical significance was determined with two-sided $p<0.05$.

Results

The overall treatment discontinuation rate in our patient population was 14.92% (95% confidence interval: 10.23-19.61). The study included 30 patients with a mean age of 10.67±3.47 years. The patients were categorized into two age groups: 5-10 years (50%) and 11-16 years (50%). Moreover, 14 (46.7%) of the patients were male, and 16 (53.3%) were female (Table 1).

Monthly eye drop renewal (80%), long treatment duration (70%), and light sensitivity (60%) were the most commonly reported reasons for treatment discontinuation (Table 2). Additionally, 32% of patients mentioned near-vision difficulties, while 15% reported ocular surface side effects (e.g., redness or irritation). Notably, inadequate information about the treatment was not cited by any participant (0%), and no systemic allergic reactions were reported. Systemic side effects were also absent in our cohort (0%), as confirmed by patient records.

When stratifying medication discontinuation by sex, we did not find a statistically significant difference in the proportions of males and females ($p=0.71$). Similarly, when stratifying by age group, no statistically significant difference was observed between the two groups ($p=1$).

We also compared the individual factors leading to medication discontinuation by sex and age. Chi-square tests did not reveal significant differences between the sexes for light sensitivity ($p=0.48$). However, the parents of female children were more likely to report discontinuation due to the need for monthly eye drop renewal ($p=0.04$) and long treatment duration ($p=0.03$; Table 3). No significant differences were observed between children from different age groups regarding discontinuation because of the need for monthly renewal ($p=0.36$), long treatment duration ($p=0.23$), or light sensitivity ($p=0.46$) (Table 4).

Discussion

The primary pharmacological treatment for myopia control is atropine eye drops, which require long-term and continuous use to prevent complications and preserve vision. Therefore, we should understand the reasons for discontinuation and develop strategies to improve adherence. In our study, the most common reasons for treatment discontinuation were the need for monthly eye drop renewal (80%), long treatment duration (70%), and light sensitivity (60%). Although overall discontinuation rates did not differ statistically by sex, the parents of female children were significantly more likely to report discontinuation due to the need for monthly renewal compared to the parents of male children (p=0.04). This finding likely reflects parental responsibilities rather than differences attributable to the children themselves. One possible explanation for the higher discontinuation rate among girls is that parents may have perceived the treatment burden differently for them, possibly due to cultural expectations or daily routines affecting compliance. The reasons for discontinuation showed no significant differences between the age groups.

It is important to note that while our study focused on identifying the primary reason for discontinuation, patients and their parents were allowed to mark more than one reason if applicable. This highlights the possibility that multiple challenges may have been experienced simultaneously, contributing to treatment discontinuation. Future studies could explore the cumulative effect of these factors to provide a more comprehensive understanding of treatment adherence. Additionally, the informed consent process included detailed explanations about the long-term nature of the treatment and the need for monthly renewal, ensuring that parents were aware of these challenges before initiating therapy. This aligns with our findings, as the need for monthly renewal and long treatment duration were identified as the leading challenges contributing to discontinuation.

Generally, ocular or systemic side effects have been assumed to be the primary factors for discontinuing atropine eye drop treatment. However, the discontinuation rates and side effects of atropine 0.01% treatment vary in the literature. Diaz-Llopis and Pinazo-Durán[13] reported a discontinuation

Table 1. Demographic distribution of the study participants (n=30)

	Frequency	Percentage (%)
Age group		
5-10 years	15	50.0
11-16 years	15	50.0
Sex		
Male	14	46.7
Female	16	53.3

Table 2. Factors contributing to medication discontinuation

	Frequency	Percentage (%)
Need for monthly renewal		
Yes	24	80.0
No	6	20.0
Long treatment period		
Yes	21	70.0
No	9	30.0
Light sensitivity		
Yes	18	60.0
No	12	40.0

"Yes" indicates patients who listed the factor as a reason for discontinuation, whereas "No" indicates those who did not give the factor as a reason

