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# COMPARATIVE EFFECTIVENESS OF TROPICAMIDE 1% VERSUS CYCLOPENTOLATE 1% IN CYCLOPLEGIC REFRACTION: A RANDOMIZED CLINICAL STUDY

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## Abstract

***INTRODUCTION*** *Accurate cycloplegic refraction is important in pediatric and adolescent populations, as active adjustment mask real refractive errors and lead to improper visual correction. Cycloplegic agents such as Tropicamide 1% and Cyclopentolate 1% are commonly used to eliminate accommodation during refraction. While Cyclopentolate is considered more potent in producing cycloplegia, Tropicamide offers advantages such as faster onset and shorter recovery time.*

***OBJECTIVE*** *To compare the effectiveness of Tropicamide 1% and Cyclopentolate 1% in achieving adequate cycloplegia for accurate cycloplegic refraction.*

***METHODOLOGY*** *This randomized, parallel-group clinical study included 50 children aged 5–15 years with suspected refractive errors. Participants were recruited through convenient sampling and randomly allocated into two groups. Each participant received two drops of the assigned agent in each eye, 5 minutes apart. Baseline visual acuity and objective refraction were recorded, followed by cycloplegic refraction after adequate dilation. Spherical equivalent was calculated, and the difference between pre- and post-cycloplegic values was taken as the primary outcome.*

***RESULTS*** *No significant difference was found in baseline characteristics or pre-*

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*cycloplegic SE. Post-cycloplegic SE showed significant difference in the right eye (p = 0.035), while the left eye was non-significant (p = 0.117). The change in SE was significantly higher in the Cyclopentolate group (p < 0.001). Adverse effects were more frequent with Cyclopentolate.*

***CONCLUSION*** *Cyclopentolate provides stronger cycloplegia but with more side effects, while Tropicamide offers better tolerability. Selection should balance accuracy and patient comfort.*

## INTRODUCTION

Accurate refractive assessment in pediatric and adolescent populations is a fundamental aspect of optometric and ophthalmological practice. Early detection and correction of refractive errors are essential to prevent visual impairment, amblyopia, and academic difficulties. However, achieving precise measurements in children is often complicated by the presence of active accommodation, which can alter refractive findings and lead to misinterpretation of refractive status. In growing eyes, strong accommodative ability can mask underlying hyperopia or create pseudo myopia, resulting in inappropriate prescriptions. This can cause persistent visual symptoms such as headaches, eye strain, and reduced concentration, especially during near tasks. In addition to that, erroneous corrections during important periods of development can affect normal development of vision and binocular vision. Children are not able to convey their symptoms of discomfort easily, which increases chances of misdiagnosis (1).

The amplitude of accommodation plays a vital role in the refractive status of the eye in pediatric and adolescent patients with high amplitudes of accommodation. The physiological process helps the eye adapt to changes in the shape of the lens so that images of near targets can be seen clearly. While assessing refractive status, the effect of accommodation leads to misdiagnosis either by masking hyperopic conditions or giving an impression of myopia, referred to as pseudo myopia. As a result, the prescription of glasses based on non-cycloplegic refractometry leads to inappropriate correction, which is not representative of the actual refractive condition. Such mistakes can result in long-term visual problems such as headaches, eye strain, blurry vision, and reduced visual clarity while viewing near objects (2).

Cycloplegic refraction is well-known and established as the gold standard test for assessing refractive errors among children and young patients. Cycloplegic refraction eliminates any effort from the accommodation process by pharmacological paralysis of the ciliary muscle, making it possible to achieve reliable and objective results in the refractive status determination. This method is important for detecting latent hypermetropia that might be undiagnosed because of its presence. Furthermore, it is critical for diagnosing accommodative esotropia and amblyopia when proper correction of the refractive error is necessary for achieving good clinical outcomes. The absence of cycloplegic refraction leads to the possibility of a mistake and overestimation of hyperopic errors. As a result, improper prescriptions could cause patients to continue experiencing visual problems (3).

Cycloplegics represent the group of anticholinergics that inhibit muscarinic receptors located in the ciliary body and iris sphincter muscle. As a result of such a pharmacological effect, they induce cycloplegia by relaxing the ciliary muscles and mydriasis by dilating the pupils, which facilitates a more thorough eye examination. By neutralizing accommodation, these agents make it possible for clinicians to achieve objective and precise determination of refractive errors, particularly in children. Among all cycloplegics, tropicamide and cyclopentolate are the most frequently utilized in clinical practice because of their efficacy and tolerability. Although these drugs share a similar chemical structure, they possess different mechanisms of action, as well as varied durations of cycloplegia. Consequently, their pharmacological distinctions play

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an integral role in their therapeutic use in diverse populations. For this reason, knowing their characteristics is necessary for choosing the optimal medication for cycloplegic refraction (4).

