

**DETERMINING THE TIME REQUIRED TO ACHIEVE PEAK CYCLOPLEGIC EFFECT
OF CYCLOPENTOLATE 1% IN CHILDREN**¹*Maiss George Rajjough, MD, ²Yusuf Suleiman and ³Mahmoud Rajab¹Department of Ophthalmology, Tishreen University Hospital, Lattakia, Syria.^{2,3}Prof, Department of Ophthalmology, Tishreen University Hospital, Lattakia, Syria.

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Article Received on 22/06/2024

Article Revised on 12/07/2024

Article Accepted on 02/08/2024

ABSTRACT

The aim of the study: To determine the time required to achieve peak cycloplegic effect of cyclopentolate 1% with the application of local anesthetic drops in children, and evaluate the correlation between this time and each of pupillary reaction, pupillary diameter and refractive status of the patient, and to study the side effects of Cyclopentolate 1% eye drops. **Materials and Methods:** This was an analytical cross-sectional study involving children aged 4 to 14 years with dark irises who attended to ophthalmology clinic at Tishreen University Hospital in Lattakia. One drop of Benoxinate 0.4% (Oxybuprocaine) (trade name: medecain 0.4%) was instilled, then after 3 minutes Cyclopentolate 1% was instilled into both eyes three times at 5 minutes intervals. The spherical equivalent, pupillary reaction, and pupillary diameter were recorded before the first drop and 13 times after the last drop at 5-minute intervals. The time required to achieve peak cycloplegic effect was defined as the time point at which the spherical equivalent reached and remained within the equivalence limit (0.25 D) of the final value at 80 minutes. **Results:** 128 children (256 eyes) were enrolled in this study. Their mean age was 9.96 ± 2.5 years (range: 4-14 years). The time required to achieve peak cycloplegic effect was 30 minutes after the first drop of cyclopentolate. A poor correlation was observed between the time of peak cycloplegic effect and the pupillary reaction ($r=0.08$). And the peak cycloplegic effect was reached earlier than the maximum pupillary dilatation. **Conclusion:** In most children, the peak Cycloplegic effect of Cyclopentolate was 30 minutes after the first instillation of cyclopentolate. The absence of a pupillary reaction or the maximum pupillary dilatation should not be used as an indicator of maximum cycloplegia.

KEYWORDS: Cycloplegia, Refractive Errors, Medecain, Cyclopentolate, Dark Irises.**INTRODUCTION**

The refractive state of the eye is one of the basic optical characteristics in determining the visual ability that can be reached without correction, therefore it is an important indicator in refractive surgery, cataract surgery and in pediatric ophthalmology.^[1,2,3] Conformity is the ability of the eye to increase its refractive power when looking at nearby objects or as a self-correction of hyperopia, and as a result, refractive changes occur (latent hyperopia, false heartbreak), especially in children as they have a large matching amplitude.^[4] The assessment of the worst refraction after the match paralysis is the gold standard in children and adolescents and in epidemiological studies, as by inhibiting the act of matching we avoid an increase in the estimate of visual impairment or a decrease in the estimate of their hyperopia.^[5,6,7] Match immobilization is done using topical drops to temporarily immobilize the ciliary muscle, completely or partially. The most common of them are atropine, cyclopentolate and tropicamide. Compared to these drops, cyclopentolate 1% remains

preferred in children, due to its fewer systemic side effects compared to atropine, and the depth of its effect in match solution compared to tropicamide.^[8,9] There is a latency period between the application of cyclopentolate and reaching the peak of its effect, and this time is wide, according to previous studies (10-90) minutes, this difference may be due to several factors, including the concentration of cyclopentolate or its participation with other factors to paralyze conformity, refractive status, or iris color in patients.^[10,11,12,13]

OBJECTIVE

Determine the required time to reach the onset of peak effect of Cyclopentolate 1% with the application of a topical anesthetic drop in children, and evaluate the correlation between this time and each of pupillary reaction, pupillary diameter and status of the patients.

Inclusion Criteria: children between 4-14 year-old with a dark Iris.

