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Original Article

Comparative Effectiveness of Tropicamide 1% Versus Cyclopentolate 1% in Cycloplegic Refraction: A Randomized Clinical Study

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ABSTRACT

Background: Accurate cycloplegic refraction is essential in children because active accommodation can mask true refractive error and influence spectacle prescription. Tropicamide 1% and Cyclopentolate 1% are commonly used cycloplegic agents, but they differ in cycloplegic strength, duration of action, recovery profile, and tolerability. **Objective:** To compare the cycloplegic effectiveness and adverse-effect profile of Tropicamide 1% versus Cyclopentolate 1% in children aged 5–15 years undergoing cycloplegic refraction. **Methods:** This randomized, parallel-group clinical study included 50 children with suspected refractive error, allocated equally to receive either Tropicamide 1% or Cyclopentolate 1%. Each participant received two drops of the assigned agent in each eye, five minutes apart. Baseline visual acuity and pre-cycloplegic objective refraction were recorded, followed by post-cycloplegic refraction after adequate dilation. Spherical equivalent was calculated, and the change from pre- to post-cycloplegic refraction was compared between groups. Ocular and systemic adverse effects were also recorded. **Results:** Baseline spherical equivalent values were comparable between groups. Cyclopentolate 1% produced a greater mean change in spherical equivalent than Tropicamide 1% in both eyes, with OD change of 1.164 ± 0.182 D versus 0.452 ± 0.130 D and OS change of 1.163 ± 0.182 D versus 0.452 ± 0.132 D, respectively ($p < 0.001$). Systemic symptoms were more frequent with Cyclopentolate 1% than Tropicamide 1% (100.0% vs 52.0%, $p < 0.001$). **Conclusion:** Both agents were effective for cycloplegic refraction, but Cyclopentolate 1% produced stronger cycloplegia, while Tropicamide 1% showed better tolerability. Agent selection should balance refractive accuracy with safety, comfort, and clinical context.
Keywords: Cycloplegic Refraction, Tropicamide 1%, Cyclopentolate 1%, Spherical Equivalent, Refractive Error, Pediatric Optometry.

INTRODUCTION

Accurate refractive assessment in children is essential because uncorrected refractive error during the visual developmental period can affect visual acuity, binocular function, academic performance, reading comfort, and timely detection of amblyopia or accommodative disorders. Children have strong accommodative ability, which may alter refractive findings during routine non-cycloplegic assessment and lead to underestimation of latent hyperopia or overestimation of myopic refractive status. For this reason, cycloplegic refraction remains a critical component of pediatric optometric and ophthalmic evaluation, particularly in children with suspected hyperopia, pseudomyopia, accommodative esotropia, unstable objective refraction, or symptoms suggestive of accommodative dysfunction (1). By temporarily inhibiting accommodation through pharmacologic blockade of muscarinic receptors in the ciliary body,

cycloplegic agents allow clinicians to obtain a more accurate estimate of the child's true refractive state (2).

The clinical need for cycloplegia is especially relevant in children and adolescents aged 5–15 years, because accommodative activity remains sufficiently strong in this age group to mask clinically meaningful refractive error. Non-cycloplegic refraction may produce misleading prescriptions, particularly where latent hyperopia is present or where active accommodation creates an apparent myopic shift. Inaccurate refractive correction may result in persistent blurred vision, asthenopia, reduced reading efficiency, poor compliance with spectacles, and delayed management of amblyogenic risk factors. Previous studies have therefore emphasized that cycloplegic refraction is more reliable than non-cycloplegic refraction in pediatric populations and is often necessary for precise clinical decision-making (3,4).

Among commonly used cycloplegic agents, Tropicamide 1% and Cyclopentolate 1% are widely available and frequently used in clinical practice, but they differ in pharmacologic potency, onset, duration, recovery profile, and adverse-effect burden. Tropicamide has a relatively rapid onset and shorter duration of action, making it convenient for busy outpatient clinics, school screening settings, and situations where rapid visual recovery is desirable. It is generally associated with less prolonged near blur and photophobia, which may improve child and parent acceptability (5). Cyclopentolate, in contrast, is considered a stronger cycloplegic agent and is often preferred when more complete suppression of accommodation is required, particularly in younger children or in patients suspected of having latent hyperopia (6).

The choice between Tropicamide and Cyclopentolate is therefore not only a question of pharmacologic strength but also one of clinical balance between refractive accuracy, patient comfort, recovery time, and safety. Cyclopentolate may reveal a greater hyperopic shift by producing deeper cycloplegia, but this stronger effect may be accompanied by more ocular and systemic adverse effects, including stinging, redness, photophobia, dry mouth, flushing, behavioral changes, or other anticholinergic symptoms. Tropicamide may be better tolerated and more practical for routine use, but incomplete cycloplegia remains a concern in children with high accommodative tone or suspected latent hyperopia (7,8).

