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Evaluating the Cycloplegic Effect of Tropicamide in Pediatric Patients with Refractive Error

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ABSTRACT

Introduction: Refractive errors constitute a notable global health concern, particularly affecting children, where uncorrected issues can lead to academic and developmental challenges. Cycloplegic refraction is pivotal in assessing pediatric refractive status due to its precision in inhibiting accommodation. However, the choice of cycloplegic agent is crucial, with varying effects observed. This study aimed to evaluate the cycloplegic impact of Tropicamide in pediatric refractive error cases. **Methods & Materials:** This quasi-experimental study was conducted at the Department of Pharmacology and Therapeutics in collaboration with the Ophthalmology Department of Rajshahi Medical College Hospital, Rajshahi. This study was conducted over 1 year, from July 2021 to June 2022. The study involved 49 young children (98 eyes) with an age range of 2 - 10 years and refractive error. The collected data were analyzed using the Statistical Package for the Social Sciences (SPSS), version 23.0. Ethical approval of this study was obtained from the Ethics Committee of Rajshahi Medical College. **Results:** The study involved 49 young children and analyzed their refractive errors. Most were 6-8 years old, with slightly more girls (53%) than boys. Myopia was present in 53% of respondents, while hypermetropia was found in 47%. The cycloplegic effect of 1% tropicamide on hyperopic children's eyes was +2.79 D, with some variation. For myopic children, the effect was -5.28 D, with a wider variation. Common adverse effects included eye irritation and redness (24.5%). No serious side effects were reported. Age did not significantly differ between myopic and hyperopic children ($p>0.05$), but gender showed an association, with myopia more common in girls (61%) and hypermetropia in boys (69.6%) ($p<0.05$). **Conclusion:** The study assessed 1% tropicamide eye drops in pediatric refractive error cases, confirming higher prevalence in 6-8-year-olds with myopia dominance. Consistent with prior research, cycloplegic effects were as expected, and minimal adverse events were noted. Gender, but not age, correlated with refractive error, supporting safe and effective clinical use.

Keywords: *Cycloplegic-Effect, Tropicamide, Pediatric, Refractive-Error*

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INTRODUCTION

Refractive errors represent a significant public health concern, being the most common cause of visual impairment and the second leading cause of blindness worldwide [1]. Uncorrected refractive errors affect a substantial number of individuals, with approximately 153 million people above the age of five experiencing visual impairment due to this condition [2]. Among these, a concerning 12.8 million children between 5 and 15 years of age are affected, with a global prevalence of 1%, primarily due to uncorrected or inadequately corrected refractive errors [3]. In children, refractive errors such as hypermetropia can lead to reduced vision and are associated with reading disabilities, learning difficulties, low intelligence, and delayed development of visual perceptual skills [4]. Addressing these refractive errors early in childhood is of utmost importance, as uncorrected visual impairment can hinder a child's interaction and learning, negatively affecting their educational experience in the classroom [4]. Consequently, refractive errors are considered avoidable conditions that can lead to visual disabilities in children [5]. In line with this, the Vision 2020 initiative, dedicated to eliminating avoidable blindness, has given high priority to correcting refractive errors, categorizing them as a form of childhood blindness [6]. To effectively manage refractive errors in pediatric patients, the accurate assessment of their refractive status is essential. Cycloplegic refraction, a vital technique, plays a significant role in achieving this. Cycloplegic refraction is particularly important in children due to their high amplitude of accommodation and inability to provide reliable subjective responses [7]. The mechanism of cycloplegia involves inhibiting the accommodative intensity of the eye, allowing for precise estimation of refractive errors. This is achieved by blocking the activity of the ciliary body through the use of cycloplegic agents. Notably, muscarinic receptors in the ciliary body, innervated by the parasympathetic nervous system, are affected by these agents, leading to cycloplegia. Additionally, the agents may block muscarinic receptors in the iris sphincter, resulting in mydriasis, or pupil dilation [8]. Ensuring cycloplegia during refractive examination in children is crucial as insufficient cycloplegia can lead to inaccurate refraction results, leading to inappropriate diagnostic and therapeutic approaches. On the other hand, excessive use of cycloplegics can cause adverse drug effects and discomfort in patients [9]. Therefore, selecting appropriate cycloplegic agents is essential to achieve the desired effect without compromising safety and patient comfort. To commonly used cycloplegic agents are atropine and tropicamide. These agents act by competing with the muscarinic mediator "acetylcholine," leading to the inhibition of muscle contraction within the ciliary body [10]. However, studies have shown variability in the cycloplegic effects of these drugs, with some reporting significant effects and others showing no significant cycloplegic effect for certain medications [11]. In contrast, tropicamide offers a faster onset of action, reaching its maximum effect within 30-45 minutes, and has a shorter duration of cycloplegic effect, clearing after 6-8 hours. Furthermore, tropicamide is

