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Comparison of effect of single drop of Tropicamide 0.8% and Phenylephrine 5% versus multiple drops on Pupil and Blood pressure.

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ABSTRACT

The quality of an intraocular examination as well as intra-ocular surgeries like cataract surgery, depends on adequate pupil dilatation. The ideal mydriatic agents should provide rapid dilatation of the pupil wide enough to permit thorough ocular evaluation without having any local or systemic adverse effects. To assess the time taken to reach the effective pupillary dilatation of 7mm in single drop of tropicamide 0.8% - phenylephrine.5% combination compared to multiple applications of the same .2)To study the effect of the drug on the pulse and blood pressure of the patient in single versus multiple application. A hospital based randomised controlled trial of minimum 100 cases in each group,who presented to the department of Ophthalmology ,Sri Siddhartha Medical College,Tumkur between November 2011 to June 2013 were taken. After recording the demographic data, a brief systemic examination for, base line pulse and blood pressure were done. Pupils were assessed for direct and indirect light reflexes and the initial pupil size was recorded using pupil gauge. The patients were randomly allocated into 2 groups, group A was administered single drop and group B was administered multiple applications (at intervals of 10 minutes for a total of 40 minutes) of a combination of 0.8% Tropicamide and 5% Phenylephrine. The time taken to achieve 7mm pupil size from the baseline pupil size in both the groups, single as well as multiple application groups, was similar(31.80±3.85 minutes in groupA; 31.70±3.77 minutes in group B; p- value was not significant), suggesting that it takes an equal time for full dilatation of the pupil whether a single or multiple drops were used for dilatation. The effective increase in the pupil size(pupil size after 40 minutes-baseline pupil size) was found to be similar in both the groups.3) The, pulse rate every 10 minutes and the pulse rate after 40 minutes in both the groups, single as well as multiple application groups was found to be similar(74.15 ± 5.9 beats/minute after 40minutes in single group A; 74.90 ± 5.97in group B. The systolic blood pressure every 10 minutes and the systolic blood pressure after 40 minutes was similar in both groups(121.52 ± 5.4 mm Hg after 40 minutes in group A; 122.56 ± 3.27 mm Hg after 40 minutes groupB; p-value was not significant. Diastolic blood pressure after 40 minutes was also similar in both the groups(79.10 ± 4.11 mm Hg after 40 minutes in group A; 79.94 ± 4.33 mm Hg after 40 minutes in group B; p-value not significant). Thus a single drop of combination of tropicamide and phenylephrine can be as efficacious as using multiple drops of the same for routine pupillary dilatation for fundoscopic examination,for producing cycloplegia as well as preoperatively before cataract surgery. There are no effects seen in the pulse and the blood pressure after these drops. They can thus reduce the financial burden caused due to multiple drops and cuts down on the man power required for the same

Keywords: Tropicamide , Phenylephrine ,mydriasis and Blood pressure

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INTRODUCTION

The quality of an intraocular examination as well as intra-ocular surgeries like cataract surgery, depends on adequate pupil dilatation [1]. The ideal mydriatic agents should provide rapid dilatation of the pupil wide enough to permit thorough ocular evaluation without having any local or systemic adverse effects.

Mydriatics / cycloplegics drugs are commonly used in ophthalmology OPDs for refraction in all age groups, and fundus examination for ocular and systemic condition in all age groups. Parasympatholytics as well as sympathomimetic drugs have been used to dilate the pupil. The parasympathetic regulation dominates over the sympathetic effect in the control of the pupil². Sympathomimetic drug cannot maintain pupil dilatation in bright light during indirect ophthalmoscopy. And parasympatholytic drug is not sufficient for pupil dilatation. Combination of both drugs offers greater pupil dilatation than single drug use [2].

Tropicamide 0.8%-Phenylephrine 5% combination is a commonly used drug in an ophthalmology OPD. Our study is designed to evaluate the efficacy of single drop of tropicamide-phenylephrine compared to multiple drop instillations.

An ideal Mydriatic should provide: maximum mydriasis, rapid onset of action and rapid attainment of maximum effect, short duration and rapid recovery, consistency in its efficacy, and freedom from toxicity, irritation or sensitivity.

Tropicamide is a parasympatholytic drug, an antimuscarinic agent that acts as a competitive antagonist to acetylcholine and other muscarinic drugs. It blocks the cholinergic action on the sphincter muscle and the ciliary muscles, thereby dilating the pupil and inhibiting accommodation (cycloplegia) [3,4].

Tropicamide should be used with caution in conditions characterised by tachycardia such as thyrotoxicosis, heart failure, myocardial infarction and in cardiac surgery where it may further accelerate the heart rate [3,4].

In Brown et al study they found a decrease in systolic and diastolic blood pressure and pulses in patients given 1 percent tropicamide, as well as no change in second group receiving 10 percent phenylephrine at different time intervals [5].

Phenylephrine is an adrenergic agonist. It contracts iris dilator muscle. Maximum dilatation is 45 to 60 minutes after instillation irrespective of the concentrations used [7,8].