Existing comparative evidence has not fully resolved this clinical question. Some studies suggest that Cyclopentolate produces stronger cycloplegia and greater hyperopic spherical equivalent values than Tropicamide, particularly in younger children and those with stronger accommodation (9). Other studies report that Tropicamide may provide clinically comparable refractive outcomes in selected groups, including older children, adolescents, young adults, or patients with lower accommodative influence (10). Reported differences between the two agents may vary according to age, baseline refractive status, iris pigmentation, dosing protocol, timing of post-cycloplegic refraction, and outcome measurement method (11,12). These variations highlight the need for population-specific evidence using clearly defined methods and clinically interpretable refractive outcomes.

In local pediatric optometry practice, both Tropicamide 1% and Cyclopentolate 1% are commonly used, yet direct comparative data remain limited. This creates uncertainty for clinicians when selecting an agent for children requiring cycloplegic refraction, particularly in settings where both diagnostic accuracy and tolerability are important. Using a PICO framework, the population of interest is children aged 5–15 years with suspected refractive error requiring cycloplegic refraction; the intervention is Tropicamide 1%; the comparator is Cyclopentolate 1%; and the main outcomes are change in spherical equivalent and frequency of adverse effects. Therefore, this randomized clinical study aimed to compare the effectiveness and tolerability of Tropicamide 1% versus Cyclopentolate 1% in pediatric cycloplegic refraction. The study tested the hypothesis that Cyclopentolate 1% would produce a greater change in spherical equivalent than Tropicamide 1%, while Tropicamide 1% would demonstrate better tolerability with fewer adverse effects.

MATERIALS AND METHODS

This randomized, parallel-group clinical study was conducted to compare the cycloplegic effectiveness and tolerability of Tropicamide 1% and Cyclopentolate 1% among children requiring cycloplegic refraction. The study design was selected because the objective was to evaluate and compare the refractive change produced by two active cycloplegic agents administered to separate participant groups under a standardized clinical protocol. The primary outcome was the change in spherical equivalent after cycloplegia, while secondary outcomes included post-cycloplegic spherical equivalent and the frequency of ocular and systemic adverse effects following drug instillation.

The study was carried out at Superior University, Lahore, Pakistan, over a period of three months following ethical approval. Children aged 5–15 years who presented with suspected refractive error and required cycloplegic refraction were considered eligible for participation. This age group was selected because accommodation is active during childhood and early adolescence and may influence non-cycloplegic refractive measurements. Participants were included if they had suspected myopia, hyperopia, or astigmatism, best-corrected visual acuity of 6/12 or better in each eye with correction where required, no use of cycloplegic drops during the preceding seven days, and written informed consent from a parent or guardian along with assent from the child. Children were excluded if they had a history of strabismus, amblyopia, binocular vision disorder, cataract, corneal opacity, glaucoma, uveitis, previous intraocular surgery, ocular trauma, known hypersensitivity to Tropicamide or Cyclopentolate, systemic neurological or developmental disorders affecting accommodation, or current use of medications known to influence pupillary response or accommodation.

A total of 50 eligible children were enrolled and allocated into two intervention groups, with 25 participants receiving Tropicamide 1% and 25 participants receiving Cyclopentolate 1%. Participants were selected after screening against the eligibility criteria, and baseline demographic and ocular information was recorded before administration of the assigned cycloplegic agent. The recruitment process included explanation of the study purpose, clinical procedures, expected temporary ocular effects of cycloplegic drops, and the right to withdraw at any stage without penalty. Written informed consent was obtained from the parent or guardian, and assent was obtained from the child before any study-related procedure was performed.

Each participant underwent a baseline ocular assessment before cycloplegia. Demographic information included age and gender, while ocular history was recorded to identify previous ocular disease, trauma, surgery, medication use, or hypersensitivity to cycloplegic agents. Baseline visual acuity was assessed using a Snellen or LogMAR visual acuity chart. An anterior segment examination was performed to exclude visible ocular pathology. Pre-cycloplegic objective refraction was then measured before instillation of the assigned drug. Objective refraction was performed using retinoscopy and autorefraction, and refractive findings were recorded separately for the right eye and left eye.

