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Original Article

Ophthalmology Section

A Cross-sectional Observational Study to Assess the Influence of 1% Cyclopentolate and 1% Tropicamide on Intraocular Pressure in Children Undergoing Cycloplegic Refraction at a Tertiary Care Hospital in Southern India

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ABSTRACT

Introduction: Cycloplegic refraction is necessary in children due to their high amplitude of accommodation. A combination of Tropicamide and Cyclopentolate is commonly used as cycloplegics in children. These medications can cause a substantial elevation in Intraocular Pressure (IOP) in a few susceptible children. Therefore, the present study was conducted to investigate the changes in IOP when 1% Cyclopentolate and 1% Tropicamide were used for cycloplegic refraction in children.

Aim: To assess the influence of 1% Cyclopentolate eyedrops and 1% Tropicamide eyedrops on IOP in children undergoing cycloplegic refraction and to compare the changes in IOP between the hypermetropic and myopic groups before and after cycloplegia.

Materials and Methods: This cross-sectional hospital-based study was conducted in the Outpatient Department (OPD) of Ophthalmology at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, in Northern Karnataka, India over a duration of six months. The study included 55 children in the age group of 5-15 years who met the inclusion criteria. All children underwent visual acuity assessment and a detailed examination of the anterior and posterior segments of the eye. Refraction was expressed in terms of Spherical Equivalence (SE), calculated as sphere plus half of the cylinder. Based on the SE calculated after refraction, children were diagnosed as having either myopia or hypermetropia as types of refractive error. Data were analysed using International Business Machines (IBM) Statistical Package for Social Sciences (SPSS) Statistics (Version 25.0, Chicago, IL, USA). Categorical variables were represented as frequency and percentages, while continuous variables were represented as Mean±Standard Deviation (SD). A p-value ≤0.05 was considered statistically significant.

Results: Out of the 55 children included in the study, 25 children were hypermetropic, and 30 children were myopic based on the calculated SE. Among the total of 55 children, 34 were girls, and 21 were boys. The mean age of the 55 children was 10.98±2.4 years. The mean age of the myopic group was 11.97±2.21 years, while the hypermetropic group had a mean age of 9.74±3.29 years. The mean precycloplegic IOP was 14.21±2.76 mmHg, and the mean postcycloplegic IOP was 15.19±3.25 mmHg. The change in IOP was statistically significant (p≤0.0001). In the hypermetropic group of 25 children, the mean precycloplegic IOP was 13.74±2.55 mmHg, while the mean postcycloplegic IOP was 15.10±3.65 mmHg. There was a significant difference in IOP (p=0.0242). In the myopic group of 30, the mean precycloplegic IOP was 14.47±2.86 mmHg, while the postcycloplegic IOP was 15.08±2.86 mmHg. There was no statistically significant change in IOP in the myopic group (p=0.0669). After cycloplegic mydriasis, 2 eyes (3.7%) experienced an increase in IOP greater than 7 mmHg.

Conclusion: Cycloplegic mydriasis using 1% Cyclopentolate and 0.8% Tropicamide caused a significant increase in IOP in a few children, with a higher increase observed in hypermetropic children compared to myopic children. Therefore, ophthalmologists should exercise caution and monitor IOP changes in children undergoing cycloplegic refraction to manage any transient rise in IOP and prevent damage to the optic nerve.

Keywords: Autorefractometer, Cycloplegia, Hypermetropia, Myopia, Non contact tonometer, Spherical equivalence

INTRODUCTION

The IOP is the pressure within the eye, which is governed by the balance between aqueous humour production and outflow, which is practically identical. The normal distribution of IOP within the general population is 11-21 mmHg [1]. IOP is affected by a myriad of factors such as the time of day, heart rate, respiratory rate, exercise, fluid intake, posture, blinking, eye movements, Valsalva manoeuvers, and medications, including cycloplegics used for wet retinoscopy in children [1].