Exclusion criteria

- Eye diseases that affect conformity (uveitis and congenital glaucoma).
- Systemic diseases affecting conformity (Diabetes Mellitus Type I / Neurological Diseases / Neuromuscular Diseases).
- Previous eye surgery.

MATERIALS AND METHODS**Examinations before Cycloplegia Refraction**

- ☒ A detailed information from the child's parents.
- ☒ Slit lamp examination.
- ☒ Measurement of refractive index and pupillary diameter.
- ☒ Assessment of pupillary reactivity.

Iris Color: the color of the iris has been classified into three grades:

- ✓ Light: blue-gray.
- ✓ Medium: green-hazel.
- ✓ Dark: brown-black.

Cycloplegia Refraction Protocol: One drop of Benoxinate 0.4% (Oxybuprocaine) is instilled then we begin to instill cyclopentolate 1% after 3 minutes in both eyes three times with 5-minute apart.

Study design: Cross-sectional study.

STATISTICAL ANALYSIS

- Graphs and tables were used to characterize descriptive data.
- Averages, standard deviations and measures of central tendency were used to characterize quantitative data.
- (Friedman) test to compare the average of several linked communities.
- ANOVA test to measure differences in treatment averages over multiple times.
- T- test (Independent T Student) to compare the average of two independent groups.
- (Chi-square) to study the relationships between qualitative variables.
- (Spearman correlation) to study the relationship between the time of absence of pupillary interaction and the time of occurrence of peak impact. Results were statistically significant with $p\text{-value} < 0.05$.
- IBM SPSS statistics program (Version20) was used to and analyze the results.

RESULTS**1. Distribution of the sample according to age and gender**

The study included 128 children (256 samples), including 60 males and 68 females who attended the ophthalmology clinic at Tishreen University Hospital, Lattakia, Syria, during the period from July 2020 to March 2021.

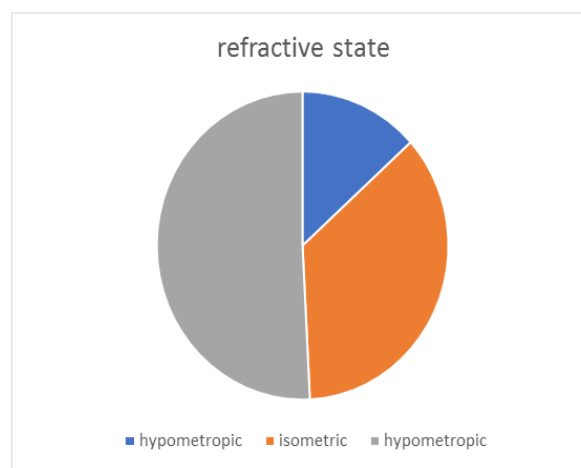
The age of the patients in study sample ranged from 4 to 14 years, their average age was 9.96 ± 2.5 years.

Table 1: Distribution of the study sample by gender.

Gender	Number	Percentage
Males	60	46.9%
Females	68	53.1%
Total	128	100%

2. Distribution of the study sample according to the refractive state before Cycloplegia Refraction**Table 2: distribution of the sample by refractive state before Cycloplegia Refraction.**

Refractive state	Number	Percentage
Hypermetropic	130	50.8%
Isometric	92	35.9%
Hypometropic	34	13.3%
Total	256	100%

**Figure 1: distribution of the sample by refractive state before Cycloplegia.****3. Distribution of the study sample according to the time required to reach the peak of the cyclopentolate effect**

The values of the spherical equivalent before Cycloplegia ranged from -4.25 to 7.00+ fractions, and the average was 0.72 ± 1.5 fractions.

Table 3: distribution of the sample by the time required to reach the peak of the cyclopentolate effect.

Time	Mean± sd	P-value
Before Cycloplegia	0.72±1.56	0.0001
20 minutes	1.84±1.56	
25 minutes	1.86±1.56	
30 minutes	2.08±1.59	
35 minutes	2.14±1.58	
40 minutes	2.16±1.58	
45 minutes	2.16±1.58	
50 minutes	2.16±1.58	
55 minutes	2.16±1.58	
60 minutes	2.16±1.58	
65 minutes	2.16±1.58	

70 minutes	2.16±1.58	
75 minutes	2.16±1.58	
80 minutes	2.16±1.58	

4. The peak of the cyclopentolate effect by time

The majority of children reached the peak effect of cyclopentolate at 30 minutes, and all the children of the sample reached the peak effect from 40 to 80 minutes.