Participants received the assigned cycloplegic agent according to group allocation. In the Tropicamide group, Tropicamide 1% eye drops were instilled in both eyes. In the Cyclopentolate group, Cyclopentolate 1% eye drops were instilled in both eyes. Each participant received two drops of the allocated agent in each eye, administered five minutes apart. After adequate cycloplegia and pupillary dilation were achieved, post-cycloplegic objective refraction was performed using the same clinical approach as the baseline assessment. Measurements were recorded separately for each eye to allow comparison of pre-cycloplegic and post-cycloplegic refractive status.

The main refractive variable was spherical equivalent, calculated for each eye using the formula: spherical power plus one-half of cylindrical power. Pre-cycloplegic spherical equivalent was defined as the spherical equivalent measured before drug instillation, while post-cycloplegic spherical equivalent was defined as the spherical equivalent measured after cycloplegia. Change in spherical equivalent was calculated as the difference between post-cycloplegic and pre-cycloplegic spherical equivalent. A greater

positive shift in spherical equivalent indicated a stronger cycloplegic response and greater relaxation of accommodation. Adverse effects were assessed after instillation of the cycloplegic agent and included ocular symptoms such as redness, stinging, and photophobia, as well as systemic symptoms following drug administration. The presence or absence of each adverse effect was recorded for each participant and compared between treatment groups.

To reduce measurement bias, the same clinical sequence was followed for all participants, including eligibility screening, baseline visual acuity assessment, anterior segment examination, pre-cycloplegic refraction, cycloplegic drug instillation, post-cycloplegic refraction, and adverse-effect assessment. The same operational definition of spherical equivalent was applied across both groups. Baseline demographic and refractive characteristics were compared between groups to assess group comparability before intervention. Eligibility criteria were applied before allocation to reduce selection of participants with ocular or systemic conditions that could affect accommodation, pupillary response, or refractive measurement. Standardized timing of drop instillation and consistent pre- and post-cycloplegic measurement procedures were used to support reproducibility and minimize procedural variation.

Data were entered and analyzed using SPSS version 27. Continuous variables, including age and spherical equivalent, were summarized using mean and standard deviation. Categorical variables, including gender and adverse effects, were summarized using frequency and percentage. Baseline comparability between the Tropicamide 1% and Cyclopentolate 1% groups was assessed for demographic and refractive variables. Between-group comparisons of pre-cycloplegic spherical equivalent, post-cycloplegic spherical equivalent, and change in spherical equivalent were performed separately for the right and left eyes. Within-group pre- to post-cycloplegic changes were assessed to determine whether each agent produced a statistically significant refractive shift after cycloplegia. Categorical adverse-effect outcomes were compared between groups using chi-square testing, and Fisher's exact test was applied where expected cell counts were small. Statistical significance was set at $p < 0.05$.

Ethical approval was obtained from the ethical board of Superior University, Lahore. The study was conducted according to ethical principles for research involving human participants. Parents or guardians were informed about the study procedures, temporary effects of cycloplegic drops, possible discomfort, confidentiality safeguards, and voluntary nature of participation. Written informed consent was obtained from parents or guardians, and assent was obtained from participating children. Participant confidentiality and anonymity were maintained throughout data collection, analysis, and reporting. All collected data were stored securely and used only for research purposes.

RESULTS

A total of 50 children aged 5–15 years were included and allocated equally into two intervention groups, with 25 participants receiving Tropicamide 1% and 25 participants receiving Cyclopentolate 1%. The mean age of the overall sample was 10.92 ± 3.12 years. Most participants were aged 13–15 years, accounting for 20 children, representing 40.0% of the sample. Eighteen children, representing 36.0%, were aged 9–12 years, while 12 children, representing 24.0%, were aged 5–8 years. The mean age was 11.32 ± 2.68 years in the Tropicamide 1% group and 10.52 ± 3.51 years in the Cyclopentolate 1% group. The gender distribution was nearly balanced, with 26 male participants, representing 52.0%, and 24 female participants, representing 48.0%. The demographic profile of the study participants is presented in Table 1.

