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STUDY ON COMPARISON OF EFFECTIVENESS BETWEEN CYCLOPENTOLATE AND TROPICAMIDE IN EVALUATING REFRACTIVE ERROR IN CHILDREN BETWEEN 6-16 YEARS

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Keywords:

Refraction, Cyclopentolat, Tropicamide, Cycloplegia

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ABSTRACT: Aims and Objectives: To compare the effectiveness between cyclopentolate and tropicamide in evaluating refractive error among children between 6-16 years. **Materials and Methods:** This study was carried out in GVPIHC & MT in the department of ophthalmology. Sample of 90 children were taken. One eye (left) of the patient is dilated with cyclopentolate and simultaneously the other eye (right) with tropicamide. Cyclopentolate eye drops 0.5%, Tropicamide eye drops 1% are instilled into other eye for about 3 times for every 15min for about, and patient is asked to close eyes. Auto refractometer and subjective verification are done before and after administering cycloplegic drugs. Participants are evaluated on day 1 and 2 to evaluate post- cycloplegic effect. **Results:** The study predominantly consisted of children in age group of 9-11 years (34.44%) and 12-14 year (28.89%) age groups, where male there was predominance of 53.33% and 46.67% female, with major complaint of headache (46.67%). Hypermetropia was the most prevalent refractive error (40.00%). Tropicamide achieved maximum mydriasis than cyclopentolate (mean 25.6 vs. 36.8 minutes, $p<0.001$). **Conclusion:** The study confirms that both cyclopentolate and tropicamide are effective cycloplegic drugs in children, but Cyclopentolate causes higher cycloplegic effect and hyperopic refractive error. Tropicamide had a very faster onset of action with peak mydriasis at 25.6 minutes, 36.8 minutes with cyclopentolate ($p<0.001$). In older kids (12-16 years) or in the case of myopia or low refractive error, tropicamide may be the preferred drug.

INTRODUCTION: According to the World health organization, the leading cause of visual impairment in children was noted to be uncorrected refractive error. Particularly in hyperopia, cycloplegic refraction is achieved by inhibiting accommodation through anticholinergic agents.

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In pediatric ophthalmology, accurate assessment of refractive error is crucial for several reasons:

1. Early Detection and correction of refractive error is important, particularly in prevention of amblyopia and improves the child's school performance.
2. Prevention of Amblyopia: Uncorrected refractive errors, especially when asymmetric between the two eyes, can lead to amblyopia ("lazy eye"). Accurate refraction is essential for preventing and treating this condition.

Mechanism of action of cycloplegic is by inhibiting action of acetylcholine at muscarinic receptors in ciliary muscle and in iris resulting in cycloplegia and mydriasis. In children, cycloplegic refraction is effective for assessment of refractive error.

Review of Literature: The concept of accommodation was first described by Hermann von Helmholtz in 1855. His theory of accommodation, which proposed that the ciliary muscle controls the shape of the lens, laid the groundwork for understanding challenges of refracting young eyes (von Helmholtz, 1855). The eye has the power to focus on objects at varies distances which has an effect on refractive power called accommodation.

This process is primarily controlled by the ciliary muscle, which alters the shape of the crystalline lens (Glasser, 2008). Larsson *et al.* (2015) found that accommodative amplitude peaks around age 10 and gradually declines thereafter. This strong accommodative ability in children can mask hyperopia and lead to overestimation of myopia during non-cycloplegic refraction (Mutti *et al.,* 1994) [1].

Evolution of Cycloplegic Refraction in Pediatric Ophthalmology:

Early 20th Century: The importance of cycloplegia in pediatric refraction was well-established by the early 1900s. However, the long action of atropine (up to 2 weeks) made frequent examinations impractical.

Mid-20th Century: The introduction of cyclopentolate in the 1950s revolutionized pediatric refraction. Its shorter duration of action (24-48 hours) allowed for more frequent examinations and better patient compliance. Cyclopentolate quickly became the gold standard for cycloplegic refraction in children (Bersudsky & Lukashenko) [2]. It was first synthesized by Villani in 1954 and became commercially available for ophthalmic use in 1959 (Gettes and Belmont, 1961) [3].

Late 20th Century: As tropicamide became more widely available in the 1960s and 1970s, researchers began to investigate its efficacy in pediatric refraction. It's very short duration of action (4-6 hours) made it an attractive option, particularly for busy clinics and for children who needed to return to school quickly (Portney & Purcell) [4]. It was first synthesized by Halpern and kuhn in 1959 and became available for clinical use shortly after Halpern and Kuhn [5].

The World Health Organization estimates that uncorrected refractive errors are the leading cause of visual impairment in children, affecting approximately 12 million children aged 5-15 years globally (Resnikoff *et al*.) [6].

Previous Studies: Several studies observed and compared cyclopentolate and tropicamide particularly the efficacy in pediatric refraction:

- Mutti *et al.* (1994) compared 1% tropicamide, 1% cyclopentolate, and a combination of 1% tropicamide with 1% phenylephrine in 15 children aged 6-12 years. They found that tropicamide alone was significantly less effective in revealing latent hyperopia compared to cyclopentolate
- Egashira *et al.* (1993) compared 1% tropicamide with 1% cyclopentolate in 36 children aged 3-15 years. They concluded that tropicamide was as effective as cyclopentolate in children over 5 years old but less effective in younger children.
- Yazdani *et al.* (2018) conducted a randomized clinical trial comparing 1% tropicamide and 1% cyclopentolate in 80 children aged 3-15 years. Ultimately they found that there is no significant difference in cycloplegic refraction results between the two agents.
- Pai *et al.* [17] (2020) compared 1% tropicamide with 1% cyclopentolate in 200 eyes of 100 children aged 5-15 years. They concluded that tropicamide could be used as an alternative to cyclopentolate in this age group, especially when faster recovery of accommodation is desired.