Table 4: The peak of the cyclopentolate effect by time.

Time	Number	Percentage
20 minutes	182	71.1%
25 minutes	199	77.7%
30 minutes	245	95.7%
35 minutes	252	98.4%
40 minutes	256	100%

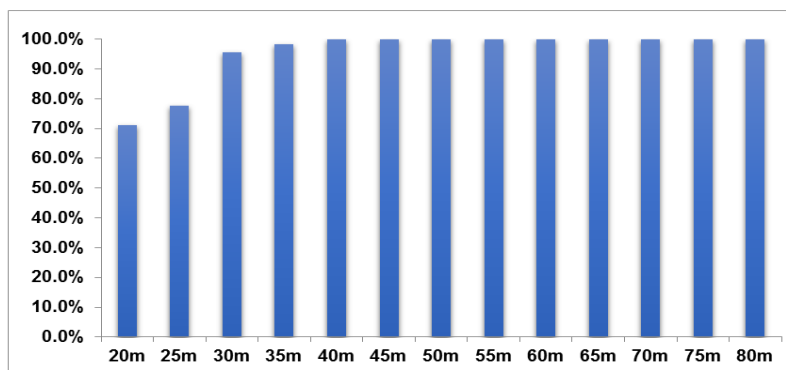


Figure 2: The peak of the cyclopentolate effect by time.

5. The coloration between Cyclopentolate and spherical equivalent

The time required to reach the peak of the Cyclopentolate effect in the Hypermetropic group was at the 30th minute, which is the point in time at which the

spherical equivalent reached and remained within the limits of 25.0 degrees. With constant values at the 40th minute and up to the 80th minute, which means a significant statistical difference ($p\text{-value} \leq 0.05$).

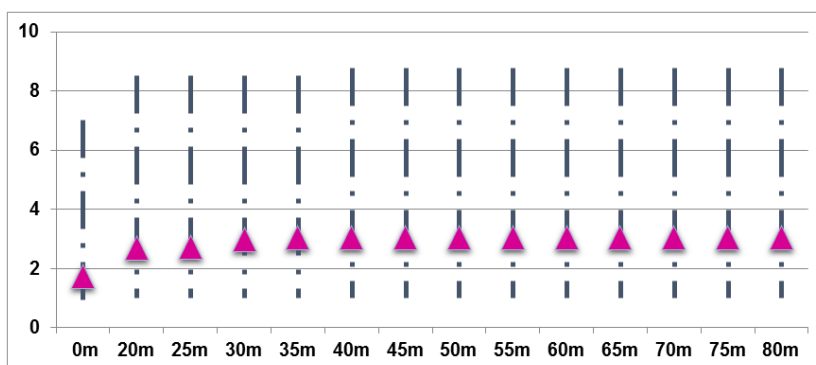


Figure 3: The coloration between Cyclopentolate and spherical equivalent in hypermetropic patients.

The time required to reach the peak of the Cyclopentolate effect in Isometric group was at the 30th minute with the observation of the constancy of the

values at the 40th minute and up to the 80th minute and with significant Statistical differences.

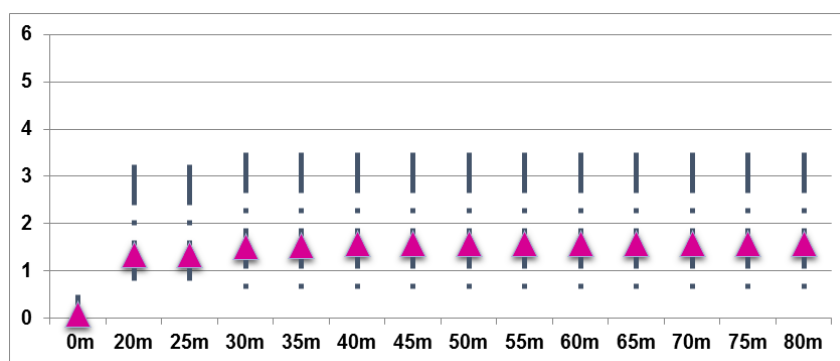


Figure 4: The coloration between Cyclopentolate and spherical equivalent in isometric patients.

