Effect of the single-drop mydriatic combination of 0.8% tropicamide with 5% phenylephrine with multiple applications of the same drop: A randomized controlled trial

Dear Editor,

We read with interest the article by Trinavarat *et al*.[1] The authors have pointed out the use of a mixture of 0.75% tropicamide and

2.5% phenylephrine as a superior dilating mixture compared to the alternate application of 1% tropicamide and 10% phenylephrine. In India, most of the commercially available drops have around 0.8% tropicamide and 5% phenylephrine.

The whole idea of reducing the concentration is to reduce the systemic side effects which may be seen with these drops. We believe that the authors should have tried to see the result of a single-drop application of this mixture. Apt and coworkers have demonstrated the efficacy of single-eye-drop mydriatic combinations.[2] However, such a study in Indian population has not been reported to the best of our knowledge.

Keeping this in mind, we designed a randomized control trial to find out whether a single drop of a commercially available mydriatic mixture (0.8% tropicamide + 5% phenylephrine) (Tropicacyl plus, Sunways Pharama) was effective in producing a dilatation of pupil to 7 mm when compared to multiple application (10 min apart) of the same mixture (a total of three drops).

The patients were examined for baseline pupil size, blood pressure, and pulse. The patients were examined every 10 min after using the drops in both single-drop application and multiple application groups. The total time taken to reach the 7-mm pupil size was calculated and recorded.

All the patients were in the 20- to 55-year age group. All patients with any history of ocular surgery, uveitis, posterior synechiae, usage of miotic drugs, narrow angles, being treated for any infectious disease were excluded. Patients with any history of arterial hypertension, cardiac disease, and diabetes mellitus were also excluded.

The sequence of patient allocation was prepared by a computer program and sealed in envelopes. The patients were allocated by one of the authors (HS). The drops were then put by another investigator. After the drops were put, the pupil diameter was vertically measured with a pupil gauge (AN) under bright light without magnification as used in the study by Trinavarat *et al*.[1]

The total number of patients participating in the study was 30. The mean age in the single-application group was 36.8 ± 12.4 years and in the multiple application group was 37.13 ± 12 years.

Baseline data of these patients are shown in Table 1. The data regarding the dilatation of pupil and the changes in the blood pressure and pulse rate are shown in Tables 2 and 3, respectively.

There was not much change in pulse and blood pressure (systolic and diastolic) in both the groups.

The mean total time taken in the single-drop group was 34.6 ± 10.5 min whereas it was 30.5 ± 7.1 min in the multiple application group. However, this result should be taken with caution since the mean baseline pupil size in the single-drop application group was 2.1 ± 0.4 mm and in the multiple application group it was 2.5 ± 0.5 mm. On calculating the net increase in the size of the pupil (that is the difference between the pupil sizes at 30 min – baseline pupil size), the mean increase (at 30 min) in the single-drop application was 4.6 ± 1.2 mm and in the multiple-drop group was 4.4 ± 1.1 mm. A student *t*-test was done and the *P*-value was 0.581 (not significant). The progression in the increase in the size of the pupil is shown in Fig. 1. As seen in the graph, the increase in the size of the pupil is almost similar on single application and on multiple applications. Apt *et al*.[2] have compared instillation of

Table 1: The baseline data of all the patients in both the groups

	Single application	Multiple application
Number of patients	15 (30 eyes)	15 (30 eyes)
Male/Female	6/9	4/11
Age, years, mean ± SD	36.8 ± 12.4	37.13 ± 12
Pupil size mean ± SD (mm)	2.13 ± 0.4	2.53 ± 0.5
Pulse	69.1 ± 8.7/min	70.7 ± 8.1/min
Blood pressure	109 ± 10.4 mmHg	112.8 ± 11.8 mmHg

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

	Pupil size mean ± SD (mm)	
	Single application	Multiple application
Baseline	2.1 ± 0.4	2.5 ± 0.5
10 min	2.7 ± 0.8	3.2 ± 0.7
20 min	4.8 ± 1.2	5.4 ± 0.9
30 min	6.8 ± 1.2	7 ± 0.9
Effective increase in the pupil size at 30 min (final pupil size at 30 min – baseline pupil size)	4.6 ± 1.2	4.4 ± 1.1
7 mm pupil (time, min)	34.6 ± 10.5	30.5 ± 7.1

Table 3: The effect on the blood pressure, both systolic and diastolic, and on the pulse rate at various intervals

