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Original Research Article

Study of Efficacy and Safety of Topical 2% Dorzolamide And 0.5% Timolol in Open Angle Glaucoma in Santhal Pargana Jharkhand Population

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Abstract

Background: Glaucoma is a group of ocular disorder involving optic neuropathy which irreversible blindness. Elevated intra ocular pressure is the most important modified risk factor for glaucoma and hence lowering the intraocular pressure (IOP) is goal of glaucoma therapy. Hence ideal pharmacotherapy remains chief management modality of patients of glaucoma.

Method: 60 adult patients with open-angle glaucoma were studied. 30 patients were randomly selected as group I (IOP between 20 to 30 mm Hg) and 50 as group II (IOP between 31 to 40) according to their IOP. Further, both groups were divided into IA (25), IB (25), IIA (25), IIB (25), Groups IA and IIA were administered Dorzolamide 2% and one drop thrice daily in both eyes. Groups IB and IIB were administered 0.5% Timolol; one drop was administered twice daily in both eyes. General examination includes examination by torchlight. Slit-lamp, distant visual acuity tested by illuminated Snellen's chart, Schistz tonometry, gonioscopy, fundus examination, and field analysis by the octopus auto-field analyzer. Ophthalmoscopy and slit-light biomicroscopy were used.

Results: Comparison of IOP has significant p values ($p<0.001$). In a comparison of IOP reduction by different drugs, Dorzolamide 2% had a significant p-value ($p<0.001$). In a comparison of IOP reduction by the same drug in different groups, Dorzolamide has a significant p-value. The effects of both drugs on blood pressure and heart rate had a significant p-value ($p<0.001$).

Conclusion: It is confirmed that Dorzolamide 2% is well tolerated, efficiently reduces the IOP, and has a low allergic response as compared to Timolol 0.5%.

Keywords: Intra-Ocular Pressure, Open-Angle Glaucoma, Dorzolamide, Timolol.

Introduction

Glaucoma is a chronic, progressive neuropathy caused by a group of ocular conditions that lead to damage to the optic nerve and loss of visual function [1]. Elevated intraocular pressure is the most important modified risk factor for glaucoma, and hence lowering the intraocular pressure is the goal of glaucoma therapy.

Pharmacotherapy remains a management modality for the patients of glaucoma and ocular hypertension [2]. Topical anti-glaucoma medications act either by decreasing aqueous production or increasing aqueous outflow (prostaglandin derivatives, cholinergic agonists).

Fixed drug combination can help to avoid complex dosing schedules of multi drug glaucoma therapy and thus improve compliance commonly available combination drug that consists of dorzolamide hydrochloride 2% and timolol melate 0.5% was introduced in 1998.

This update focuses on previous studies [3] on the efficacy and tolerability profile of dorzolamide-timolol in adult ocular hypertension and open-angle glaucoma patients. As there is no direct pharmacodynamic interaction between the two drugs [4]. Hence, an attempt is made to administer both drugs individually, and the in different eye (right or left eye) in the different intraocular drug is evaluated.

Material and Method

60 (sixty) patients visited Sadar hospital Dumka cum upgraded phulo Jhano Medical College hospital, Dumka, Jharkhand-814101 were studied.

Inclusive Criteria: Patients above 21 years old with chronic open-angle glaucoma, ocular hypertension, pseudo-exfoliative glaucoma, and pigmentary glaucoma who gave their consent in writing for the study were selected.

Exclusion Criteria: Patients already under treatment, pregnant and lactating mothers, patients with dry eyes, corneal abnormalities, or any other conditions that prevent related applanation tonometry, and patients with ocular infection, advanced cataract ocular inflammation, or a history of renal or hepatic impairment were excluded from the study.

Method or plan of study: Out of 60 patients, 30 patients were randomly selected as group I (IOP between 20 to 30 mm of Hg, number 40) and 30 group II (IOP between 31 to 40 mm of Hg, number 50). According to their intraocular pressure (IOP), measured by schiotz tonometry, both groups were further divided into IA (n = 25), IB (n = 25), IIA (n = 25), and IIB (n = 25).