Table 3. Comparison of factors leading to medication discontinuation by sex

Factor	Sex	n (%)	p value
Need for monthly renewal (n=24)	Female	14 (87.5)	**0.04**
	Male	10 (71.4)	
Long treatment duration (n=21)	Female	12 (75.0)	0.53
	Male	9 (64.3)	
Light sensitivity (n=18)	Female	10 (62.5)	0.48
	Male	8 (57.1)	

Table 4. Comparison of factors leading to medication discontinuation by age group

Factor	Age group	n (%)	p value
Need for monthly renewal (n=24)	5-10 y	12 (80.0)	0.36
	11-16 y	12 (80.0)	
Long treatment duration (n=21)	5-10 y	10 (66.7)	0.23
	11-16 y	11 (73.3)	
Light sensitivity (n=18)	5-10 y	9 (60.0)	0.46
	11-16 y	9 (60.0)	

rate of 2% due to side effects such as photophobia, reading difficulties, mydriasis, and headache. Our findings highlight light sensitivity as the most common ocular side effect leading to treatment discontinuation (60%), consistent with its frequent mention in the literature as a known side effect of atropine. Similarly, Diaz-Llopis and Pinazo-Durán[13] also reported photophobia as a notable side effect.

Sacchi et al.[14] conducted a retrospective study to evaluate the efficacy and safety of atropine 0.01% in slowing myopia progression in European pediatric patients. They reported a discontinuation rate of 0%, with only 10% of patients complaining of temporary headaches. However, while Sacchi et al.[14] reported no discontinuation due to photophobia, our study identified it as a significant reason for discontinuation. This discrepancy may reflect local cultural or environmental factors, as well as differing perceptions of tolerability among patients.

Pérez-Flores et al.[15] reported a discontinuation rate of 4% due to side effects such as tachycardia, vertigo, and ocular discomfort. In contrast, no systemic reactions were reported in our study.

Moriche-Carretero et al.[16] reported a discontinuation rate of 1% due to mydriasis and blurred vision. Kaymak et al.[17] reported side effects such as mydriasis, ocular discomfort, and photophobia, with a discontinuation rate of 0%. Similarly, our findings identified light sensitivity (60%) as a common side effect, consistent with the observations of Kaymak et al.[17] However, unlike their study, light sensitivity was a contributing factor to treatment discontinuation in our study. Myles et al.[18] conducted a retrospective analysis of Australian children prescribed low-dose atropine for myopia treatment and reported a discontinuation rate of 23% due to eye discomfort, mydriasis, photophobia, and headache.

The Myopia Outcome Study of Atropine in Children reported a discontinuation rate of 18.6% in the 0.01% atropine group.[19] Seven adverse events, including eye discomfort, temporary blurred near vision, temporary pupil dilation, and eyelid rash, were possibly or probably related to atropine 0.01%. Joachimsen et al.[20] observed 1-mm pupil dilation in children treated with atropine 0.01%, with negligible hypoaccommodation and no effect on near vision. In contrast to their findings, 32% of our patients reported near-vision difficulties.

Clark and Clark[21] conducted a study using low-concentration atropine on 60 school-aged children in California and reported that only 3 subjects in the atropine group had intermittent blurred vision or light sensitivity, which was not severe enough to discontinue treatment. Hansen et al.[22] conducted a clinical trial investigating the efficacy and safety of atropine 0.01% in the Danish pediatric population and reported that no patients discontinued the 0.01% atropine treatment during the 2-year treatment period.

Ocular surface side effects, such as redness or irritation (15%), were less frequently reported in our study compared to headache and eye discomfort in other studies. Overall, while the discontinuation rates and reasons for atropine 0.01% use vary across studies, our results are broadly consistent with the literature, though some regional differences in side effect profiles and tolerability are evident.

In the literature, the rates of atropine discontinuation vary between 2% and 23%, consistent with our results (14.92%). Although side effects were cited as the primary reason for discontinuation, our study identified additional factors unique to our population. Specifically, the unavailability of commercially prepared atropine drops in Türkiye and the long-term nature of the therapy were more significant reasons for discontinuation than side effects. These factors have not been highlighted in the previous literature.