	Single application			Multiple application		
	Blood pressure (mmHg)		Pulse (per min)	Blood pressure (mmHg)		Pulse (per min)
	Systolic	Diastolic		Systolic	Diastolic	
10 min	109.3 ± 10.3	72.5 ± 8.9	70.1 ± 9.1	113.1 ± 12.2	75.5 ± 8.3	73.6 ± 7.2
20 min	109.5 ± 10	72.7 ± 8.8	71.9 ± 8.4	114.7 ± 12.2	75.3 ± 8	74.4 ± 6
30 min	110.4 ± 9.6	72.6 ± 8.6	73.6 ± 9.5	113.7 ± 10.7	75.2 ± 7.4	75.7 ± 7.3
40 min	109.9 ± 10	72.4 ± 8.6	73.5 ± 9.7	113.9 ± 10.6	75.4 ± 7.6	75.6 ± 7.2

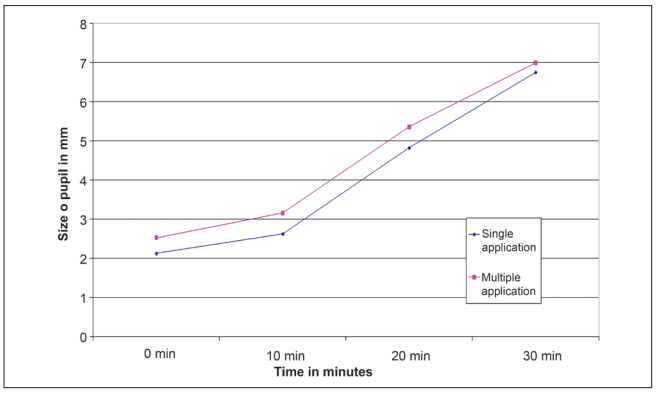

Figure 1: The progressive increase in the size of the pupil at various time intervals in single-application and multiple application groups

a combination of cyclopentolate HCL 0.5% with phenylephrine 2.5% (solution A), tropicamide 0.5% with phenylephrine 2.5% (solution B) with and without the usage of proparacaine 0.5%. They found that at the end of 30 minutes, solution A without and with proparacaine had a mean dilation of 6.6 and 7.4 mm and solution B without and with proparacaine had a mean dilation of 6.9 and 7.5 mm respectively. The effect was measured following a single application of these solutions which was similar to our study. Dubois *et al*.[3] did a randomized trial for conventional versus depot drug delivery. The study had used multiple applications (at 15-min intervals, total four applications) versus a single depot. The mean size of pupil in depot and multiple applications was 8.19 ± 1.2 and 7.96 ± 0.87 mm at 60 min and the difference between the two was not significant.

We believe that apart from the systemic side effects of these drugs, using two drops less for one eye can save a large financial burden especially in an average eye hospital with a daily out-patient number of around 150 patients (8 bottles per day, 2400 bottles per year, Rs 120,000 per year) apart from the need for manpower for dilatation of pupils. Importantly, all the patients in our study were asked to keep their eyes closed which prevent the dilution of the drug as it reduces the lacrimal pump mechanism.

Jitendra Jethani, Himanshu Solanki, Amod Nayak

Department of Pediatric Ophthalmology and Strabismus, Dr. Thakorbhai V Patel Eye Institute, Haribhakti Complex, Salatwada, Vadodara, Gujarat, India

Correspondence to: Dr. Jitendra Jethani, Department of Pediatric Ophthalmology and Strabismus, Dr. Thakorbhai V Patel Eye Institute, Haribhakti Complex, Salatwada, Vadodara – 390 001, Gujarat, India.
E-mail: xethani@rediffmail.com

References

1. Trinavarat A, Pitulsung A. Effective pupil dilataton with a mixture of 0.75% tropicamide and 2.5% phenylephrine: A randomized controlled trial. Indian J Ophthalmol 2009;57:351-4.
2. Apt L, Henrick A. Pupillary dilatation with a single eye drop mydriatic combinations. Am J Ophthalmol 1980;89:553-9.
3. Dubois V, Wittles N, Lamont M, Madge S, Luck J. Randomised controlled single-blind study of conventional versus depot mydriatic drug delivery prior to cataract surgery. BMC Ophthalmol 2006;6:36.

Access this article online

Quick Response Code:

Website: www.ijo.in

DOI: 10.4103/0301-4738.82008