



## RESEARCH ARTICLE

**A RANDOMIZED COMPARATIVE STUDY OF PHARMACOLOGICAL EFFECTS OF 1 % TROPICAMIDE WITH 10% PHENYLEPHRINE ON HUMAN EYES**S. Manju Bhargavi<sup>1</sup>, B. Ramanath<sup>\*2</sup><sup>1</sup>Department of Pharmacology, M.V.J Medical College and Hospital, Hoskote, Karnataka, India.<sup>\*2</sup>Department of Pharmacology, Basaveshwara Medical College, Hospital and Research Center, Chitradurga, Karnataka, India.

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**ABSTRACT****Aim and objectives:** Comparison of the pharmacological effects like, pupillary diameter, intraocular tension, blood pressure, heart rate, of 1 % Tropicamide with 10 % Phenylephrine eye drops**Methods:** Present studies taken 60 individual patients, were divided into two groups: Group-1: 30 patients were in this group who received 1% Tropicamide eye drop, Group-2: 30 patients were in this group who received 10% Phenylephrine eye drop. After instillation of drugs on both eyes, pupillary diameter, intraocular tension, blood pressure and heart rate measured with using of various equipments and results were evaluated.**Results:** After 45 minutes 1% Tropicamide induced a marked mydriatic effect greater than that produced by 10% phenylephrine with no changes in refraction or visual acuity. IOT was significantly decreased only in normal patients after instillation of 1% tropicamide, whereas 10% phenylephrine shown no statistically significant changes. In the present study there was increased in Blood pressure and Heart rate in Phenylephrine group, when compared with Tropicamide group.**Conclusion:** In our study because of rapid onset, brief duration of mydriatic action, greater diffusibility of the drug into cornea, 1% Tropicamide was found to be a better mydriatic than 10% Phenylephrine. Adverse effect like, Blood pressure and heart rate were major drawbacks for Phenylephrine but the overall safety of Tropicamide was better in our study.**Key Words:** Mydriatic, 1% Tropicamide, 10% Phenylephrine, PD, IOT, BP, HR**INTRODUCTION:**

Mydriasis is the pupillary dilation caused by contraction of the dilator of the iris. It is a normal response to decreased light, strong emotional stimuli, and topical administration of mydriatic and cycloplegic drugs. It can also result from ocular and neurological disorders, eye trauma, sexual stimulation<sup>[1]</sup>, serotonin syndrome<sup>[2]</sup> and disorders that decrease level of consciousness. Mydriasis may be an adverse effect of antihistamines or other drugs.<sup>[3]</sup>

There are two types of muscle that control the size of the iris: circular muscle and radial muscle. The former is innervated by the parasympathetic nervous system, the latter by the sympathetic nervous system. Sympathetic stimulation of  $\alpha_1$  adrenergic receptors causes the contraction of the radial muscle, and subsequent dilation of the pupil. Conversely, parasympathetic stimulation causes contraction of the circular muscle and constriction of the iris. The mechanism of mydriasis depends on the agent being used. It usually involves either a disruption of the parasympathetic nerve supply to the eye (which causes contraction of the pupil), or over activity of the sympathetic nervous system.<sup>[3]</sup>

Mydriasis is often necessary for thorough examination of retina, optic disc, and in the treatment of iridocyclitis, choroiditis, in persons with centrally located cataracts (Nuclear cataracts, posterior cataracts; the persons may experience significant improvement in visual acuity) who are at surgical risk.

In ocular therapy, there are four commercially available mydriatic – cycloplegic drugs. They are Homatropine, Atropine, Cyclopentolate and Tropicamide.<sup>[3]</sup> They have different potencies and durations of action. Hence, their clinical uses vary. Among the four available drugs, Phenylephrine and Tropicamide are commonly used in the routine ophthalmic practice. Phenylephrine is a sympathomimetic drug that causes mydriasis, but lacks cycloplegic property. It is the most commonly used directly acting adrenergic mydriatic. It can be used alone, or more commonly, in combination with a cycloplegic drug. Tropicamide, a synthetic derivative of tropic acid, became available for ocular use in the late 1950s. It is an antimuscarinic drug. Phenylephrine ensures maximal stimulation of dilator pupillae, while Tropicamide paralyzes constrictor pupillae. Both of them work in synergistic action for causing Mydriasis. 1% Tropicamide

and 10% Phenylephrine were found to be efficacious in producing mydriasis and cycloplegia.

So, in the present study, we were compared the pharmacological effects like, pupillary diameter, intraocular tension, blood pressure, heart rate, of 1 % Tropicamide with 10 % Phenylephrine.