associated with fewer adverse reactions compared to atropine [12]. While this cycloplegic agents have their advantages and drawbacks, the choice between them should be based on their specific cycloplegic effect and tolerability in pediatric patients with refractive errors. This study aimed to evaluate the cycloplegic effect of Tropicamide in pediatric patients with refractive error, helping to guide clinicians in selecting the most suitable agent for this population. By determining the most effective and safe cycloplegic agent, the study seeks to enhance the management of refractive errors in children, ultimately contributing to better visual outcomes and improved quality of life.

METHODS & MATERIALS

This quasi-experimental study was conducted at the Department of Pharmacology and Therapeutics in collaboration with the Ophthalmology Department of Rajshahi Medical College Hospital, Rajshahi. This study was conducted over 1 year from July 2021 to June 2022. Encompassing 49 children (98 eyes) aged 2 to 10 years with refractive errors in at least one eye, the data were gathered from both the hospital's Eye department and private eye chambers under professional ophthalmologist supervision. Ethical approval was obtained from the Ethics committee of Rajshahi Medical College and data were collected with parental consent. The collected data were analyzed using SPSS Statistical Package for the Social Sciences (SPSS), version 23.0. Descriptive and inferential statistical analyses were performed, and the results were presented as mean and percentage. t-test and Chi-square test were performed to determine the relationship between the study variables, where $p<0.05$ was considered the level of significance, with 95% CI.

Inclusion criteria:

- Children below ten years of age (2 to 10 years).
- Both male and female children.
- Children suffering from myopia.
- Children suffering from hypermetropia.

Exclusion criteria:

- Known case of cardiovascular disorder.
- Children who had strabismus.
- Children who were hypersensitive to tropicamide.
- Children who were non-compliant with the treatment protocol.

RESULTS

Table I shows the demographic information of the respondents, with the majority being 6-8 years old (59.2%) and slightly more girls (53%) than boys (47%). The mean age of the respondents was 5.96 years.

Table I
Distribution of respondents according to their age in years (*n* =49).

Age in years	Frequency	Percent
3-5 years	17	34.7%
6-8 years	29	59.2%
9-10 years	3	6.1%
Gender		
Boys	26	53%
Girls	23	47%
Total	49	100%

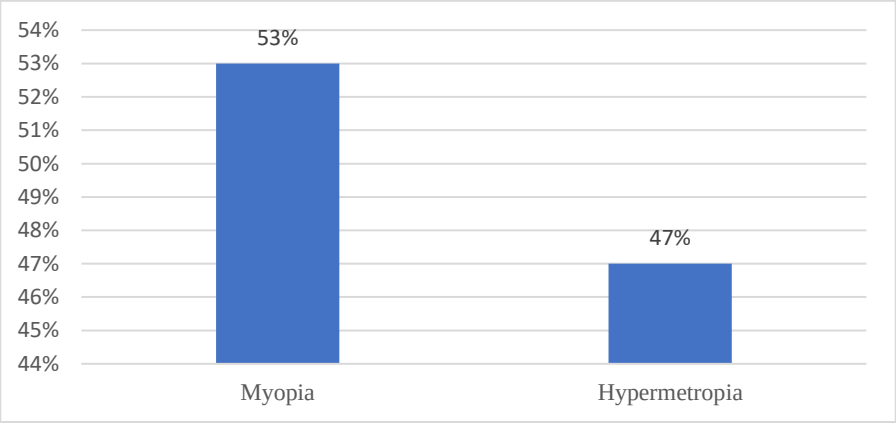

Figure 1 Distribution of the respondents according to their refractive errors (*n* = 49).