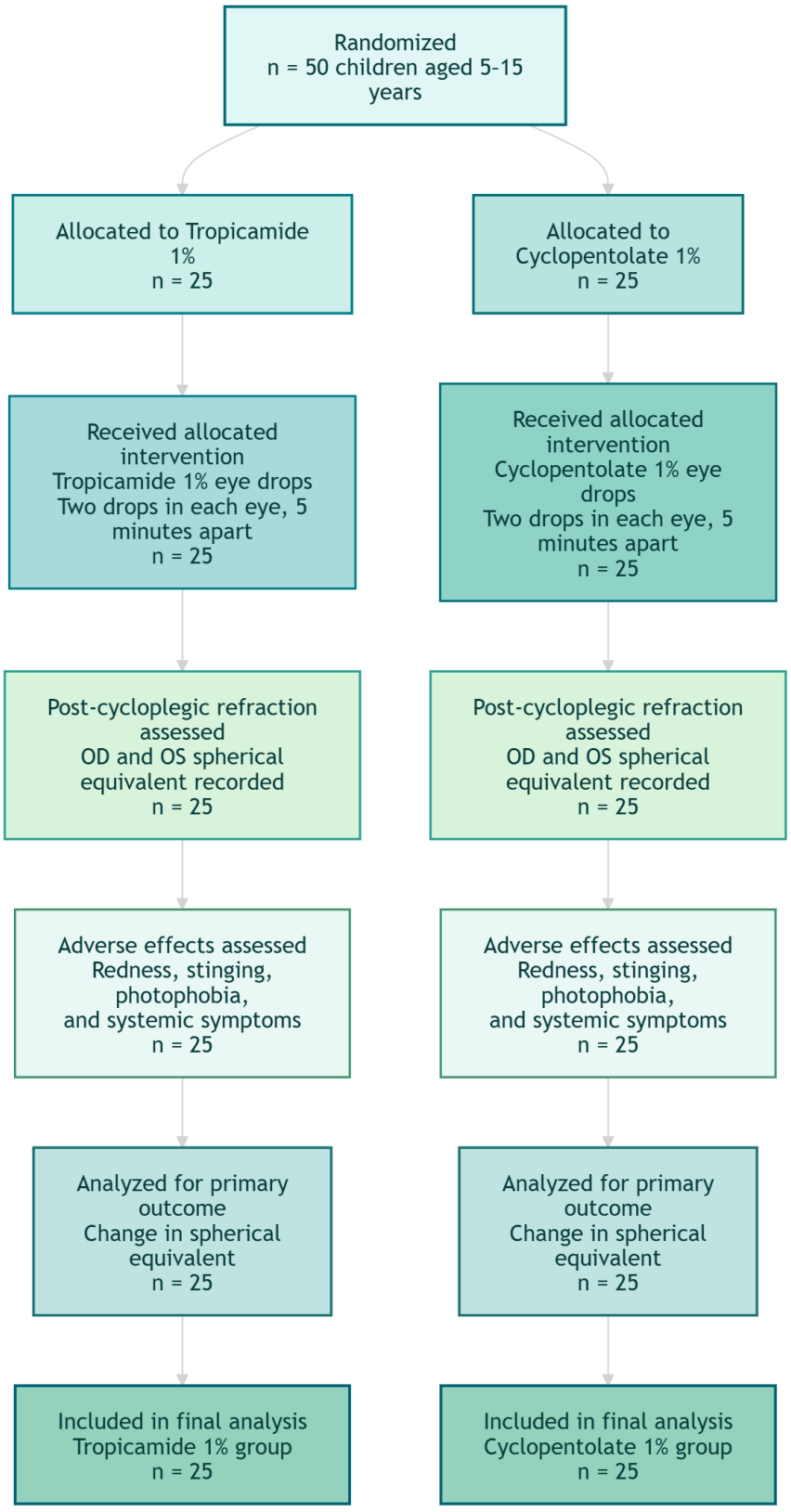

Figure 1. CONSORT Flow Diagram from Randomization to Final Analysis

The flow diagram summarizes participant progression after randomization. A total of 50 children were randomized equally into two intervention groups: 25 received Tropicamide 1% and 25 received Cyclopentolate 1%. All randomized participants received their allocated intervention, underwent post-cycloplegic refraction assessment, were evaluated for ocular and systemic adverse effects, and were included in the final analysis for change in spherical equivalent.

Table 1. Demographic Characteristics of Study Participants

Variable	Category	Frequency (n)	Percentage (%)
Age group	5–8 years	12	24.0
	9–12 years	18	36.0
	13–15 years	20	40.0
Gender	Male	26	52.0
	Female	24	48.0
Total		50	100.0
Overall age	Mean ± SD	10.92 ± 3.12 years	—
Tropicamide 1% group age	Mean ± SD	11.32 ± 2.68 years	—
Cyclopentolate 1% group age	Mean ± SD	10.52 ± 3.51 years	—

Baseline spherical equivalent values were comparable between the two intervention groups before cycloplegia. In the right eye, the mean pre-cycloplegic spherical equivalent was -0.73 ± 1.71 D in the Tropicamide 1% group and -0.73 ± 1.72 D in the Cyclopentolate 1% group, with not statistically significant between-group difference. In the left eye, the mean pre-cycloplegic spherical equivalent was -0.67 ± 2.08 D in the Tropicamide 1% group and -0.73 ± 1.71 D in the Cyclopentolate 1% group, also showing no statistically significant difference. After cycloplegia, the right eye showed a statistically significant between-group difference in post-cycloplegic spherical equivalent, with mean values of -0.279 ± 1.748 D in the Tropicamide 1% group and -0.746 ± 1.588 D in the Cyclopentolate 1% group. In the left eye, the post-cycloplegic spherical equivalent was -0.219 ± 2.142 D in the Tropicamide 1% group and -0.691 ± 1.882 D in the Cyclopentolate 1% group, with a non-significant between-group difference. These findings are summarized in Table 2.