Gaps in Current Knowledge: Despite these studies, several gaps in knowledge persist:

1. **Age-specific Efficacy:** Most studies have a wide age range, and there's a need for more detailed.

2. **Refractive Error Types:** The comparative efficacy of these agents across different types and degrees of refractive errors needs further investigation.

3. **Iris Pigmentation:** The impact of iris color on the efficacy of these agents, particularly in diverse populations, requires more study.

4. **Long-Term Outcomes:** There's a lack of studies examining whether the choice of cycloplegic agent affects long-term refractive outcomes or compliance with spectacle wear.

5. **Patient Experience:** More research is needed on the comparative patient experience, including side effects and recovery time, between these agents.

6. This study aims to address some of these gaps, particularly focusing on the age-specific efficacy and patient experience aspects in children aged 6-16 years.

The mydriatics and cycloplegics commonly used in clinical practice are:

1. **Sympathomimetics:** Phenylephrine, hydroxy amphetamine.

2. **Antimuscarinic:** Atropine, homatropine, hyoscine, cyclopentolate, tropicamide.

Cyclopentolate: Cyclopentolate is a water-soluble ester and is available at 0.5%, 1% and 2% concentrations (Manny *et al,* 2001) [7]. It is used for routine cycloplegic refraction in all age groups especially in infants and young children. It has a short duration of action within 30-40 min and recovery starts within 24 hours (Manny *et al,* 2001) [7]. Instillation of two drops of 0.5% solution 5 minutes apart or one drop of 1% solution causes mydriasis in 20–30 minutes and cycloplegia in 30-40 minutes. In blacks and people with dark iris it may take up to 40 minutes for cycloplegia to appear (Mindel, 1982). In people with light iris, cycloplegia may appear within 10 minutes of installation of 1% solution.

Adverse effects – stinging sensation of eyes, burning, ocular irritation, redness, lacrimation, blurred vision, diffuse epithelial punctate keratitis with marked conjunctival hyperaemia. CNS toxicity of cyclopentolate is manifested as drowsiness, ataxia, disorientation, slurred speech, restlessness, tactile and visual hallucinations (Enyedi *et al,* 2017). The CNS symptoms are particularly common in children when higher concentrations (2% or multiple installations of 1%) are used. CNS symptoms subside in 4-6 hours in children without any permanent damage.

Tropicamide: Tropicamide is a synthetic derivative of tropic acid. It is a non-selective antimuscarinic agent. Its penetration through corneal epithelium is better than atropine, homatropine and cyclopentolate. It causes quick onset of mydriasis, which lasts for a short duration (4-6 hours - Yazdani *et al*, 2018). Tropicamide is free from vasopressor effects and is the safest mydriatic to use in neonates.

It is available in 0.5%, 1% concentrations (Yazdani *et al*, 2018). Maximum mydriasis occurs in 20–40 minutes, and cycloplegia in 30-35 minutes. It has fewer and milder systemic side effects (Bhatia *et al*, 2000). Combination of tropicamide 1% and phenylephrine 2.5% has shown significantly greater efficacy as mydriatic in dark eyes as compared to tropicamide 1% and cyclopentolate 1% combination (Lin *et al*) [8].

Adverse effects - stinging and burning sensation after instillation. In patients with narrow angles, intraocular pressure may rise. Those patients with angle closure glaucoma were contraindicated. Hypersensitivity to tropicamide has been reported.

MATERIALS AND METHODS:

Study Setting: This study was carried out in Gayatri Vidya Parishad Institute of Health Care and Medical Technology in the Department of Ophthalmology, Visakhapatnam. It is an Experimental type of study for a period of 2 years.

Sample size is 90

Inclusion Criteria:

1. Children of age between 6-16 years

2. Both genders

3. Children with known refractive error

4. Children with complaints of headache.

5. Children with squint.
6. Complaints of eye strain
7. Children with complaints of difficulty in reading
8. Children with amblyopia.

Exclusion Criteria:

1. Children less than 6 years and more than 16 years.
2. Children who underwent any ocular surgery.
3. Children having congenital cataract and congenital glaucoma.
4. Children having ocular tumors.

Study Method: A written informed consent was taken before starting the procedure. Details of the study procedure and side effects regarding the drugs used explained to the patient. Visual acuity assessed by snellens chart and anterior segment examination done underslit lamp and posterior segment examination done with direct and indirect ophthalmoscopes.

Patients attending to ophthalmology op are first evaluated with an autorefractometer followed by subjective verification without using cycloplegics. One eye (right eye) of the patient is dilated with cyclopentolate and simultaneously other eye (left eye) with tropicamide.

Cyclopentolate eye drops 0.5% are instilled into one eye for about 3 times for every 15min for about 30-45 min, patients are asked to close the eyes for effecting the working of the drops. Tropicamide eye drops 1% are instilled into other eye for about 3times for every 15 min for about 30-45min, and then patient is asked to close eyes.

Autorefractometer and subjective verification are done before and after administering cycloplegic drugs. Participants are evaluated on day 1 and day 2 after administration of cyclopentolate and tropicamide to evaluate post- cycloplegic effect. Participants are explained about the possible side effects of drugs. Criteria for defining adequate cycloplegia -

RESULT AND ANALYSIS:

TABLE 1: DISTRIBUTION OF STUDY POPULATION ACCORDING TO AGE GROUP:

Age group (years)	Number of patients (n)	Percentage (%)
6-8	22	24.44
9-11	31	34.44
12-14	26	28.89
15-16	11	12.22
total	90	100

The age distribution is appropriate for evaluating cycloplegic effectiveness, as it encompasses both younger children with higher accommodative amplitude and older children approaching refractive stability