Tropicamide 1% is a cycloplegic agent with relatively short duration of action and rapid onset of action. The peak cycloplegic effect is generally attained in 20 to 30 minutes and recovery takes approximately 4 to 6 hours. This pharmacokinetic profile makes it particularly useful in outpatient clinics, screening camps and school based vision programs where rapid examination and fast visual recovery is needed. It is shorter-acting than longer-acting agents, so patients experience less prolonged blurring of near vision and less photophobia. This means it causes less disruption to normal activities such as reading, writing and school work and therefore increases patient comfort. In addition, the rapid recovery time improves compliance in pediatric patients and reassurance in parents. And that is why tropicamide is often considered a practical, convenient choice (5).

Cyclopentolate 1% works through the production of long-lasting and powerful cycloplegia as opposed to the short-acting drugs. Cyclopentolate takes about 30-45 minutes before its effects set in and can last for up to 24 hours. The extended period of action makes it efficient in producing potent cycloplegia that results in a total suppression of accommodation in the case of young people with great accommodative power. As such, it plays an important role in detecting latent hyperopia which would otherwise be hidden. Thus, it is highly recommended in pediatrics for the determination of proper prescription. It also plays a key role in the diagnosis of accommodative abnormalities such as accommodative esotropia (6).

The comparison between the two drugs shows that there Is a larger hyperopic shift in cyclopentolate, which indicates that the accommodative system is relaxed more effectively. It is evident from the spherical equivalent results that there are higher hyperopic values with cyclopentolate use. This observation occurs among young children who possess an increased accommodative ability. These higher values indicate the effectiveness of cyclopentolate in detecting latent hyperopia compared to other less potent cycloplegics. Such comparisons are clinically significant since the lack of detection of latent hyperopia results in wrong treatment plans and visual disturbances (7).

For such age ranges, the accommodating amplitude is low relative to the younger subjects, hence the similar refractive results obtained when using either drug. In effect, tropicamide provides satisfactory measurements, and may thus be applied clinically in specific populations without any concern for error. Furthermore, the shorter period for effects is beneficial in terms of increased comfort during the visual testing process. It is easier for patients to recover their vision after the procedure, and there will be less interruption to regular activities (8).

The inconsistency in results from various studies shows the effect of many variables, including age, initial refractive state, and differences in research methods or design. Young subjects, who tend to have greater accommodation, show marked differences in results obtained using different cycloplegic drugs due to high accommodation effects. Older subjects, on the other hand, tend to produce similar results regardless of the type of drug used, since their accommodation is lower. Other possible variables could include degree of hyperopia, presence of binocular vision problems, and testing environment, among others. These variations show that it is not always best to use one kind of cycloplegic drug for all subjects (9).

Patient comfort and safety are factors that also have to be considered from a clinical standpoint when choosing a drug for cycloplegia. Cyclopentolate has been noted to produce side effects in the form of systemic reactions, which include facial flushing, increased heart rate, dry mouth, and sometimes behavioral changes in young children due to their sensitivity to anticholinergic medications. While these side effects tend to be minimal and self-resolving, they may still pose a problem to the healthcare provider and family members alike. CNS signs of restlessness and confusion were rarely documented among others. Such

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possible complications could guide the choice of medication, especially during mass screenings or outpatient clinics (10).

**Methodology**

This was a randomized, parallel-group clinical trial conducted over 3 months at [insert hospital name]. Fifty children aged 5–15 years with suspected refractive errors were recruited from the outpatient department using non-probability convenient sampling. Sample size was calculated as n= D2Z2P (1−P) with 95% confidence level and 5% margin of error. Inclusion criteria: children requiring cycloplegic refraction, with suspected myopia, hyperopia or astigmatism, BCVA ≥6/12, and no cycloplegic use in the past 7 days. Exclusion criteria: strabismus, amblyopia, ocular pathology, intraocular surgery, allergy to cycloplegics, and systemic/neurological disorders affecting accommodation. Participants were randomly allocated to Group A: Tropicamide 1% or Group B: Cyclopentolate 1%. After informed consent, baseline VA, slit-lamp, and auto refraction were recorded. Cycloplegic drops were instilled twice, 5 minutes apart. Cycloplegia was confirmed at 30 min for tropicamide and 45 min for cyclopentolate. Cycloplegic refraction was done by retinoscopy and auto refraction. Data were analyzed using SPSS v27. Independent t-test and Chi-square were used. p≤0.05 was considered significant.