Phenylephrine can cause short term raised blood pressure, headache, increased heart rate (tachycardia) and blanching of the skin. Adverse systemic reactions have been reported following topical application of 10% phenylephrine like elevated blood pressure, tachycardia, reflex bradycardia, cardiac arrhythmias [7,8].

Tropicamide and phenylephrine combination eye drops are widely used for mydriasis in routine ophthalmoscopic examinations [14,9] and prior to cataract surgery to achieve maximal pupil dilation [4].

By comparing the efficacy of single drop versus multiple drops of Tropicamide and Phenylephrine, using few drops less for one eye can save a large financial burden.

In addition to that the need for man power for dilatation of pupils can also be reduced.

Moreover, the occasional adverse drug reactions after instillation of multiple drops of Phenylephrine like tachycardia, elevated blood pressure and stroke can also be avoided.

MATERIALS AND METHODS

A hospital based randomised controlled trial of minimum 100 cases in each group, who present to the department of Ophthalmology, Sri Siddhartha Medical College, Tumkur, between November 2011 to June 2013 were included.

All patients between 20 to 40 age group , except those falling in the inclusion criteria were taken in the study. Exclusion criteria, patients with age below 20 and above 40, pre-existing pupillary abnormality, ocular surgeries, uveitis, cardiac problems, arterial hypertension, diabetes were excluded.

- After taking informed consent, detailed history regarding patients name, age, sex, occupation, address, presenting symptoms, duration, progression, were recorded. The patient was also enquired about his past history, personal history and family history.
- A brief general physical and systemic examination was carried out, base line pulse and blood pressure were recorded..
- Pupils were assessed for direct and indirect light reflexes and the initial pupil size was recorded using pupil gauge.

The patients were randomly allocated into 2 groups, group A was administered single drop and group B was administered multiple applications (at intervals of 10 minutes for a total of 40 minutes) of a combination of 0.8% Tropicamide and 5% Phenylephrine.

- The pulse, blood pressure, pupil size, were assessed every 10 minutes for a total duration of 40 minutes, along with the effective increase in the pupil size at 40 minutes and the time taken to reach a pupillary diameter of 7mm in all patients of both the groups.

Observation

Table 1: Demographic profile of the patients

	Single Application	Multiple Application
Number of Patients	100 (200 eyes)	100 (200 eyes)
Male / Female	52 / 48	53 / 47
Age, in years, Mean ± SD	25.3 ± 2.83	24.83 ± 2.66
Pupil size mean ± SD (in mm)	3.02 ± 0.14	3.04 ± 0.2
Pulse mean	70.80 ± 5.55 / min	71.58 ± 5.40 / min
Blood Pressure, mean systolic	118.66 ± 5.07 mm Hg	119.26 ± 2.75 mm Hg
Blood Pressure, mean Diastolic	76.24 ± 3.86 mm Hg	76.78 ± 4.36 mm Hg

Table 2: The effect on pupillary size in each group at various time intervals.

	Pupil size mean ± SD (mm)		T – test
	Single Application	Multiple Application	P – value
Baseline	3.02 ± 0.14	3.04 ± 0.2	0.247*
10 mins	4.00 ± 0.0	4.00 ± 0.0	--
20 mins	5.25 ± 0.43	5.26 ± 0.44	0.818*
30 mins	6.82 ± 0.39	6.83 ± 0.38	0.795*
40 mins	7.00 ± 0.0	7.00 ± 0.0	--
Effective increase in pupil size (40 mins - baseline)	3.98 ± 0.14	3.96 ± 0.2	
7 mm pupil (time in min)	31.80 min ± 3.85	31.70 min ± 3.77	

* p-Values are not significant.

Table 3. The effect on pulse rate in each group at various time intervals .

	Pulse rate mean \pm SD (per min)		T - test
	Single Application	Multiple Application	P - value
Baseline	70.80 \pm 5.55	71.58 \pm 5.4	0.315*
10 mins	71.33 \pm 5.62	72.22 \pm 5.58	0.263*
20 mins	72.34 \pm 5.69	73.11 \pm 5.86	0.347*
30 mins	73.35 \pm 5.88	74.13 \pm 6.05	0.356*
40 mins	74.15 \pm 5.9	74.90 \pm 5.97	0.372*

* p- Values are not significant

Table 4: The effect on systolic blood pressure in each group at various time intervals.

	Systolic Blood pressure, mean \pm SD (mm Hg)		T – test
	Single Application	Multiple Application	P – value
Baseline	118.66 \pm 5.07	119.26 \pm 2.75	0.300*
10 mins	119.02 \pm 5.04	119.94 \pm 2.85	0.114*
20 mins	120.18 \pm 5.27	121 \pm 2.82	0.172*
30 mins	121.90 \pm 8.57	122.18 \pm 3.06	0.792*
40 mins	121.52 \pm 5.4	122.56 \pm 3.27	0.101*

* p-values are not significant.

Table 5: The effect on diastolic blood pressure in each group at various time intervals.