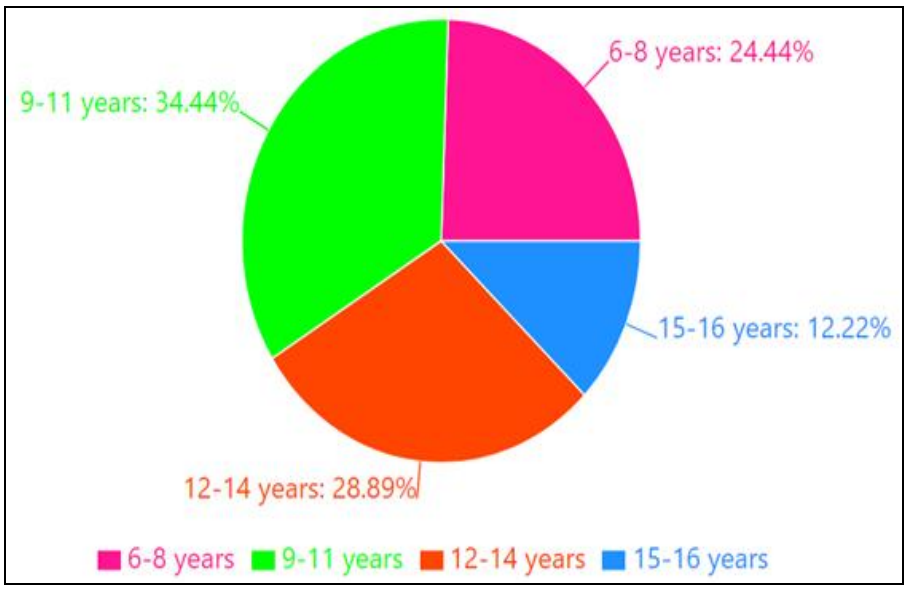

FIG. 1:

TABLE 2: DISTRIBUTION OF STUDY POPULATION ACCORDING TO GENDER

Gender	Number of patients(n)	Percentage (%)
Male	48	53.33
Female	42	46.67
Total	90	100

The gender distribution showed a relatively balanced representation with a slight male predominance. This balanced distribution minimizes gender as a potential confounding variable when evaluating the efficacy of cycloplegic agents. The proportion aligns well with the typical gender distribution observed in pediatric ophthalmology clinics for refractive error assessment, supporting the generalizability of the study findings.

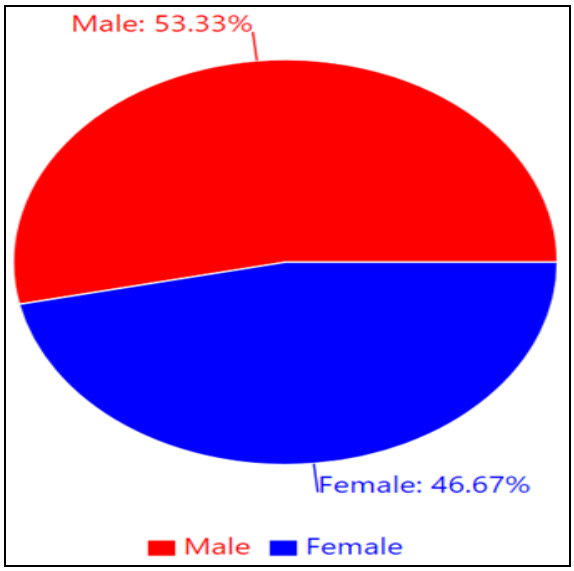

FIG. 2:

TABLE 3: DISTRIBUTION OF STUDY POPULATION ACCORDING TO PRESENTING COMPLAINTS

Presenting complaint	Number of patients(n=90)	Percentage (%)
headache	42	46.67
difficulty in reading	38	42.22
eye strain	31	34.44
squint	14	15.56
amblyopia	12	13.33
others	8	8.89

Headache (46.67%) and difficulty in reading (42.22%) were the most common presenting complaints, consistent with symptoms typically associated with uncorrected refractive errors in school-aged children. These symptoms highlight the functional impact of refractive errors and underscore the importance of accurate cycloplegic refraction for appropriate management, particularly for conditions like accommodative esotropia where the choice of cycloplegic agent may significantly influence the measured refractive outcome.

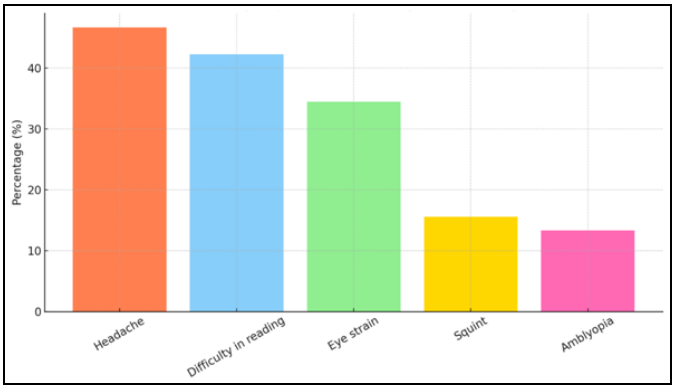

FIG. 3: DISTRIBUTION OF STUDY POPULATION ACCORDING TO PRESENTING COMPLAINTS

TABLE 4: DISTRIBUTION OF STUDY POPULATION ACCORDING TO REFRACTIVE ERROR DIAGNOSIS

Refractive error	Number of patients (n=90)	Percentage (%)
Myopia	31	34.44
Hypermetropia	36	40.00
Astigmatism	16	17.78
Mixed	5	5.56
Anisometropia	2	2.22
Emmetropia	0	0.00
Total	90	100

The higher prevalence of hypermetropia is consistent with the age range studied, as many children in this age group have physiologic hypermetropia. The distribution of refractive errors in this study population provides an appropriate spectrum for evaluating cycloplegic effectiveness, particularly for hypermetropia, which is more susceptible to accommodation-induced measurement error and thus more dependent on effective cycloplegia for accurate assessment.