Table 2. Baseline and Post-Cycloplegic Spherical Equivalent Between Treatment Groups

Variable	Eye	Tropicamide 1% Mean ± SD	Cyclopentolate 1% Mean ± SD	Mean Difference, Cyclopentolate − Tropicamide (95% CI)	p-value
Pre-cycloplegic SE	OD	-0.73 ± 1.71 D	-0.73 ± 1.72 D	0.00 D (-0.98 to 0.98)	0.503
Pre-cycloplegic SE	OS	-0.67 ± 2.08 D	-0.73 ± 1.71 D	-0.06 D (-1.14 to 1.02)	0.721
Post-cycloplegic SE	OD	-0.279 ± 1.748 D	-0.746 ± 1.588 D	-0.47 D (-1.42 to 0.48)	0.035
Post-cycloplegic SE	OS	-0.219 ± 2.142 D	-0.691 ± 1.882 D	-0.47 D (-1.62 to 0.68)	0.117

The change in spherical equivalent after cycloplegia was greater in the Cyclopentolate 1% group than in the Tropicamide 1% group for both eyes. In the right eye, the mean change in spherical equivalent was 0.452 ± 0.130 D in the Tropicamide 1% group compared with 1.164 ± 0.182 D in the Cyclopentolate 1% group. The between-group mean difference was 0.712 D, with a 95% confidence interval from 0.622 to 0.802 D, and this difference was statistically significant. In the left eye, the mean change was 0.452 ± 0.132 D in the Tropicamide 1% group and 1.163 ± 0.182 D in the Cyclopentolate 1% group. The between-group mean difference was 0.711 D, with a 95% confidence interval from 0.620 to 0.802 D, and this difference was also statistically significant. Within-group comparisons showed statistically significant pre- to post-cycloplegic refractive changes in both treatment groups for both eyes. The change in spherical equivalent after cycloplegia is presented in Table 3.

Table 3. Change in Spherical Equivalent After Cycloplegia

Eye	Treatment Group	Mean Change in SE ± SD	95% CI for Mean Change	Between-Group Mean Difference, Cyclopentolate − Tropicamide (95% CI)	Within-Group p-value	Between-Group p-value
OD	Tropicamide 1%	0.452 ± 0.130 D	0.398 to 0.506 D	0.712 D (0.622 to 0.802)	<0.001	<0.001
OD	Cyclopentolate 1%	1.164 ± 0.182 D	1.089 to 1.239 D		<0.001	
OS	Tropicamide 1%	0.452 ± 0.132 D	0.398 to 0.506 D	0.711 D (0.620 to 0.802)	<0.001	<0.001
OS	Cyclopentolate 1%	1.163 ± 0.182 D	1.088 to 1.238 D		<0.001	

Adverse effects were recorded after cycloplegic drug instillation and compared between the two groups. Redness was reported by 14 participants, representing 56.0%, in the Tropicamide 1% group and 18

participants, representing 72.0%, in the Cyclopentolate 1% group. The risk difference for redness was 16.0 percentage points higher with Cyclopentolate 1%, but this difference was not statistically significant. Stinging was reported by 12 participants, representing 48.0%, in the Tropicamide 1% group and 15 participants, representing 60.0%, in the Cyclopentolate 1% group, with a non-significant risk difference of 12.0 percentage points. Photophobia was reported by 12 participants, representing 48.0%, in the Tropicamide 1% group and 16 participants, representing 64.0%, in the Cyclopentolate 1% group, with a non-significant risk difference of 16.0 percentage points. Systemic symptoms showed the largest difference between groups, occurring in 13 participants, representing 52.0%, in the Tropicamide 1% group and all 25 participants, representing 100.0%, in the Cyclopentolate 1% group. The risk difference for systemic symptoms was 48.0 percentage points, with a 95% confidence interval from 28.4 to 67.6 percentage points, and this difference was statistically significant. These adverse-effect comparisons are shown in Table 4.