Discontinuing medication is a key aspect of non-adherence and directly affects treatment outcomes, as the effectiveness of pharmacological treatments relies on both the drug's efficacy and the patient's adherence. Poor adherence is linked to suboptimal clinical outcomes, whereas good adherence improves treatment effectiveness.[23,24] Adherence rates for chronic disease medications range from 43% to 78%, with rates over 80% generally considered acceptable.[25,26] Patient-related factors, such as sex, age, and education, along with medication-related issues such as side effects and dosing frequency, significantly influence adherence.[27,28] Additionally, access to healthcare and cultural factors vary by country and can also affect adherence.[29,30] In our study, the key factors for reduced adherence were the need for monthly renewal of atropine drops and prolonged treatment duration. However, enhancing adherence through education, motivation, and supportive aids can address these challenges.[31]

Treatment continuity can be ensured by developing strategies to address the reasons for treatment discontinuation. For patients discontinuing treatment because of the challenges associated with monthly renewal of the medication, several strategies may be considered. A system could be established in collaboration with local pharmacies that would ensure proper preparation and allow families to pick up the ready medication from the pharmacy monthly. Alternatively, developing preprepared or more user-friendly formulations or providing patients with detailed training on medication preparation, along with written or video materials demonstrating the preparation process step by step, could be beneficial.

There are also various approaches that can be considered for patients who discontinue atropine due to its prolonged duration. Providing detailed education about the long-term benefits of atropine treatment may encourage patients to continue the treatment. Automated notification systems or applications that regularly monitor patients and remind them of the treatment process, regular follow-ups, and examinations should be considered to enhance treatment adherence. Additionally, establishing a support line or online platform where patients can ask questions and share their concerns could be useful.

Our study results also showed that another common factor for treatment discontinuation is light sensitivity. If children experience photophobia or glare associated with atropine 0.01%, using polychromatic glasses or sunglasses can encourage patients to continue the treatment.

Study Limitations

The strengths of this study include providing a thorough evaluation of adherence challenges by considering both patient- and medication-related factors. Moreover, comparing the results with international studies adds depth to the global discussion on the use of atropine in myopia control. Unlike previous studies that primarily focus on regions where commercially prepared atropine is readily available, this study sheds light on the practical barriers and adherence challenges faced in settings with limited access to such resources. As commercially prepared low-dose atropine is unavailable in Türkiye, this study provides valuable insights into the challenges and solutions for myopia management in regions with similar healthcare limitations. By addressing these issues, our study contributes a unique perspective to the international literature.

The limitations of the study include a small sample size, which may limit the generalizability of the findings, and a retrospective design that could introduce recall bias or incomplete data. Potential biases from the retrospective design were minimized by carefully reviewing patient records and excluding incomplete or conflicting data. The observational nature of the study restricts the ability to establish causality, and being a single-center study, the results may not be representative of other populations. Therefore, future research with larger, multi-center, prospective studies is needed to validate these findings.

Conclusion

The primary factor contributing to the discontinuation of atropine 0.01% treatment was the need for monthly renewal, particularly for the girls in our study sample. While treatment duration and light sensitivity also contributed to discontinuation, their impact was less significant compared to the challenge of monthly renewal. This study underscores the importance of simplifying medication protocols and developing supportive systems tailored to the specific needs of patients and their families to address adherence challenges. Particularly in healthcare settings where access to preprepared atropine solutions is limited, these findings encourage the design of globally adaptable strategies to mitigate adherence barriers. By highlighting the specific challenges in a Turkish population, this study offers actionable insights that can guide interventions in similar low-resource settings, thus broadening the applicability of myopia management strategies worldwide.

Ethics

Ethics Committee Approval: The study was reviewed and approved by the Acıbadem Mehmet Ali Aydınlar University Medical Research Evaluation Board Ethics Committee (approval no: 2024-2/93, date: 15.02.2024).

Informed Consent: Informed consent was obtained from the parents or guardians of the patients after explaining the study's purpose and benefits, with the understanding that it involved only data review and publication.

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Declarations

Authorship Contributions

Surgical and Medical Practices: N.A., U.E.A., Concept: N.A., Design: N.A., Data Collection or Processing: N.A., Analysis or Interpretation: N.A., U.E.A., Literature Search: N.A., Writing: N.A.

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