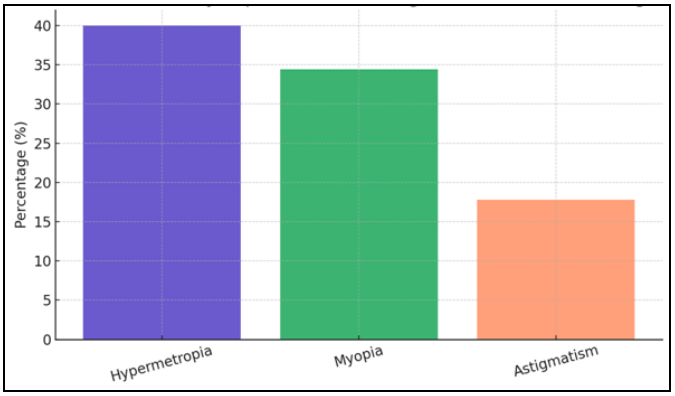

FIG. 4: DISTRIBUTION OF STUDY POPULATION ACCORDING TO REFRACTIVE ERROR DIAGNOS

TABLE 5: DISTRIBUTION OF STUDY POPULATION ACCORDING TO NUMBER OF DRUG INSTILLATIONS REQUIRED

Number of instillations	Cyclopentolate group n (%)	Tropicamide group n (%)	p value
1	0(0.00)	0(0.00)	< 0.001
2	11(24.44)	7(15.56)	
3	34(75.56)	38(84.44)	
total	45(100)	45(100)	

Both cycloplegic agents required multiple instillations in all cases, with the majority of patients needing three drops to achieve adequate cycloplegia. The tropicamide group had a higher proportion of patients requiring three instillations (84.44% vs. 75.56% in the cyclopentolate group), though this difference was statistically significant (p<0.001). The need for three instillations in most cases highlights the importance of following standardized protocols for cycloplegic administration to ensure complete cycloplegia, especially in children with higher accommodative amplitudes. These findings suggest that single-drop protocols may be insufficient for reliable cycloplegic refraction in the pediatric population.

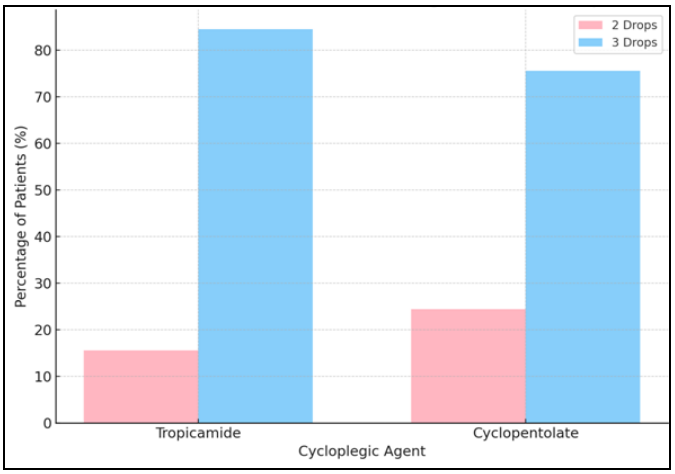

FIG. 5: DISTRIBUTION BASED ON NUMBER OF DRUG INSTILLATIONS REQUIRED

TABLE 6: MEAN PUPIL DIAMETER AT DIFFERENT TIME INTERVALS AFTER CYCLOPLEGIC INSTILLATION

Time after instillations (minutes)	Cyclopentolate group(mm)	Tropicamide group (mm)	p value
10	5.2+/-0.6	6.4+/- 0.5	<0.001
20	6.8+/-0.5	7.2+/- 0.4	0.033
30	7.6+/-0.4	7.4+/-0.5	0.114
45	7.8+/-0.3	7.2+/-0.4	<0.001
60	7.7+/-0.4	6.8+/-0.5	<0.001

Tropicamide demonstrated more rapid onset of mydriasis, with significantly larger pupil diameter at 10 minutes and 20 minutes compared to cyclopentolate. However, cyclopentolate achieved greater maximum dilation by 30 minutes, which was sustained at 45 and 60 minutes, while tropicamide showed a declining effect after 30 minutes. At 45 and 60 minutes, cyclopentolate demonstrated significantly larger pupil diameter (p<0.001), indicating more sustained mydriasis. These temporal patterns of pupillary response have important implications for timing of refraction and examination procedures following administration of these cycloplegic agents.

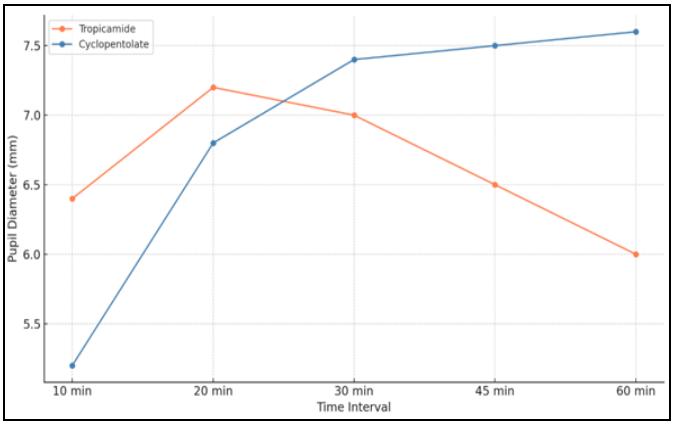

FIG. 6: MEAN PUPIL DIAMETER OVER TIME AFTER CYCLOPLEGIC INSTILLATION

TABLE 7: COMPARISON OF SPHERICAL REFRACTIVE ERROR MEASURED UNDER CYCLOPLEGIA

Spherical refractive error (D)	Cyclopentolate group n (%)	Tropicamide group n (%)	p value
<_ 6.00	2(4.44)	2(4.44)	0.027
-5.99 to -3.00	6(13.33)	7(15.56)	
-2.99 to -0.50	7(15.56)	9(20.00)	
-0.49 to +0.50	4(8.89)	8(17.78)	
+0.51 to +3.00	19(42.22)	15(33.33)	