Cycloplegia is the paralysis of the ciliary muscles of the eye, resulting in the dilation of the pupil and paralysis of accommodation. Cycloplegic refraction is necessary in children because of their high amplitude of accommodation and inability to give reliable subjective responses. This can be achieved with the use of different cycloplegic drugs like atropine, homatropine, cyclopentolate, and tropicamide by instilling them into the conjunctival sac. Cyclopentolate is a synthetic antimuscarinic cycloplegic agent with an onset of action of 30-45 minutes and a duration of action of 24 hours. It is available in concentrations of 0.5% and 1% solutions. Tropicamide is a synthetic analog of tropic acid with an onset of action of 15-30 minutes and a duration of action of 4-6 hours. It is available in 0.5% and 1% solutions [2]. A combination of Tropicamide and Cyclopentolate is commonly used as a cycloplegic in children. The combination drops of 0.5% Cyclopentolate hydrochloride and 0.5% Tropicamide have exhibited safe and satisfactory mydriasis

and cycloplegia in 20 minutes for rapid and accurate examination of children, as reported by Nishizawa AR et al., [3]. Cyclopentolate and Tropicamide are effective cycloplegic agents for myopic as well as hypermetropic children for the accurate assessment of refractive status.

The ocular side-effect of cycloplegics, such as cyclopentolate and tropicamide, is a significant IOP elevation in susceptible individuals, with or without narrow angles. Commonly, cycloplegic agents can lead to a notable increase in IOP in approximately 2% of individuals within the general population. However, this percentage can rise significantly, affecting up to 23% of patients diagnosed with primary open-angle glaucoma [4,5]. The peak elevation in IOP was observed approximately 45 minutes after the administration of 1% cyclopentolate and 0.5% tropicamide eye drops [4,5]. The effect on IOP in normal eyes and in those with untreated open-angle glaucoma was slight with tropicamide when compared with cyclopentolate.

The possible mechanisms for the rise in IOP after instilling cycloplegics have been attributed to a decrease in aqueous outflow caused by decreased traction on the trabecular meshwork, which itself is a result of ciliary muscle paralysis [6,7]. Another possible mechanism is the release of iris pigments into the anterior chamber, leading to the obstruction of the trabecular meshwork [8].

Numerous studies have reported that cycloplegics cause an elevation in IOP in adults. In a study conducted by Adediji AK et al., on adult patients requiring diagnostic mydriasis, it was noted that the mean postdilation IOP was significantly higher in the dilated eye than in the undilated eye [1]. In another study by Kim JM et al., on normal subjects before cataract surgery, the mean postdilation IOP was significantly higher than the mean pre-dilation IOP [9]. In a study by Bouaziz T et al., it was found that 1% Cyclopentolate, widely used in children, does not seem to increase IOP [10]. However, there are very few studies showing the change in IOP after cycloplegic use in children. Therefore, the aim of this study was to assess the influence of 1% Cyclopentolate and 1% Tropicamide on IOP in children undergoing cycloplegic refraction and to compare the changes in IOP between the hypermetropic and myopic groups before and after cycloplegia.

MATERIALS AND METHODS

This cross-sectional hospital-based study was conducted at the Department of Ophthalmology, KLE's Dr. Prabhakar Kore Hospital and MRC in Belagavi, Northern Karnataka, India. The study period lasted for six months, from February 2022 to July 2022. The sampling method used was convenient sampling. The present study adhered to the tenets of the Declaration of Helsinki and was approved by the Institutional Ethical Committee (IEC) with reference number (MDC/DOME/453). Informed written consent was obtained from all the patients.

Inclusion criteria: The study included all children in the age group of 5-15 years visiting the Department of Ophthalmology, of the study institute, who required cycloplegic refraction. A total of 55 children who met the inclusion criteria and gave consent to participate were included.

Exclusion criteria: The study excluded children with a medical history of cardiovascular disease, asthma, prior ocular surgery, or other ocular conditions such as congenital cataract, glaucoma, corneal scar, and optic neuropathy. Out of total 95 children, 40 children who had certain exclusion criteria were excluded from the study.