**RESULTS**

**Demographics Distribution**

**Table 1 : Mean Age Distribution of Participants**

| Variable | | Frequency (n) | Percent (%) | Mean age | SD |
|---|---|---|---|---|---|
| Age Category (Years) | 5-8 | 12 | 24% | | |
| | 9-12 | 18 | 36% | | |
| | 13-15 | 20 | 40% | | |
| | **Total** | **50** | **100%** | **10.92** | **3.122** |

The mean age in the Tropicamide 1% group was 11.32 ± 2.68 years, while in the Cyclopentolate 1% group it was 10.52 ± 3.51 years.

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**Table 2:Pre-Cycloplegic Spherical Equivalent (OD and OS) Between Groups Using Independent Sample T-test**

| Variable | | Mean ±SD | p-value |
|---|---|---|---|
| SE OD (Pre) | Tropicamide | -0.73 ±1.71 | |
| | Cyclopentolate | -0.73±1.72 | 0.503 |
| SE OS (Pre) | Tropicamide | -0.67± 2.08 | |
| | Cyclopentolate | -0.73 ±1.71 | 0.721 |

The independent sample t-test showed no statistically significant difference in pre-cycloplegic spherical equivalent between the Tropicamide and Cyclopentolate groups for both right and left eyes ($p > 0.05$). These findings indicate that both groups had comparable baseline refractive status before administration of cycloplegic agents. The similarity in pre-cycloplegic values suggests proper group allocation and baseline homogeneity. Therefore, any post-cycloplegic differences observed are likely due to the effect of the interventions rather than pre-existing variation.

**Post Intervention Comparison between Groups**

**Table 3: Post-Cycloplegic Spherical Equivalent (OD and OS) Between Groups Using Independent Sample T-test**

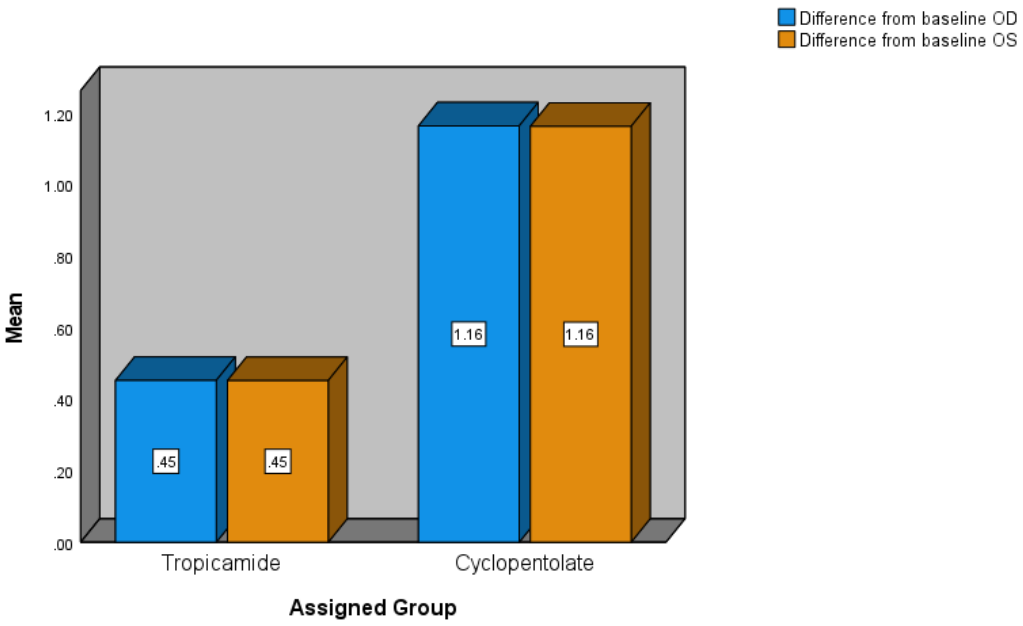
| Variable | | Mean ±SD | p-value |
|---|---|---|---|
| SE OD (Post) | Tropicamide | -0.279 ±1.748 | |
| | Cyclopentolate | -0.7460 ±1.58773 | 0.035 |
| SE OS (Post) | Tropicamide | -0.2188± 2.14193 | |
| | Cyclopentolate | -0.6908 ±1.88182 | 0.117 |

Post-cycloplegic spherical equivalent values showed a greater hyperopic shift in the Cyclopentolate group compared to the Tropicamide group for both eyes. For OD, the difference between groups was statistically significant ($p = 0.035$), indicating a stronger cycloplegic effect of Cyclopentolate. However, for OS, the difference was not statistically significant ($p = 0.117$). Overall, Cyclopentolate produced relatively greater changes in SE compared to Tropicamide. These findings suggest that Cyclopentolate may provide a stronger cycloplegic effect.