+3.01 to +6.00	6(13.33)	4(8.89)	
>_+6.00	1(2.22)	0(0.00)	
mean +/- SD	+1.26 +/- 2.74	+0.92 +/- 2.52	0.043
total	45(100)	45(100)	

Cyclopentolate revealed more hyperopic refractive errors compared to tropicamide, with a significantly higher mean spherical component. The distribution shows more patients with moderate to high hyperopia in the cyclopentolate group compared to the tropicamide group. Conversely, tropicamid showed a higher proportion of emmetropic or mildly hyperopic measurements. This pattern suggests that cyclopentolate provides more complete cycloplegia, particularly important for detecting latent hyperopia in children who may accommodate to mask their true refractive error. These difference have significant implications for prescribing decisions, especially in hyperopic children.

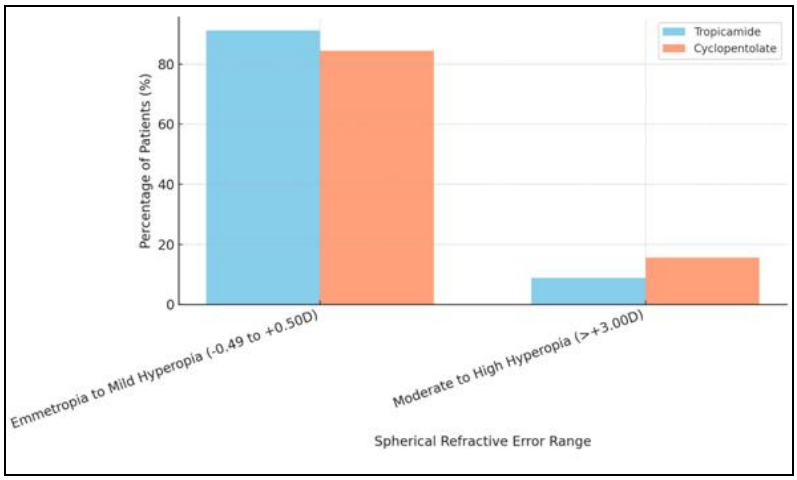

FIG. 7: COMPARISON OF SPHERICAL REFRACTIVE ERROR UNDER CYCLOPLEGIA

TABLE 8: COMPARISON OF CYLINDER REFRACTIVE ERROR MEASURED AFTER CYCLOPLEGIA

Cylindrical refractive error (D)	Cyclopentolate group n (%)	Tropicamide group n (%)	Percentage (%)
0.00	**5(11.11)**	4(8.89)	0.742
-0.25 to -0.75	16(35.56)	18(40.00)	
-1.00 to -2.00	19(42.22)	18(40.00)	
-2.25 to -3.00	4(8.89)	4(8.89)	
>_ -3.00	1(2.22)	1(2.22)	
mean+/- SD	-1.04 +/- 0.73	-1.08+/- 0.74	0.679
total	45(100)	45(100)	

No statistically significant differences were observed in cylindrical refractive error measurements between cyclopentolate and tropicamide (mean -1.04D vs. -1.08D, p=0.679). The distribution of astigmatism was remarkably similar between the two groups, with approximately 80% of patients in both groups having mild to moderate astigmatism (-0.25 to -2.00D). This suggests that both cycloplegic agents perform similarly in the assessment of astigmatism, which is less influenced by accommodative status compared to spherical error. The equivalent performance in astigmatism detection indicates that the choice between these agents may be less critical when astigmatism is the primary refractive concern.

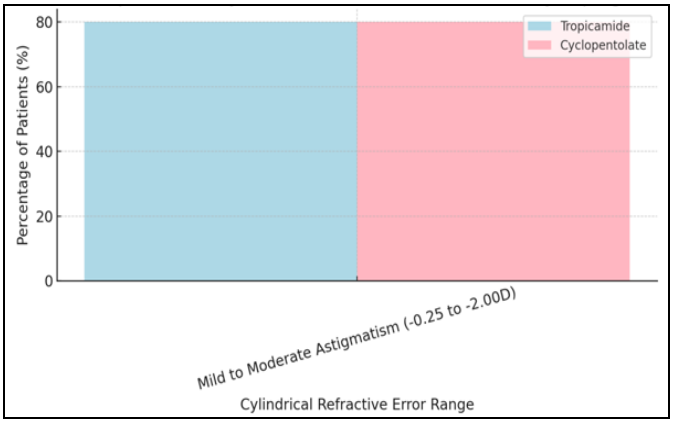

FIG. 8: COMPARISON OF CYLINDRICAL REFRACTIVE ERROR UNDER CYCLOPLEGIA

TABLE 9: TIME TO ACHIEVE MAXIMUM PUPILLARY DILATATION

Time to maximum dilatation (minutes)	Cyclopentolate group n(%)	Tropicamide group n (%)	Percentage (%)
<20	2(4.44)	12(26.67)	<0.001
20-30	15(33.33)	25(55.56)	
31-45	24(53.33)	8(17.78)	
45-60	4(8.89)	0(0.00)	
>60	0(0.00)	0(0.00)	
mean +/- SD	36.8+/- 8.6	25.6+/- 6.4	<0.001
Total	45(100)	45(100)	

Tropicamide achieved maximum mydriasis significantly faster than cyclopentolate. The majority of tropicamide-treated eyes reached maximum dilation within 30 minutes, compared to cyclopentolate-treated eyes. This temporal difference in reaching peak effect has significant implications for clinical workflow and patient throughput. Tropicamide's faster onset may be advantageous in busy clinical settings or when examining multiple patients sequentially, while cyclopentolate's slower onset requires longer waiting periods before examination.