Table 4. Comparison of Adverse Effects Between Tropicamide 1% and Cyclopentolate 1% Groups

Adverse Effect	Tropicamide 1% n (%)	Cyclopentolate 1% n (%)	Risk Difference, Cyclopentolate − Tropicamide (95% CI)	Relative Risk (95% CI)	p-value
Redness	14 (56.0%)	18 (72.0%)	16.0% (-10.2 to 42.2)	1.29 (0.84 to 1.97)	0.239
Stinging	12 (48.0%)	15 (60.0%)	12.0% (-15.4 to 39.4)	1.25 (0.74 to 2.10)	0.395
Photophobia	12 (48.0%)	16 (64.0%)	16.0% (-11.2 to 43.2)	1.33 (0.81 to 2.20)	0.254
Systemic symptoms	13 (52.0%)	25 (100.0%)	48.0% (28.4 to 67.6)	1.92 (1.32 to 2.80)	<0.001

The association between treatment group and systemic symptoms was further evaluated using a cross-tabulation and chi-square analysis. Among participants receiving Tropicamide 1%, 13 out of 25 participants, representing 52.0%, reported systemic symptoms, while 12 participants, representing 48.0%, did not report systemic symptoms. In contrast, all 25 participants in the Cyclopentolate 1% group, representing 100.0%, reported systemic symptoms, and no participant in this group was free from systemic symptoms. Pearson chi-square testing showed a statistically significant association between cycloplegic agent and systemic symptoms, $\chi^2(1) = 15.789$, $p < 0.001$. The continuity correction, likelihood ratio, Fisher's exact test, and linear-by-linear association all supported the same statistically significant pattern, as shown in Table 5.

Table 5. Association Between Cycloplegic Agent and Systemic Symptoms

Treatment Group	Systemic Symptoms: Yes n (%)	Systemic Symptoms: No n (%)	Total
Tropicamide 1%	13 (52.0%)	12 (48.0%)	25
Cyclopentolate 1%	25 (100.0%)	0 (0.0%)	25
Total	38 (76.0%)	12 (24.0%)	50
Statistical Test	Value	df	p-value
Pearson chi-square	15.789	1	<0.001
Continuity correction	13.268	1	<0.001
Likelihood ratio	20.491	1	<0.001
Fisher's exact test	—	—	<0.001
Linear-by-linear association	15.474	1	<0.001
Number of valid cases	50	—	—

Overall, both Tropicamide 1% and Cyclopentolate 1% produced statistically significant changes in spherical equivalent after cycloplegia. Cyclopentolate 1% produced a larger mean change in spherical equivalent than Tropicamide 1% in both eyes, with between-group differences of 0.712 D in the right eye and 0.711 D in the left eye. Ocular adverse effects, including redness, stinging, and photophobia, were numerically more frequent in the Cyclopentolate 1% group but did not differ significantly between groups. Systemic symptoms were significantly more frequent with Cyclopentolate 1%, affecting 100.0% of participants compared with 52.0% in the Tropicamide 1% group.

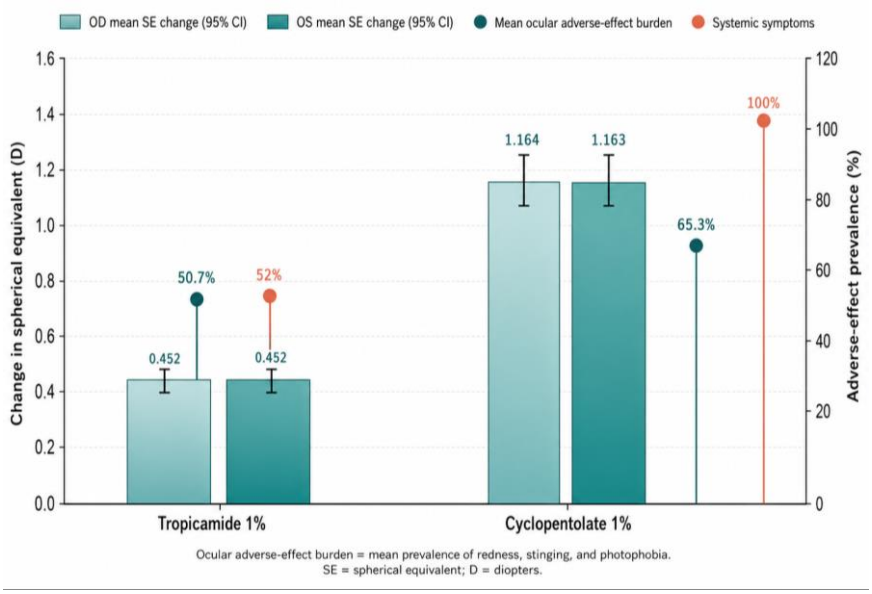

Figure 2. Benefit–Risk Profile of Tropicamide 1% and Cyclopentolate 1% in Cycloplegic Refraction