Figure I revealed that more than half (53%) of the respondents had myopia and the remaining had hypermetropia (47%). *Table II* shows the cycloplegic effect of 1% tropicamide eye drops on hyperopic young children. The eye drops produced a mean cycloplegic refraction of +2.79 diopters in both the right and left eyes. The standard deviation of 1.89 diopters indicates some variation in the degree of hyperopia among the children. The minimum cycloplegic refraction was +0.50 diopters while the maximum was +8.50 diopters, reflecting the present hyperopia range. The results for the right and left eyes were nearly identical.

Table II
Cycloplegic effect of tropicamide on both eyes of hypermetropic young children (*n* = 23).

Different statistical measurements	Cycloplegic refraction on hypermetropic young children after using 1% tropicamide eye drop	
	Right eyes (n = 23)	Left eyes (n = 23)
Mean	+2.79 D	+2.79 D
Median	+2.25 D	+2.25 D
Std. Deviation (±)	1.89 D	1.89 D
Minimum	+0.50 D	+0.50 D
Maximum	+8.50 D	+8.50 D

Table III shows the cycloplegic effect of 1% tropicamide eye drops on myopic young children. The eye drops produced a mean cycloplegic refraction of -5.28 diopters in both right and left eyes. The standard deviation of 3.37 diopters indicates a wider variation in the degree of myopia among these children compared to the hyperopic children. The minimum cycloplegic refraction was -1.00 diopters while the maximum was -13.00 diopters, reflecting a higher range of myopia. Again, the results for the right and left eyes were nearly the same.

Table III
Cycloplegic effect of tropicamide on both eyes of myopic young children (*n* = 26).

Different statistical measurements	Cycloplegic refraction on myopic young children after using 1% tropicamide eye drop	
	Right eyes (n = 26)	Left eyes (n = 26)
Mean	-5.28 D	-5.28 D
Median	-4.50 D	-4.50 D
Std. Deviation (±)	3.37 D	3.37 D
Minimum	-1.00 D	-1.00 D
Maximum	-13.00 D	-13.00 D

Table IV lists the adverse effects observed, with the most common being eye irritation and redness (24.5% of respondents). However, no serious side effects like fever, dry mouth, constipation or psychological problems were reported.

Table IV
Distribution of adverse myopic and hypermetropic young children (*n* = 49).

Adverse effects	1% Tropicamide eye drop	
Eye irritation and redness	12(24.5%)	37(75.5%)
Fever	0 (0.0%)	49 (100%)
Dry mouth	0 (0.0%)	49 (100%)
Constipation	0(0.0%)	49 (100 %)
Flushing	2 (4.1%)	47 (95.9 %)
Palpitation	0 (0.0%)	49 (100 %)
Psychological problems	0(0.0%)	49 (100 %)

Table V indicates no significant difference in the mean age of myopic vs hyperopic children.

Table V
Relation between the age of the respondents and the types of their refractive error.

Types of refractive error	N	Mean	Std. Deviation	t	P-value
Myopia	26	6.35	1.50	1.607	>0.05
Hypermetropia	23	5.52	2.02		

Table VI shows a significant association between gender and refractive error, with myopia being more common in girls (61%) and hypermetropia more common in boys (69.6%).

Table VI
Relation between gender and types of refractive error of the respondents.