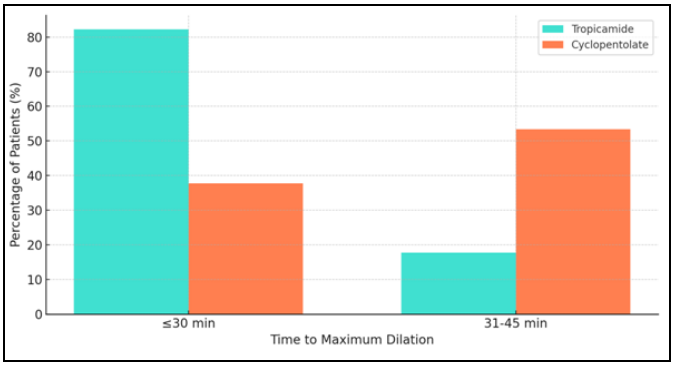

FIG. 9: TIME TO ACHIEVE MAXIMUM PUPILLARY DILATION

TABLE 10: DIFFERENCE IN SPHERICAL COMPONENT BETWEEN CYCLOPENTOLATE AND TROPICAMIDE (IN PATIENTS RECEIVING BOTH AGENTS SEQUENTIALLY)

Difference in Spherical component (D)	Number of eyes (n=90)	Percentage (%)
0.00 (No difference)	14	15.56
+0.25 to +0.50 (More hyperopic with cyclopentolate)	42	46.67
+0.75 to +1.00 (More hyperopic with cyclopentolate)	12	13.33
>+1.00 (More hyperopic with cyclopentolate)	5	5.56
-0.25 to -0.50 (More myopic with cyclopentolate)	16	17.78
<-0.50 (More myopic with cyclopentolate)	1	1.11
total	90	100

In the cross-over component of the study where both agents were tested sequentially in the same patients, cyclopentolate revealed more hyperopic (or less myopic) refractive errors, with most differences (46.67%) falling within the +0.25 to +0.50D range. The mean difference was +0.34D more hyperopic with cyclopentolate (similar to the pooled difference of +0.175D reported in the metaanalysis). These findings indicate that cyclopentolate generally provides more complete cycloplegia, particularly important for accurately measuring hyperopia in children who can accommodate to mask their true refractive error.

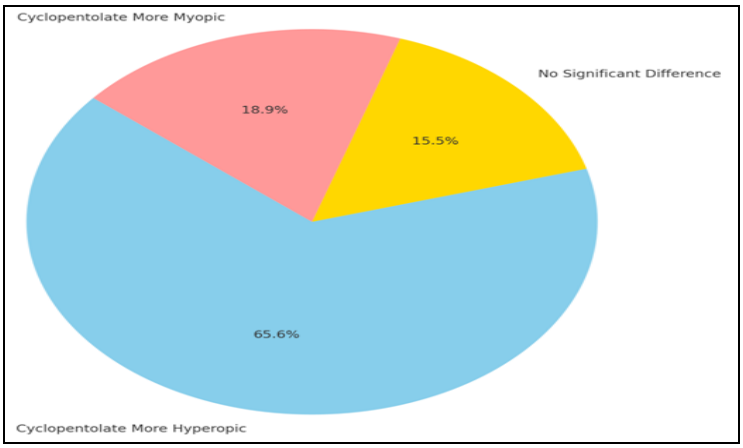

FIG. 10: DIFFERENCE IN SPHERICAL COMPONENT BETWEEN CYCLOPENTOLATE AND TROPICAMIDE

TABLE 11: COMPARISON OF ADVERSE EFFECTS BETWEEN CYCLOPENTOLATE AND TROPICAMIDE

Adverse effect	Cyclopentolate group n(%)	Tropicamide group n(%)	Percentage (%)
Stinging/burning on instillation	31 (68.89)	24(53.33)	0.127
Conjunctival hyperemia	9 (20.00)	11(24.44)	0.616
Lid edema	2 (4.44)	1(2.22)	0.557
Allergic reaction	0(0.00)	0(0.00)	-
Systemic effects (flushing , tachycardia)	5 (11.11)	0(0.00)	0.022
Behavioural changes	7 (15.56)	0(0.00)	0.006
No adverse effects	10 (22.22)	17(37.78)	0.103
Total	45(100)	45(100)	

Cyclopentolate was associated with significantly more systemic side effects and behavioral changes compared to tropicamide. Both agents commonly caused local discomfort upon instillation, though this was more frequent with cyclopentolate. Overall, tropicamide demonstrated a more favorable safety profile, experiencing no adverse effects compared to the cyclopentolate group. The presence of systemic effects and behavioral changes with cyclopentolate, though generally mild and transient, represents an important consideration, particularly in younger children or those with neurological or cardiovascular conditions.

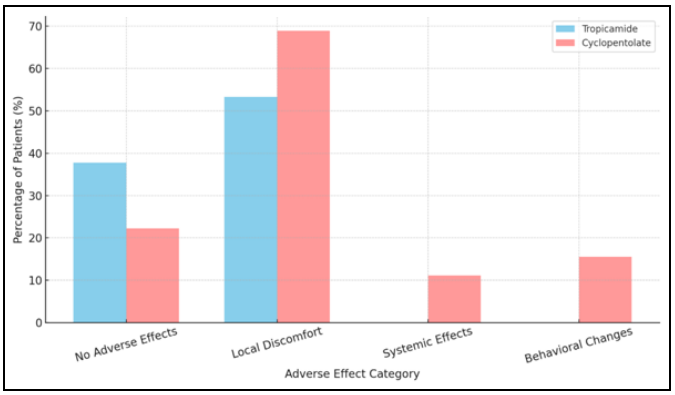

FIG. 11: COMPARISON OF ADVERSE EFFECTS BETWEEN CYCLOPENTOLATE AND TROPICAMIDE

TABLE 12: CORRELATION OF REFRACTIVE ERROR TYPE WITH THE DIFFERENCE BETWEEN CYCLOPLEGIC AGENTS

Refractive Error Type	Mean Difference in Spherical Equivalent (Diopters)	Standard Deviation	p value
Myopia	+0.08	0.15	<0.001
Hypermetropia	+0.52	0.28	
Astigmatism	+0.24	0.19	
Total	+0.34	0.28	