The figure demonstrates the comparative efficacy and tolerability profile of Tropicamide 1% and Cyclopentolate 1%. Cyclopentolate 1% produced a markedly greater mean change in spherical equivalent than Tropicamide 1% in both eyes, with OD change of 1.164 D versus 0.452 D and OS change of 1.163 D versus 0.452 D, respectively. The 95% confidence intervals remained narrow for both treatment groups, indicating consistent refractive change within each group. However, this greater cycloplegic effect was accompanied by a higher adverse-effect burden. Mean ocular adverse-effect prevalence was 65.3% with Cyclopentolate 1% compared with 50.7% with Tropicamide 1%, while systemic symptoms were reported in 100% of participants receiving Cyclopentolate 1% compared with 52% receiving Tropicamide 1%. Overall, the figure highlights the clinical trade-off between stronger cycloplegic efficacy with Cyclopentolate 1% and better tolerability with Tropicamide 1%.

DISCUSSION

The present randomized clinical study compared the cycloplegic effectiveness and tolerability of Tropicamide 1% and Cyclopentolate 1% in children aged 5–15 years undergoing cycloplegic refraction. The findings showed that both agents produced statistically significant refractive changes after cycloplegia, confirming that each drug was effective in reducing accommodative influence during objective refraction. However, Cyclopentolate 1% produced a substantially greater mean change in spherical equivalent than Tropicamide 1% in both eyes, with mean changes of 1.164 ± 0.182 D in the right eye and 1.163 ± 0.182 D in the left eye, compared with 0.452 ± 0.130 D and 0.452 ± 0.132 D, respectively, in the Tropicamide 1% group. The between-group difference of approximately 0.71 D in both eyes indicates that Cyclopentolate achieved a stronger cycloplegic response and revealed a greater latent refractive component. This finding is clinically meaningful because even moderate differences in spherical equivalent may alter refractive classification, spectacle prescription, and management decisions in children with active accommodation.

The greater refractive shift observed with Cyclopentolate 1% is consistent with its stronger antimuscarinic activity and longer cycloplegic duration compared with Tropicamide. In pediatric patients, accommodation is often active and variable, and incomplete cycloplegia may lead to underestimation of hyperopia or overestimation of myopic refractive status. By producing a deeper suppression of accommodation, Cyclopentolate may provide a more complete estimate of the refractive state, particularly in younger children, children with suspected latent hyperopia, and patients with unstable or inconsistent non-cycloplegic refraction. Previous comparative studies have also reported that Cyclopentolate generally produces stronger cycloplegia than Tropicamide and may reveal greater

hyperopic spherical equivalent values in children, although the magnitude of difference varies according to age, baseline refractive error, iris pigmentation, dosing schedule, and timing of post-cycloplegic assessment (13,14).

Although Cyclopentolate demonstrated superior cycloplegic efficacy, the tolerability findings showed an important clinical trade-off. Ocular adverse effects, including redness, stinging, and photophobia, were numerically more frequent in the Cyclopentolate 1% group than in the Tropicamide 1% group, although these differences were not statistically significant. Redness was reported in 72.0% of children receiving Cyclopentolate compared with 56.0% receiving Tropicamide, stinging in 60.0% compared with 48.0%, and photophobia in 64.0% compared with 48.0%. These findings suggest that Cyclopentolate may be associated with greater ocular discomfort, but the observed differences in ocular symptoms were not large enough to reach statistical significance in this sample. In contrast, systemic symptoms were significantly more frequent with Cyclopentolate, occurring in 100.0% of participants compared with 52.0% in the Tropicamide group. This statistically significant difference indicates that the stronger cycloplegic effect of Cyclopentolate was accompanied by a higher systemic adverse-effect burden.

The higher frequency of systemic symptoms with Cyclopentolate is pharmacologically plausible because Cyclopentolate has stronger and longer anticholinergic activity than Tropicamide. Systemic absorption of cycloplegic drops through the conjunctival and nasolacrimal mucosa may produce anticholinergic effects, particularly in children, who may be more sensitive to topical ophthalmic medications. Although most adverse effects associated with diagnostic cycloplegic agents are temporary, their occurrence remains clinically important because discomfort, photophobia, behavioral symptoms, or systemic complaints may reduce child cooperation, increase parental concern, and affect suitability for screening or high-volume outpatient settings. Tropicamide, with its shorter duration of action and generally better tolerability profile, may therefore be preferable when rapid recovery, patient comfort, and lower systemic symptom burden are priorities (15,16).