## MATERIALS AND METHODS:

The present study was conducted on subjects suffering from refractive error attending the department of Ophthalmology, Prathima Institute of Medical Sciences, Nagunur, Karimnagar. Procedures followed by ICMR's Ethical guidelines for biomedical research on human subjects (2000). Present studies were divided into two groups: *Group-1*: 30 patients were in this group who received 1% Tropicamide eye drop (2 drops in each eye). *Group-2*: 30 patients were in this group who received 10% Phenylephrine eye drop (2 drops in each eye). The present study is a single blinded study where the patients were not aware of the drug (mydriatic/cycloplegic).

### 1. Pupillary diameter

**Autorefractometer:** Autorefractors basically comprise of an infrared source, a fixation target and a Badal optometer. An infrared light source (around 800-900nm) is used primarily because of the ocular transmission and reflectance characteristics achieved at the sclera.<sup>[4]</sup> At this wavelength, light is reflected back from the deeper layers of the eye (choroid and sclera) and this, together with the effects of longitudinal chromatic aberration, means that a systematic error of approximately -0.50DS must be added to compensate for ocular refraction with visible light.<sup>[5]</sup> A variety of targets have been used for fixation ranging from less interesting 'stars' to pictures with peripheral blur to further relax accommodation. Practitioners may recall in the past patients stating that the target is blurred prior to measurements being taken – this is the effect of the fogging lens. However, even with this fogging technique, micro fluctuations in accommodation

occur up to 0.50DS.<sup>[6]</sup> Some of this effect is counteracted by averaging multiple readings – however, the error is not eliminated.

### 2. Intra Ocular Tension:

The depth of indentation of the cornea is measured with Schiottz Tonometer. The cornea is anaesthetized with suitable local anesthetic e.g., xylocaine 4% eye drops. Lids are separated and tonometer carrying a weight of 5.5 gm is gently placed on the cornea. Deflection is measured and reading is millimeter of mercury can be read from a chart.

### 3. Blood Pressure:

Blood pressure was measured in all patients participated in our study with the use of sphygmomanometer before and 45 minutes after administration of drug.

**4. Heart Rate** is counted per min before and after 45 min. of treatment.

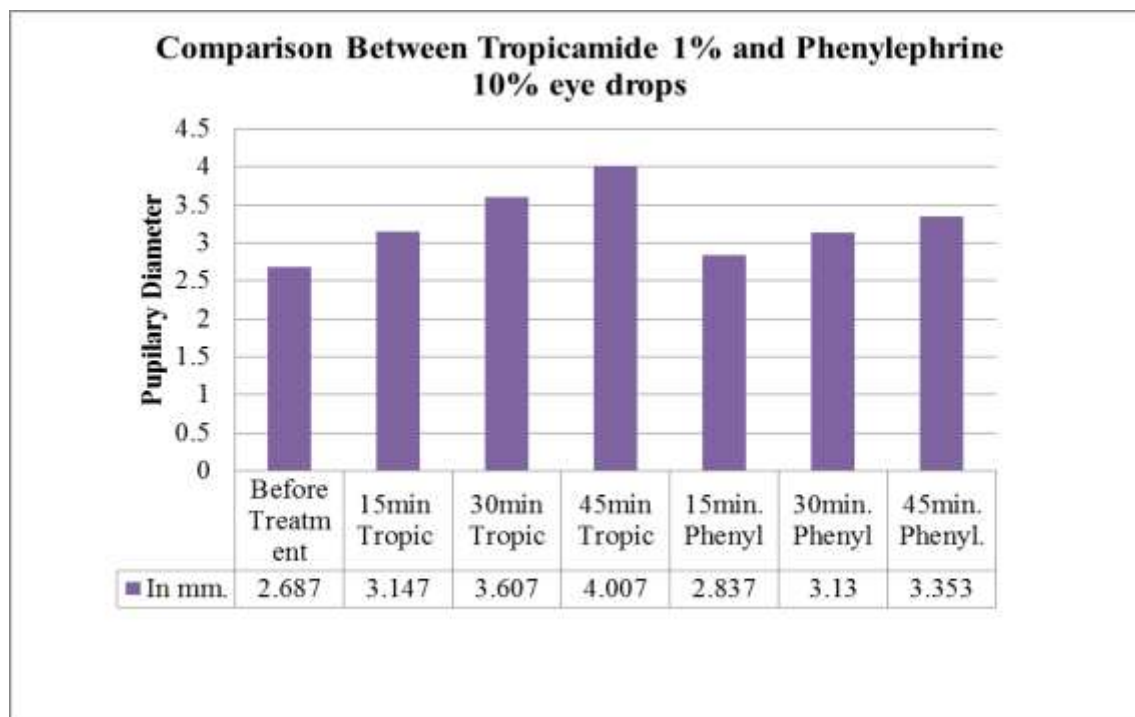
## RESULTS:

The change in pupil size before drug baseline measurement and after drug at 15min, 30min and 45min. were measured in both the eyes. Increase pupil size is absorbed after 15 min administration of both the drug, but maximum level obtained after 45min.duration. When we compared tropicamide1% with phenylephrine10% eye drops, pupillary diameter shows more in tropicamide1% users at the duration of 45min. In Tropicamide group, there was a greater decrease in IOT in both eyes in comparison to Phenylephrine. Blood pressure was measured in all patients participated in our study with the use of sphygmomanometer before and 45 minutes after administration of drug. There was increase of systolic and diastolic blood pressure in Phenylephrine group with compare to Tropicamide group. Table-1 shows that the heart rate in Phenylephrine group has been increased when we compare with Tropicamide group after 45 min of administration of drug.

Table 1: Comparison of Tropicamide 1% with Phenylephrine 10% eye drops on Humans with various parameters

		Before drug administration	After drug administration					
			Tropicamide 1%			Phenylephrine 10%		
			15min	30min	45min	15min	30min	45min
1	Pupillary diameter	2.687±0.49	3.147 ±0.40	3.607 ± 0.37	4.007 ± 0.37	2.837 ± 0.48	3.130 ± 0.42	3.353 ± 0.37
2	IOT	14.417 ±0.78	-	-	14.370±1.38	-	-	14.347±0.76
3	Systolic Blood pressure	123.667±11.89	-	-	121.80±8.17	-	-	132.13±10.42
4	Diastolic Blood pressure	79.0±6.07	-	-	78.667±3.07	-	-	88.0±8.07
5	Heart rate	75.67±2.38	-	-	75.33±2.85	-	-	76.63±2.39

All results were mentioned in mean ± SD (Standard Deviation)

**Graph-1****DISCUSSION:**

Cycloplegia and mydriasis are two important tools in ophthalmological examination, especially in the examination of refractive errors. In ocular therapy, important and commercially available mydriatic-cycloplegic drugs are Phenylephrine, Atropine, Cyclopentolate and Tropicamide. They have different potencies and durations of action. Among these four available drugs, Phenylephrine and Tropicamide are commonly used in the routine ophthalmic practice. In the present study, we have compared the pharmacological effects and tolerability of 1 % Tropicamide with 10 % Phenylephrine.

Phenylephrine and Tropicamide both was potent mydriatic drugs. The percentage changes were compared and found that the changes in both eyes at 30min. and 45min. post drug in Tropicamide were more than Phenylephrine so analyzing all the data we can conclude that tropicamide is a better mydriatic than Phenylephrine.

Tropicamide group, there was a greater decrease in IOT in both the eyes in comparison to Phenylephrine. So our study showed the effect of Tropicamide on IOT for diagnostic mydriasis and our findings closely match with previous review results.<sup>[7]</sup>

In the present study there was increase of systolic blood pressure in Phenylephrine group in comparison to Tropicamide group. In Phenylephrine group, in 11 patients there was increase in blood pressure but in Tropicamide group there was marginal increase in blood pressure in only 4 patients. The pressor activity of Phenylephrine is

attributed to its sympathomimetic activity having direct effects on adrenergic receptors. It has predominantly  $\alpha$ -adrenergic activity and is without significant stimulating effects on the CNS at usual doses. The results of our study support the findings of the previous studies.<sup>[8]</sup> In Phenylephrine group, in 17 patients there was increase in heart rate but in Tropicamide group there was nominal increase in heart rate in only 4 patients.<sup>[9]</sup> The increase in heart rate and palpitations are due to its sympathomimetic activity. Its pressor activity is weaker than that of noradrenalin but of longer duration. The results of our study support the findings of the previous studies.<sup>[10]</sup>

**CONCLUSION;**

In our study because of rapid onset of mydriatic action, brief duration of action, greater diffusibility of the drug into cornea, 1% Tropicamide was found to be a better mydriatic than 10% Phenylephrine. As 1% Tropicamide produced complete cycloplegia at 45 minutes after drug administration in 90% patients, 1% Tropicamide is an effective cycloplegic whereas 10% Phenylephrine has no cycloplegic effect. Adverse effect profile including changes in vital signs (Blood pressure and heart rate) were major drawbacks for Phenylephrine but the overall safety of Tropicamide was better in our study.

So it can be concluded that Tropicamide is a better mydriatic-cycloplegic drug than Phenylephrine in ophthalmologic practice especially in the examination of eye in the patients suffering from refractive errors.

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