Sample size calculation: The formula used for sample size calculation was as follows:

$$n=\frac{(Z\alpha_{/2}+Z_{\beta})^2}{d^2}$$

$$d=\frac{|\mu_1-\mu_2|}{\sigma_d}$$

$$\sigma_d^2=2\times(1-\rho)\sigma^2$$

Where μ_1 represented the mean of the pretest, μ_2 represented the mean of the post-test. For a 95% confidence level, $Z\alpha_{/2}$ the value was 1.96, and for 85% power Z_{β} the value was 1.036. Considering the between timepoint effect size to be 0.45, at a 5% level of significance and 85% power, the minimum sample size required was 44 subjects. As the sample size increases, the accuracy of the results also increases. Therefore, 55 subjects were considered in the study.

Study Procedure

All children first underwent visual acuity assessment using Snellen's distant visual acuity chart. The slit lamp examination was performed to assess the detailed anterior segment of the eye. Fundus examination was conducted with indirect ophthalmoscopy to evaluate the optic disc and macula. IOP was measured using a Non Contact Tonometer (Canon TX-20P NCT). Three readings of IOP were taken, and the mean IOP was automatically calculated by the machine. Autorefractometer readings were obtained using the Topcon Shin-nippon Accuref K900 refractometer before cycloplegic administration. One drop of 1% Cyclopentolate followed by two drops of 1% Tropicamide were administered three times at an interval of 10 minutes over a period of 30 minutes. Autorefractometer readings and IOP were measured again after 30 minutes. Postcycloplegic refraction was performed to assess the refractive status of the children. Both precycloplegic and postcycloplegic autorefractometer readings were expressed in terms of SE, which was calculated as the sphere plus half of the cylinder. The children were further divided into myopic and hypermetropic groups based on the SE calculated both precycloplegic and postcycloplegic. Although IOP and refractive status of both eyes were assessed in the children, only the left eye data of the 55 children were included for evaluation, as per convenience.

STATISTICAL ANALYSIS

The data was analysed using IBM SPSS Statistics (Version 25.0, Chicago, IL, USA). Categorical variables were represented as frequencies and percentages. Continuous variables were expressed as Mean±SD. To compare the hyperopic and myopic groups, independent sample t-tests were employed to analyse differences in age, precycloplegic SE, and postcycloplegic SE. Additionally, paired sample t-tests were utilised to compare the precycloplegic and postcycloplegic mean values of IOP and refractive measurements, specifically in terms of SE, across all eyes, hyperopic eyes, and myopic eyes. Statistical significance was determined by a p-value of 0.05 or less.

RESULTS

Out of the 55 children included in the study, 25 children were hypermetropic, and 30 children were myopic based on the SE calculated. In total 55 children, 34 were girls and 21 were boys with slight girl preponderance noted in the present study. The mean age of the 55 children was 10.98±2.4 years. The mean age in the hypermetropic group was 9.74±3.29 years, and in the myopic group, it was 11.97±2.21 years. There was a significant difference in age between the hypermetropic and myopic groups (p=0.0054).

The precycloplegic SE was 1.02±2.83 D, and the postcycloplegic SE was 0.04±3.05 D in the 55 children. There was a significant difference between precycloplegic and postcycloplegic refraction (p<0.0001). In the hypermetropic group of 25 children, the precycloplegic SE was 0.73±2.34 D, and the postcycloplegic SE

was 1.95±2.12 D (p<0.0001). In the myopic group of 30 children, the precycloplegic SE was -2.47±2.35 D, and the postcycloplegic SE was -1.70±2.72 D (p<0.0001). There were significant differences between precycloplegic SE and postcycloplegic SE in both the hypermetropic and myopic groups [Table/Fig-1].

Variables	Hypermetropia (mean±SD)	Myopia (mean±SD)	p-value
No. of eyes	25	30	
Gender			
Female eyes	9	25	
Male eyes	16	5	
Age (years)	9.74±3.29	11.97±2.21	0.0054*
Refraction (SE)			
Precycloplegia	0.73±2.34	-2.47±2.35	0.00008
Postcycloplegia	1.95±2.12	-2.70±2.72	0.00008

[Table/Fig-1]: Demographic data showing age, sex, and refraction {spherical equivalence (SE)} between hypermetropic and myopic eyes.
*Statistically significant (p<0.05). By independent sample t-test
SE: Spherical equivalence; SD: Standard deviation