The clinical interpretation of these findings should be based on balancing diagnostic precision with patient-centered tolerability. Cyclopentolate 1% appears more appropriate when the purpose of examination is to obtain maximum accommodative relaxation, especially in younger children, suspected latent hyperopia, accommodative esotropia, pseudomyopia, or inconsistent refractive findings. In these situations, a stronger cycloplegic response may prevent under-prescription of hyperopia and improve diagnostic accuracy. Tropicamide 1%, however, remains clinically useful where a shorter examination pathway, faster recovery, and better tolerability are needed, such as routine refractive assessment, follow-up visits, school screening programs, or cases where the expected accommodative influence is lower. Therefore, the choice of cycloplegic agent should not be based solely on refractive shift but should incorporate age, clinical indication, baseline refractive profile, risk of adverse effects, and the practical context of care.

The similarity of baseline refractive values between groups supports the comparability of the two treatment arms before cycloplegic intervention. Pre-cycloplegic spherical equivalent values were nearly equivalent in the right eye and showed no statistically significant difference in the left eye, indicating that post-cycloplegic differences were unlikely to be explained by major baseline imbalance. The post-cycloplegic comparison showed a statistically significant between-group difference in the right eye but not in the left eye, whereas the change-score analysis demonstrated highly significant differences in both eyes. This pattern suggests that the change from baseline may be a more sensitive and clinically informative outcome than post-cycloplegic spherical equivalent alone, because it directly reflects the refractive shift induced by the cycloplegic agent. Reporting both absolute post-cycloplegic values and change scores provides a broader interpretation of treatment effect.

The findings also reinforce the importance of cycloplegic refraction in pediatric practice. Children's accommodative tone can mask clinically relevant refractive error, and non-cycloplegic measurements may not fully represent the refractive state needed for accurate prescribing. In the present study, both

agents produced significant pre- to post-cycloplegic changes, demonstrating that accommodation meaningfully influenced baseline refraction. This supports the use of cycloplegic assessment in children with suspected refractive error, particularly when symptoms, age, or objective findings suggest accommodative involvement. The larger change observed with Cyclopentolate further indicates that the depth of cycloplegia can influence refractive outcomes, and that different agents may not be interchangeable in all pediatric patients (17).

Despite its clinical relevance, the study has limitations that should be considered when interpreting the findings. The sample size was modest, with 25 participants in each group, which may limit precision for some adverse-effect comparisons and subgroup interpretation. The study was conducted at a single center, which may restrict generalizability to broader pediatric populations with different demographic, refractive, or iris pigmentation profiles. The results were analyzed separately for right and left eyes, although both eyes belong to the same participant and may show correlated responses. In addition, adverse effects were recorded as present or absent, while severity, duration, and time to recovery were not graded, limiting deeper interpretation of tolerability. Future studies with larger samples, standardized adverse-effect grading, longer follow-up of recovery time, and statistical models accounting for inter-eye correlation would provide more robust evidence for clinical decision-making.

Overall, the study demonstrates that Tropicamide 1% and Cyclopentolate 1% are both effective cycloplegic agents for pediatric refractive assessment, but they differ meaningfully in efficacy and tolerability. Cyclopentolate 1% produced a greater cycloplegic refractive shift, indicating stronger suppression of accommodation and greater ability to uncover latent refractive error. Tropicamide 1% produced a smaller refractive shift but showed a more favorable tolerability pattern, particularly for systemic symptoms. These findings support an individualized approach in which Cyclopentolate is selected when maximal cycloplegic accuracy is required, while Tropicamide may be suitable when comfort, safety, rapid recovery, and clinical efficiency are prioritized (18).

CONCLUSION

Tropicamide 1% and Cyclopentolate 1% both produced significant cycloplegic refractive changes in children aged 5–15 years, confirming their clinical usefulness for pediatric cycloplegic refraction. Cyclopentolate 1% demonstrated a stronger cycloplegic effect, producing a greater mean change in spherical equivalent in both eyes and therefore showing greater ability to relax accommodation and reveal latent refractive error. However, this increased efficacy was accompanied by a higher adverse-effect burden, particularly systemic symptoms, which were more frequent in the Cyclopentolate group. Tropicamide 1% produced a smaller refractive shift but showed better tolerability, making it a practical option for routine pediatric refraction, screening settings, and cases where rapid recovery and patient comfort are important. Overall, Cyclopentolate 1% may be preferred when maximum cycloplegic accuracy is required, whereas Tropicamide 1% may be more suitable when tolerability, safety, and clinical convenience are prioritized.

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