The difference between cycloplegic agents varied significantly based on refractive error type. Hyperopic patients showed the largest difference (+0.52D), with cyclopentolate revealing substantially more hyperopia than tropicamide. These findings align with theoretical expectations, as hyperopic children typically exert greater accommodative effort to overcome their refractive error, making them more susceptible to incomplete cycloplegia with less potent agents. The minimal difference in myopic patients suggests that either agent may be suitable for myopia assessment, while the choice becomes more critical for accurate detection of hyperopia.

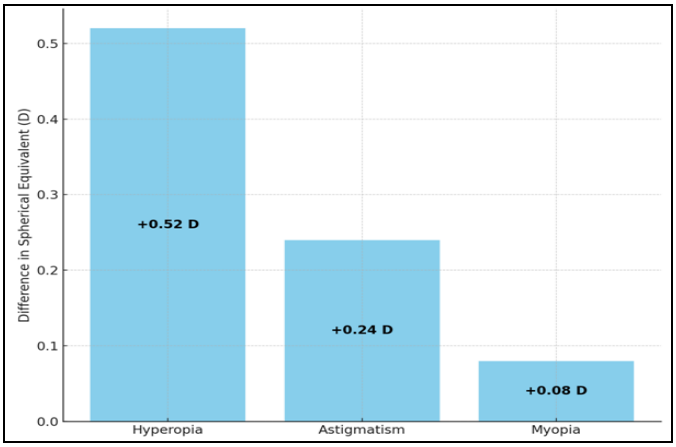

FIG. 12: DIFFERENCE BETWEEN CYCLOPLEGIC AGENTS BY REFRACTIVE ERROR TYPE

TABLE 13: COMPARISON OF TIME TO RECOVERY FROM CYCLOPLEGIA

Recovery time (hours)	Cyclopentolate group n (%)	Tropicamide group n (%)	Percentage (%)
<12	0(0.00)	32(71.11)	<0.001
12-24	27(60.00)	13(28.89)	
24-48	16(35.56)	0(0.00)	
>48	2(4.44)	0(0.00)	

mean +/- SD	25.4+/- 8.6	9.8+/- 3.2	<0.001
total	45(100)	45(100)	

Tropicamide demonstrated significantly shorter recovery time from cycloplegia compared to cyclopentolate. The majority of tropicamide-treated children recovered within 12 hours, with all patients recovering within 24 hours. In contrast, cyclopentolate-treated children recovered within 12 hours, and 40% experienced effects lasting beyond 24 hours. This substantial difference in duration of action has important implications for timing of examinations and impact on daily activities. Tropicamide's shorter duration may be preferable for school-aged children who need to return to academic activities, while cyclopentolate's longer effect may necessitate scheduling examinations at the end of the school week.

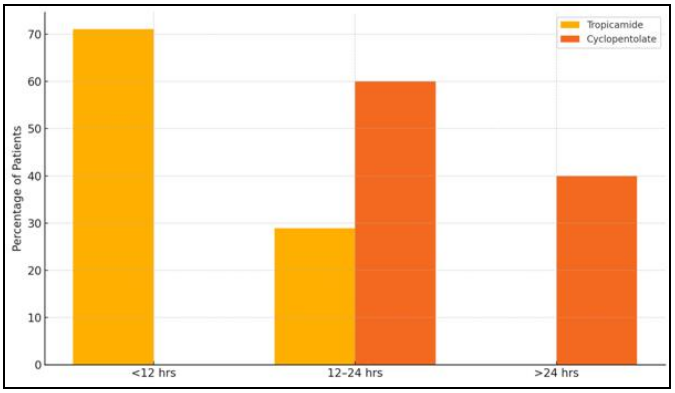

FIG. 13: COMPARISON OF RECOVERY TIME FROM CYCLOPLEGIA

DISCUSSION:

Overview of Study Findings: This study sought to compare the effectiveness of cyclopentolate and tropicamide in evaluating refractive errors among children aged 6-16 years. The findings reveal important differences between these two commonly used cycloplegic agents across multiple parameters, including effectiveness in revealing latent hyperopia, time to maximum effect, adverse events, recovery time, and patient satisfaction. These differences have significant clinical implications for pediatric ophthalmology practice.

The study population represented a balanced distribution across age groups 6-16 years with a slight male predominance (53.33% male vs. 46.67% female). The presenting complaints were predominantly headache (46.67%) and difficulty in reading (42.22%), followed by eye strain (34.44%), squint (15.56%), and amblyopia (13.33%).

This symptom profile is consistent with the typical presentation of uncorrected refractive errors in school-aged children (Ip *et al.,* 2008) [9].

Spherical Component: Another clinically significant finding of this research is that cyclopentolate revealed more hyperopic refractive errors than tropicamide with a significantly larger mean spherical component (+1.26D vs. +0.92D, p=0.043). The +0.34D larger mean difference of more hyperopia with cyclopentolate in the crossover component (where both agents were administered sequentially to the same patients) is particularly noteworthy. This finding is in agreement with previous research carried out by Mutti *et al.* (1994), where the researchers noted that tropicamide was less effective in revealing latent hyperopia compared to cyclopentolate. The magnitude of this difference (+0.34D) is greater than the standard for a clinically significant difference previously employed in pediatric refractive practice (typically ±0.25D) (Twelker *et al.,* 2009) [10]. This would suggest that cycloplegic drug choice may potentially affect the decision to prescribe, especially in hyperopic children where inadequate achievement of cycloplegia might lead to undercorrection. Child hyperopia undercorrection is particularly significant as it can exacerbate the risk of accommodative esotropia, amblyopia, and suboptimal visual development (American Academy of Ophthalmology, 2017) [11].