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**Table 4: Comparison of Change in Spherical Equivalent (ΔSE OD and OS) Between Groups Using Independent Sample T-test**

| Variable | | Mean ±SD | p-value |
|---|---|---|---|
| Diff OD (Pre) | Tropicamide | 0.4524 ± 0.13007 | |
| | Cyclopentolate | 1.1640±0.18232 | <0.001 |
| Diff OS (Pre) | Tropicamide | 0.4520 ± 0.13210 | |
| | Cyclopentolate | 1.1628 ±0.18227 | <0.001 |




**Difference from Baseline**

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**Table 5: Paired Sample t-test for spherical equivalent comparison between groups**

| Variable | Treatment Group | Pre Mean ± SD | Post Mean ± SD | Paired Difference | p-value |
|---|---|---|---|---|---|
| SE (OD) | Tropicamide | -0.7320 ± 1.71370 | -0.2796 ± 1.74845 | 0.452 | <0.001 |
| | Cyclopentolate | -0.4180 ± 1.57158 | 0.7460 ± 1.58773 | 1.164 | <0.001 |
| SE (OS) | Tropicamide | -0.6708 ± 2.08078 | -0.2188 ± 2.14193 | 0.452 | <0.001 |
| | Cyclopentolate | -0.4720 ± 1.82505 | 0.6908 ± 1.88182 | 1.163 | <0.001 |

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The paired sample t-test showed a statistically significant difference between pre- and post-cycloplegic spherical equivalent in both the Tropicamide and Cyclopentolate groups ($p < 0.001$). Both agents effectively altered refractive measurements after cycloplegia. However, the Cyclopentolate group demonstrated a greater mean change in spherical equivalent compared to the Tropicamide group, indicating a stronger cycloplegic effect. These findings suggest that Cyclopentolate provides more complete inhibition of accommodation and more accurate refractive assessment.

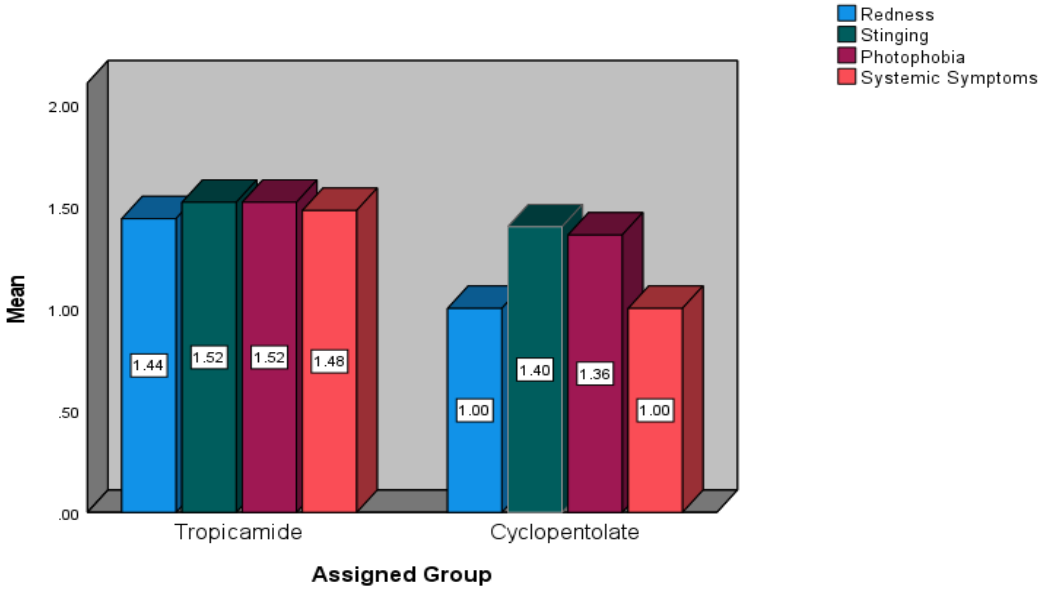
**Table 6: Comparison of Adverse Effects between Groups**

| Adverse Effect | Tropicamide | Cyclopentolate | p-value |
|---|---|---|---|
| Redness | 14 (56%) | 18 (72%) | 0.239 |

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| | | | |
|---|---|---|---|
| **Stinging** | 12 (48%) | 15 (60%) | 0.395 |
| **Photophobia** | 12 (48%) | 16 (64%) | 0.254 |
| **Systemic Symptoms** | 13 (52%) | 25(100%) | <0.001 |

The negative effects such as redness, stinging, photo phobia and systemic effects were experienced by the two groups of patients. The occurrence of these effects was more frequent among the Cyclopentolate group than the Tropicamide group. Nevertheless, there were no statistically significant differences in the prevalence of redness ($p = 0.239$), stinging ($p = 0.395$), and photophobia ($p = 0.254$). There was a statistically significant difference between the two groups regarding systemic effects ($p < 0.001$).