	Diastolic Blood pressure, mean \pm SD (mm Hg)		T – test
	Single Application	Multiple Application	P – value
Baseline	76.24 \pm 3.86	76.78 \pm 4.36	0.355*
10 mins	76.38 \pm 3.97	77.04 \pm 4.38	0.265*
20 mins	77.74 \pm 4.05	78.46 \pm 4.23	0.220*
30 mins	78.34 \pm 4.02	79.30 \pm 4.36	0.107*
40 mins	79.10 \pm 4.11	79.94 \pm 4.33	0.161*

* p-values are not significant.

DISCUSSION

The mean age of the participants in my study was 25.3 \pm 2.83 years in the single application group and 24.83 \pm 2.66 years in the multiple application group(range 20-40 years).48.5% were in the 20-24 years category,44.5% in the 25-29 years category, 7% in the 30-34 years category and none in the 35-40 years category with a mean age of 25.07 years (minimum of 20 years and maximum of 34 years).

The sex distribution in our study was 47.5% females and 52.5% males.

In our study the time taken to achieve full pupillary dilatation of 7 mm in 2 randomised groups, one receiving a single drop of the drug combination and the other receiving multiple drops(a single drop every 10

minutes) of the same combination drug, comparing the results after 40 minutes, was similar whether a single drop of the combination drug was used or multiple drops were used.

Jitendra Jethani et al found in their study that the mean total time taken to achieve a 7mm pupil size was significantly more in the single application group than the multiple application group but the main drawback was that the mean baseline pupil size was smaller in the single application group than the multiple application group [1].

Kergoat H et al conducted a study where a continuously recording high-resolution pupillometer was used to measure changes in pupil size and pupil reactivity to temporally modulated light, following topical application of a phenylephrine HCl 5%-tropicamide 0.8% combination mydriatic (Phenyltrope) and those caused by one drop of tropicamide 1% alone.

Their results showed that while the combination is a fast acting mydriatic; it does not differ appreciably in efficacy from the mydriatic effect of tropicamide 1% alone in healthy subjects between 20 to 36 years of age [4].

Trinavarat et al did a study to compare the efficacy in pupil dilatation between a mixture containing 0.75% tropicamide and 2.5% phenylephrine and the alternate application of 1% tropicamide and 10% phenylephrine eye drops and found that the former combination is superior to the latter in providing faster and more successful pupil dilatation within 40 minutes [7].

In our study the effective increase in the pupil size (pupil size after 40 minutes-baseline pupil size) was found to be similar in both the groups, the single application as well as the multiple application groups Jitendra Jethani et al in their study had similar findings [1].

The baseline pulse rate, the pulse rate every 10 minutes and the pulse rate after 40 minutes in both the groups, was found to be similar (70.80 ± 5.55 beats/minute baseline in single group; 71.58 ± 5.4 beats/minute baseline in multiple group; p-value not significant and 74.15 ± 5.9 beats/minute after 40 minutes in single group; 74.90 ± 5.97 beats/minute after 40 minutes in multiple group; p-value not significant). The increase in the heart rate was not found to be significant in both the groups

In our study the baseline systolic blood pressure, systolic blood pressure every 10 minutes and the systolic blood pressure after 40 minutes was similar in both the groups (118.66 ± 5.07 mm Hg baseline in single group; 119.26 ± 2.75 mm Hg baseline in multiple group; p-value not significant and 121.52 ± 5.4 mm Hg after 40 minutes in single group; 122.56 ± 3.27 mm Hg after 40 minutes in multiple group; p-value was not significant). The increase in the systolic blood pressure was not significant in both the groups

The baseline diastolic blood pressure, diastolic blood pressure every 10 minutes and the diastolic blood pressure after 40 minutes was also similar in both the groups in our study.

In Jethani et al study there was not much change in pulse and blood pressure (systolic and diastolic) in both the groups in this study [1].

Motta M et al compared the cardiovascular effects of phenylephrine 2.5% versus phenylephrine 10%. Their results corroborate the finding that one single drop of either 2.5 or 10% has no effect on blood pressure and, when 1% tropicamide is combined, satisfactory pupil dilation is achieved [6].

In a study by Bhatia et al [9] mild rise in systolic BP about 3 mm of Hg (SD 19.03) and 1 mmHg in Diastolic (SD 11.5) was seen, and hence they concluded though not much change is seen in normotensive patients, care should be taken in using 10% phenylephrine in hypertensives.

Chin et al reported significant increase in BP after instilling 2.5% or 10% phenylephrine in preoperative patient, However their study does not take into account the effect of anxiety and adrenalin mixed in local anaesthetic [10].



CONCLUSION

- Thus a single drop of combination of tropicamide and phenylephrine can be as efficacious as using multiple drops of the same for routine pupillary dilatation for fundoscopic examination, as well as preoperatively before cataract surgery.
- This can lowers the risk of adverse reactions which have been reported with the use of phenylephrine and is thus safer, as compared to multiple applications.
- Moreover this can significantly reduce the cost as well as the need for manpower for instillation of drops.

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