The time required to reach the peak of the Cyclopentolate effect in the Hypometropic group was at the 30th minute with the observation of the constancy of

the values at the 40th minute and up to the 80th minute and with the presence of significant Statistical differences.

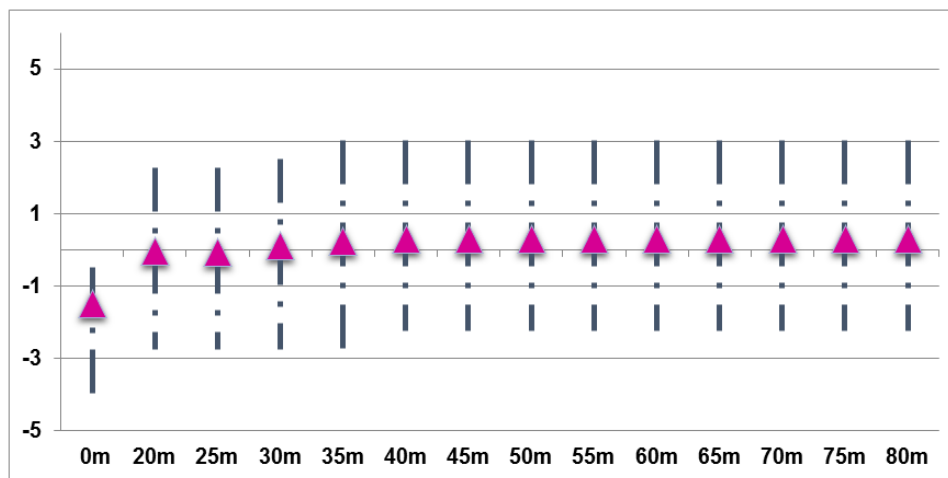


Figure 5: The coloration between Cyclopentolate and spherical equivalent in hypometropic patients.

CONCLUSION

It is enough to wait for 30 minutes after the first drop of Cyclopentolate as a latency period before measuring the condition. Therefore, a local anesthetic drop can be used before applying Cyclopentolate, in order to reduce the time required to reach the peak of Cyclopentolate effect and decrease the resulting side effects.

DISCUSSION

In our study, the majority of patients were between 4-14 year-old, with dark Iris. The time required to reach the peak of Cyclopentolate 1% was 30 minutes after the first drop. We didn't find any statistically significant difference in the time to reach the peak effect of Cyclopentolate peak according to gender, age and sight situation.

A study (yola et al., 2020)^[14] conducted at Tishreen University Hospital / Syria, on 58 patients, aged 6 to 15 years, with an average age of 9.8 ± 2.7 years, and with a dark Iris, it was found that the time required to reach the peak effect of cyclopentolate 1% was at the 40th minute after the first drop of it, while in our study it was at the 30th minute after the first drop, and this may be due to our use of a local anesthetic drop.

However, In a study of (Kyei et al., 2017)^[15] at the University of Cape Coast / Ghana, on 77 patients, aged 15 to 24 years. Which studied the temporal evolution of the matching shell after the application of cyclopentolate 1% and tropicamide 1% compared with cyclopentolate alone, they found that the peak effect of cyclopentolate was at 90 minutes after the application of cyclopentolate alone compared to 55 minutes after the application of the combination of Cyclopentolate with Tropicamide.

In comparison with the results of our study we found that Topical anesthesia reduces the time it takes to reach the

peak. This result is consistent with the results reached by (Andrew et Al, 1991), (Klinstein et al., 1991), (Sittikorn et al., 2016), (Bagheri et al., 2007) in their studies.^[16-19]

Ethical Approval

This research received approval from the scientific research ethics committee at Tishreen University and Tishreen University Hospital.

ACKNOWLEDGEMENT

The authors have no financial interests to disclose. This research didn't receive any specific grant from funding agencies in public, commercial or non-profit sectors.

We wish to thank all medical staff for their hard work even with great difficulties.

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