**Comparison of Adverse Effect**

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## DISCUSSION

The present study was conducted to compare the effectiveness of 1% Tropicamide and 1% Cyclopentolate for cycloplegic refraction in pediatric and adolescent participants. The findings demonstrated a significant difference in post-cycloplegic spherical equivalent between the two groups, particularly in the right eye, with Cyclopentolate producing a greater hyperopic shift compared to Tropicamide. This signifies a superior effect of Cyclopentolate as a cycloplegic agent that nullifies accommodative activity and brings latent hypermetropia to the fore. These findings are similar to the current scientific literature, which indicates the superior power of Cyclopentolate as compared to Tropicamide due to deep cycloplegic effect, particularly in younger patients.

Intra-group comparison showed a significant difference in the values before and after applying cycloplegic drops of spherical equivalent for both the groups, thereby establishing the efficacy of Tropicamide and Cyclopentolate in reducing accommodation. But the change in the values was more in the latter, thereby reflecting the higher level of cycloplegia in that case. The results are consistent with those obtained from the randomized clinical study done by Sarayar et al., (2026) (11).

Comparison of post-cycloplegic measurements between the two groups demonstrated a significant difference in the right eye, while no statistically significant difference was detected in the left eye. Such differences could arise due to different accommodative responses. However, based on the findings presented here, it is evident that Cyclopentolate has a superior effect in producing cycloplegia. This assertion is reinforced by recent comparative data such as Fitriyani et al. (2025). The study revealed no significant difference in the final refractive value irrespective of the superior regimen.

The current study also explored the side effects related to both the drugs. Side effects like redness, burning sensation, and sensitivity to light were experienced by participants in both groups, but at a more frequent rate for Cyclopentolate, although not statistically significant. In contrast, the frequency of systemic side effects was significantly higher for Cyclopentolate ($p < 0.001$). These results are in agreement with the findings reported by Sarayar et al. (2026) that Cyclopentolate had significantly more side effects than Tropicamide.

In this regard, from a medical standpoint, it is crucial to find the balance between effectiveness and comfort. As Cyclopentolate shows higher activity as compared to Tropicamide, it can be considered a more appropriate drug for cases when reliable identification of latent hyperopia is required. In turn, Tropicamide stands out in terms of shorter action time, fewer side effects, and better compliance with the treatment, thus being applicable in routine tests and screenings. It corresponds to the Idea proposed by Tao et al. (2023) (12).

The findings of the current study highlight the function of accommodation in assessing refraction as well as the need for cycloplegics for obtaining reliable results. Under accommodation can lead to a misjudgment of myopia or under correction of hyperopia. The conclusions drawn in the current study are supported by GU et al. (2022), who revealed an overestimation of myopia because of accommodation (13). Additional evidence provided by Lin et al. (2022) supports the notion that Tropicamide and Cyclopentolate have an identical influence on the eye, but Cyclopentolate can be slightly more potent pharmacologically (14)

While the advantages of the current research are evident, there are some issues that require mentioning. First, the number of patient was small and represented only one particular age group. Furthermore, variations in accommodative responses might have affected the results. Additional research conducted with larger samples is encouraged.

To conclude, the current research shows that both 1% Tropicamide and 1% Cyclopentolate are efficient drugs for cycloplegics; however, the latter demonstrates a more pronounced effect, as well as a more

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pronounced hyperopic shift. Despite their similarity, the two methods cannot be fully replaced by each other. Given the superior tolerability and short duration of action, Tropicamide may serve as a suitable alternative in selected cases.

CONCLUSION

According to the findings of this research, both 1% Tropicamide and 1% Cyclopentolate were effective in bringing about cycloplegia for refractive error measurement. Nevertheless, there was significantly more improvement in the spherical equivalent following use of Cyclopentolate, suggesting the better efficacy and greater ability of Cyclopentolate to detect refractive error. Despite being more effective, Cyclopentolate caused a relatively greater number of side effects than Tropicamide.

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