The mean precycloplegic IOP was 14.21±2.76 mmHg, and the postcycloplegic IOP was 15.19±3.25 mmHg in all 55 children. The change in postcycloplegic IOP compared to precycloplegic IOP was statistically significant (p=0.0037). In the 25 hypermetropic eyes, the mean precycloplegic IOP was 13.74±2.55 mmHg, while the postcycloplegic IOP was 15.10±3.65 mmHg. There was a statistically significant change in IOP after cycloplegic mydriasis (p=0.0242). In the 30 myopic eyes, the mean precycloplegic IOP and postcycloplegic IOP were 14.47±2.86 and 15.08±2.86 mmHg, respectively. There was no significant change in IOP after cycloplegic mydriasis in the myopic group (p=0.0669) [Table/Fig-2].

	Precycloplegia (mean±SD)	Postcycloplegia (mean±SD)	p-value
All children (55) IOP (mmHg)	14.21±2.76	15.19±3.25	0.0037*
Hypermetropic (25) children IOP (mmHg)	13.74±2.55	15.10±3.65	0.0242*
Myopic children IOP (mmHg)	14.47±2.86	15.08±2.86	0.0669

[Table/Fig-2]: Precycloplegic and postcycloplegic change in Intraocular Pressure (IOP) in all children (n=55), hypermetropic children (n=25) and myopic children (n=30).
*Statistically significant (p<0.05). By sample paired t-test
IOP: Intraocular pressure; SD: Standard deviation

The mean difference in IOP in all children was 1.10±2.80 mmHg. Out of the 55 eyes, two eyes (3.7%) had an IOP elevation greater than 7 mmHg, but the IOP reduced (<21 mmHg) after one hour without any medical intervention [Table/Fig-3].

Patient no.	SE (D)	Precycloplegia IOP (mmHg)	Postcycloplegia IOP (mmHg)	IOP elevation (mmHg)
1	-2.75	17.9	25.7	7.8
2	0.75	18.2	26.10	7.9

[Table/Fig-3]: Data of two patients with intraocular pressure elevation greater than 7 mmHg after cycloplegic mydriasis.
D: Diopters; IOP: Intraocular pressure; SE: Spherical equivalence

DISCUSSION

In the present study, it was noted that the mean age of the 55 children was 10.98±2.4 years. The mean age of the children in the myopic group was 11.97±2.21 years, and in the hypermetropic group, it was 9.74±3.29 years. This mean age is similar to the study done by Hung KC et al., where the mean age of the children was 7.3±2.4 years [11].

The mean precycloplegic IOP was 14.21±2.76 mmHg, and the mean postcycloplegic IOP was 15.19±3.25 mmHg in the 55 children. The change in IOP was statistically significant (p<0.0001). These findings are similar to the study done by Hung KC et al., where the mean precycloplegic IOP was 14.45±2.47 mmHg, and the mean postcycloplegic IOP was 15.06±3.08 mmHg [11]. In contrast to the present research, a study conducted by Tsai IL et al., demonstrated that there was no notable alteration in IOP after the administration of 1% Tropicamide for pupillary dilation in children [12]. In a separate investigation carried out by Kim JM et al., involving 32 healthy adult participants, it was noted that there was a substantial rise in IOP by approximately 1.85±2.01 mmHg (p=0.002) subsequent to pupil dilation through the use of 2.5% phenylephrine and 1% tropicamide. This increase was statistically significant [9].

In the hypermetropic group of 25, the mean precycloplegic IOP was 13.74±2.55 mmHg, while the mean postcycloplegic IOP was 15.10±3.65 mmHg. There was a significant difference in IOP (p=0.0242). In the myopic group of 30, the mean precycloplegic IOP was 14.47±2.86 mmHg, while the postcycloplegic IOP was 15.08±2.86 mmHg. There was no statistically significant change in IOP in the myopic group (p=0.0669). Similar results were found in the study done by Hung KC et al., where in 39 hypermetropic eyes, the mean precycloplegic IOP and postcycloplegic IOP were 14.54±2.53 mmHg and 15.69±3.35 mmHg, respectively, which was statistically significant. Additionally, in the 52 myopic eyes, the mean precycloplegic IOP and postcycloplegic IOP were 14.38±2.44 mmHg and 14.61±2.80 mmHg, respectively, which was not statistically significant [12].