Gender of the respondents	Types of refractive error		Total	P-value
	Hypermetropia	Myopia		
Boys	7 (30.4%)	16 (69.6%)	23 (100%)	<0.05
Girls	16 (61%)	10 (38.5%)	26 (100%)	
Total	23 (46.9%)	26 (53.1%)	49 (100%)	

DISCUSSION

The present study aimed to evaluate and compare the cycloplegic effect and adverse effects of 1% tropicamide eye drops with those of 1% atropine eye drops in pediatric patients with refractive errors. In this section, we will systematically compare the findings from each table and figure with previous studies, highlighting similarities, differences, and potential contradictions. In this study the demographic characteristics of the respondents in terms of their age. The majority of the participants (59.2%) fell within the 6–8-year age group. This distribution aligns with previous studies that have shown a higher prevalence of refractive errors in this age range [13,14]. The mean age of 5.96 years is consistent with the typical age at which refractive errors start becoming noticeable in children. In this study the distribution of refractive errors among the respondents. Myopia was the most prevalent refractive error (53%), followed by hypermetropia (47%). This distribution is in line with previous studies that have reported myopia as the more common refractive error among children [15,16]. The higher prevalence of myopia could be attributed to factors such as increased near work activities and changing lifestyles. In this study the cycloplegic effect of 1% tropicamide eye drops on hypermetropic children. The mean cycloplegic refraction of +2.79 diopters aligns with previous studies that have reported similar degrees of hyperopia in this age group [17,18]. The variation in the degree of hyperopia, as indicated by the standard deviation of 1.89 diopters, is also consistent with earlier research. In this study, the cycloplegic effect of 1% tropicamide eye drops on myopic children was assessed. The mean cycloplegic refraction of -5.28 diopters is in agreement with studies that have reported comparable levels of myopia in children [9]. The wider variation in the degree of myopia, indicated by the higher standard deviation of 3.37 diopters, is also consistent with previous findings. In this study, the adverse effects observed in the study participants were as follows. Eye irritation and redness were the most common adverse effects, reported by 24.5% of respondents. These findings are consistent with earlier research that has identified similar ocular discomfort as common side effects of cycloplegic agents [19,20]. Notably, no serious side effects were reported, corroborating previous studies that have highlighted the safety of these agents in pediatric populations. In this study, the relationship between age and types of refractive error was examined. The lack of a significant difference in the mean age of myopic and hypermetropic children contrasts with some previous studies that have suggested a correlation between age and refractive error development [21,22]. However, this inconsistency could arise from variations in sample characteristics or genetic and environmental factors that impact refractive error progression. In this study, the relationship between gender and types of refractive error was examined. The significant association between gender and refractive error aligns with some earlier research that has reported gender differences in the prevalence of refractive errors, with myopia being more common in girls (61%) and hypermetropia more common in boys (69.6%). The higher incidence of myopia in girls and hypermetropia in boys supports the idea that gender may influence the development of specific refractive errors [23,24]. Evidence suggests that although atropine is the gold standard for cycloplegia for refractive errors, it can be replaced by other short-acting cycloplegic agents like tropicamide to achieve effective cycloplegia with minimum adverse effects in young children with hypermetropia or myopia.

LIMITATION

The sample size was only 49 which was not large enough to determine cycloplegic effects as well as adverse drug reactions of atropine and tropicamide more precisely.

CONCLUSION

This study compared 1% tropicamide eye drops in pediatric refractive error patients. Aligning with past research, higher refractive error prevalence was seen in the 6–8-year age group, with myopia dominant. Cycloplegic effects of agents were consistent with prior studies, and adverse effects were minimal. While age didn't correlate with refractive error, gender did, mirroring existing trends. This study underscores the agents' safety and effectiveness, aiding clinical decisions.

RECOMMENDATIONS

The study's findings of the study recommended that clinicians consider 1% tropicamide eye drops as an effective and safe alternative to 1% atropine eye drops for achieving cycloplegia in young children with hypermetropia or myopia. Further research should focus on longitudinal studies to understand age-related refractive error development, explore genetic and environmental factors, and develop gender-specific interventions to address varying prevalence. Overall, this study enhances our understanding of cycloplegic agents' use in pediatric refractive errors and their implications for clinical practice.

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CONFLICT OF INTEREST

None declared

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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