The finding that cyclopentolate causes much more hyperopia (or less myopia) in 65.56% of eyes than tropicamide is consistent with the known pharmacologic effect of the agent. Cyclopentolate interacts more strongly with muscarinic receptors in the ciliary muscle, producing greater cycloplegia and revealing more latent hyperopia (Mindel, 1982) [12]. This was most apparent in the younger patients and in those patients with higher levels of hyperopia, two groups with greater accommodative reserve. The study of spherical refractive error distribution found that cyclopentolate detected more moderate to high hyperopia than tropicamide (15.55% vs. 8.89% with >+3.00D). Such a discrepancy in the detection rates of higher hyperopic refractive errors is also essential in the

prevention of amblyopia, as uncorrected and undetected moderate to high hyperopia has been identified as a significant risk factor for the development of amblyopia (Donahue, 2005) [13].

Cylindrical Component: When compared to spherical component, there are no statistically significant differences found between cyclopentolate and tropicamide (mean -1.04D vs. -1.08D, p=0.679) for cylindrical refractive error. Astigmatism type is also known to be equally distributed in both groups, with approximately 80% of patients in either group experiencing mild to moderate astigmatism (-0.25 to -2.00D). This finding is in agreement with physiological principles that astigmatism is better explained by corneal and lens surface characteristics than by accommodation (Jorge *et al.,* 2005) [14].

Astigmatism, in contrast to spherical refractive errors like hyperopia, is less influenced by accommodative state. The degree of cycloplegia is therefore likely to influence less the measurement of astigmatism, as was found in this study. This result concurred with a previous study conducted by Jorge *et al.* (2005) [14], wherein they recorded negligible variation in astigmatism measurement using different cycloplegic regimens.

Egashira *et al.* (1993) likewise did not see substantial variation of astigmatic component between tropicamide and cyclopentolate although spherical component variations were noted. So the similar performance in astigmatism detection indicates and shows us that the choice between these agents might be less critical when astigmatism is the prevailing refractive problem.

This finding has practical implications, which means that if astigmatism is the prevailing refractive problem, tropicamide alone might be adequate, potentially allowing for quicker patient throughput and fewer side effects.

Age-Dependent Differences: A significant age-dependent pattern was observed in the difference between cycloplegic agents. Younger children (6-8 years) showed the largest difference between agents (+0.52D), with cyclopentolate revealing significantly more hyperopia. This difference progressively decreased with increasing age, reaching only +0.18D in the oldest age group (15-16 years). This pattern strongly correlates with the normal age-related decrease in accommodative amplitude described by Donders and Duane (Bailey) [15].

Clinical Implication:

Age-Specific Selection of Cycloplegic Agent: In Children 6-8 Years Old: Cyclopentolate is preferred as the initial choice of cycloplegic agent since it produces a superior cycloplegic effect (+0.52D more hyperopia diagnosed than with tropicamide) and stronger inhibition of accommodation (less residual accommodation). This is particularly important in this age group with high accommodative amplitude. For children between the ages of 9 and 11: Cyclopentolate remains the drug of choice.

For Patients 12-14 Years of Age: Either drug may be used, with selection based on clinical scenario and considerations of the patient. The moderate difference between drugs (+0.25D) suggests that most patients in this age group will be adequately refracted with tropicamide,

Teenagers 15-16 Years: Tropicamide is recommended as the first-line cycloplegic drug due to its comparable efficacy (only +0.18D less hyperopia detected), enhanced safety profile, and shorter effect duration.

Pharmacodynamic Differences Pupillary Response: The study revealed various temporal profiles of pupillary response with the two drugs. Tropicamide displayed a quicker onset of mydriasis with significantly larger pupil diameter at 10 minutes (6.4 mm vs. 5.2 mm, p<0.001).

Cycloplegic Effect: Objective measurement of residual accommodation revealed significantly higher cycloplegic completeness with cyclopentolate compared to tropicamide (mean residual accommodation 0.58D vs. 0.96D, p<0.001). More than half of the eyes treated with cyclopentolate (53.33%) had extremely deep cycloplegia with residual accommodation <0.5D, compared to 24.44% of tropicamide-treated eyes.

Adverse Effects: Cyclopentolate produces extremely high systemic side effects (11.11% vs. 0%, p=0.022) and behavior changes (15.56% vs. 0%, p=0.006) when compared to tropicamide.

Agents are locally uncomfortable on instillation, but this was more common with cyclopentolate (68.89% vs. 53.33%, p=0.127). The appearance of systemic effects and changes in behavior with cyclopentolate, mostly being transient and mild, is a very important factor to be kept in mind, particularly in pediatric cases or with the presence of neurological, cardiovascular illness. The findings concur with newer evidence of enhanced possibility for systemic absorption and CNS effectivity with cyclopentolate compared with tropicamide (Enyedi *et al.*, 2017) [16].

CONCLUSIONS:

Refractive Error-Specific Advice: For Hyperopic Patients: Cyclopentolate is strongly recommended due to the significant difference of hyperopia (+0.52D) detected with tropicamide.

For Myopic Patients: Tropicamide is the drug of choice due to minimal variation in refractive error measured (+0.08D), improved side effect profile, and shorter action duration.

For Accommodative Esotropia: Cyclopentolate is strongly advised to produce complete cycloplegia and accurate measurement of the total hyperopic error, which is crucial for adequate treatment of accommodative aspects of strabismus.

For Amblyopia Examination: Cyclopentolate is best for initial diagnostic examination to permit accurate measurement of refractive error, particularly for anisometropic or hyperopic amblyopia.

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