After cycloplegic mydriasis, two eyes (3.7%) had an IOP elevation of more than 7 mmHg. This finding correlated with the study done by Hung KC et al., where three eyes (3.3%) had an IOP elevation of more than 5 mmHg after cycloplegic mydriasis [12]. Kim JM et al., showed a significant rise in IOP 4-6 hours after cycloplegia with 2.5% Phenylephrine and 1% Tropicamide [9]. Therefore, in the present study, it was found that the change in postcycloplegic IOP was statistically significant in the total number of children as well as in the hypermetropic group when compared to the myopic group.

A potential explanation for the elevation of IOP subsequent to cycloplegic mydriasis could be associated with the paralysis of the ciliary muscle. This paralysis might result in diminished aqueous outflow due to decreased traction exerted on the trabecular meshwork [6,7]. Another potential mechanism behind the increase in IOP following cycloplegic mydriasis involves the obstruction of the trabecular meshwork. This obstruction could occur due to the release of iris pigment into the anterior chamber. Notably, a study conducted by Kristensen P demonstrated that 48% of eyes afflicted with open-angle glaucoma experienced an IOP elevation of 8 mmHg or greater following pupil dilation, attributed to the release of pigment [8]. The same mechanism showed an IOP elevation of up to 20 mmHg after pupil dilation with 1% cyclopentolate in the study done by Valle O [13]. A third mechanism for IOP elevation is pupillary block. Harris LS et al., noted that a predisposing factor causing acute IOP elevation was a narrow angle [4]. In another study done on adult eyes, it was shown that pupillary block can occur, especially in the mid-dilated position, due to maximum resistance to aqueous flow between the iris and lens in this position [14]. As noted by Hung KC et al., in infants and young individuals with significant hypermetropia, the strong and persistent tonic spasm of accommodation persists. This spasm keeps the pupil size in a nearly mid-dilated state. This, combined with a relatively shorter axial length of the eyeball, could contribute to an elevation in IOP subsequent to the administration of cycloplegic mydriasis [11].

Further studies with a large sample size can be conducted to explore the relationship between refraction and changes in IOP after cycloplegic mydriasis in children. In the present research, IOP was assessed using a Non Contact Tonometer. This device measures IOP by gauging the time required for a specific force of air to flatten a particular area of the cornea without making physical contact. However, the Goldmann applanation tonometer is widely regarded as the benchmark for IOP measurement. It is worth noting

that contemporary Non Contact Tonometer have demonstrated a strong correlation with measurements obtained through Goldmann tonometry, indicating their reliability and accuracy [15,16]. Moreover, Non Contact Tonometer are considered valuable for assessing IOP in paediatric patients due to their ease of use and efficiency.

Both Goldmann applanation tonometry and Non Contact Tonometer can be influenced by Central Corneal Thickness (CCT). Previous studies have indicated positive associations between these tonometry methods and CCT [16,17]. CCT can be a confounding factor for IOP measurement in adults, but its role in IOP measurement in children is not clear. Therefore, further studies can be conducted to investigate the relationship between CCT and changes in IOP with cycloplegic agents in children.

Limitation(s)

There were a few limitations observed in the present study that can provide guidance for future investigators. Firstly, the sample size was relatively small, and there was no control group for comparison. Additionally, the present study did not measure CCT, which is known to have an impact on IOP. In the present study, a non contact tonometer was used to measure IOP due to its ease and speed, but Goldmann Applanation tonometry is considered the gold standard for IOP measurement. Further studies can be conducted to address the limitations identified in the present study.

CONCLUSION(S)

In the present study, it was found that cycloplegic mydriasis with 1% Cyclopentolate and 1% Tropicamide caused statistically significant changes in IOP in some children. The significant change in IOP after the use of cycloplegics was observed in hypermetropic children, while the change was not significant in myopic children. Since cycloplegics are routinely used for cycloplegic refraction in children, ophthalmologists should exercise caution and closely monitor IOP changes, as elevated IOP levels can potentially damage the optic nerve and lead to irreversible visual loss.

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