1. Groups IA and IIA: Patients were administered 2% Dorzolamide Hydrochloride, one drop thrice daily, in both eyes.
2. Group IB and IIB B: 0.5% Timolol maleate, one drop, was administered twice daily to both eyes.

During each visit, the following examinations were done on the day of enrollment and then on the 1st, 4th, 8th, and 24th weeks.

1. History and chief complaints were any ocular or systemic complaints suggestive of narrow-angle and open-angle glaucoma. Duration of illness and family history of glaucoma. If any were noted, anti-glaucoma medication, if taken previously, was also noted.
2. General examination: including external examination by torchlight and slit-lamp examination. Distant visual acuity was tested by an illuminated Snellen's chart, schiotz tonometry, gonioscopy, fundus examination, and field analysis by the Humphreys field analyzer. Ophthalmoscopy and slit lamp biomicroscopy were also used.
3. Any complaint regarding adverse effects of the drug during the study period was noted.

Every patient was instructed not to administer their eye drops on the morning of the check-up visits (1st, 4th, 8th, and 24th weeks) to measure the efficacy 12 hours after the previous evening dose.

The duration of the study was from March 2024 to January 2025.

Statistical Analysis: Various parameters between Dorzolamide and Timlol were compared with the t-test. The statistical analysis was carried out in SPSS software. The ratio of males and females was 2:1.

Observation and Results

Table 1: Comparative Study of Intraocular Pressure had significant p value ($p<0.001$).

Table 2: In the comparison of Intraocular pressure (IOP) reduction by the same drugs in the different groups: Timolol 0.5% had insignificant p value on the other hand Dorzolamide 2% had a significant p value ($p<0.001$).

Table 3: In the comparison of IOP reduction by the same drug in different groups, Timolol 0.5% had insignificant p value, but Dorzolamide Hydrochloride (2%) had significant p value ($p<0.001$).

Table 4: Effect of Dorzolamide and Timolol 0.5% on Blood Pressure Level had significant p value ($p<0.001$).

Table 5: The effect of both drugs on heart rate has significant p value ($p<0.001$).

Table 1: Comparative study of intraocular pressure

Pretreatment	Group	Right Eye (mm Hg) Mean ±SD	t test	p value	Left Eye (mm Hg) Mean ±SD	t test	p value
Pre- treatment	IA	29.05 (±2.50)	2.39	P<0.04	27.80 (±2.20)	2.86	P<0.001
	IB	27.28 (±3.18)			26.20 (±2.12)		
	IIA	32 (±4.8)	3.20	P<0.01	35.04 (±3.30)	2.54	p>0.00
	IIB	35.11 (±2.30)			33.20 (±2.2)		
End of Week 1	IA	23.28 (±2.20)	3.94	P<0.001	22.60 (±2.58)	2.38	P<0.01
	IB	26.02 (±3.10)			21.30 (±1.50)		
	IIA	25.20 (±4.12)	4.83	P<0.001	27.20 (±2.40)	3.33	P<0.01
	IIB	29.28 (±2.10)			30.20 (±4.30)		
End of Week 4	IA	21.03 (±1.58)	3.11	p>0.40	21.80 (±1.60)	3.36	P<0.01
	IB	22.20 (±1.78)			20.18 (±2.10)		
	IIA	27.13 (±2.58)	8.78	P<0.001	28.10 (±2.40)	10.57	P<0.001
	IIB	21.20 (±2.65)			29.82 (±3.10)		

End of Week 8	IA	20.11 (±3.2)	2.35	P<0.001	21.28 (±1.22)	2.07	P<0.001
	IB	21.68 (±1.80)			20.20 (±2.58)		
	IIA	26.89 (±3.58)	2.87	P<0.02	28.12 (±1.50)	2.60	P<0.001
	IIB	29.62 (±3.78)			29.82 (±3.20)		
End of Week 24	IA	21.03 (±2.40)	2.88	p>0.01	21.82 (±1.58)	3.48	P<0.001
	IB	22.90 (±2.62)			20.24 (±1.92)		
	IIA	26.22 (±3.28)	4.98	P<0.001	28.28 (±2.13)	2.59	P<0.001
	IIB	30.04 (±2.62)			29.06 (±1.20)		

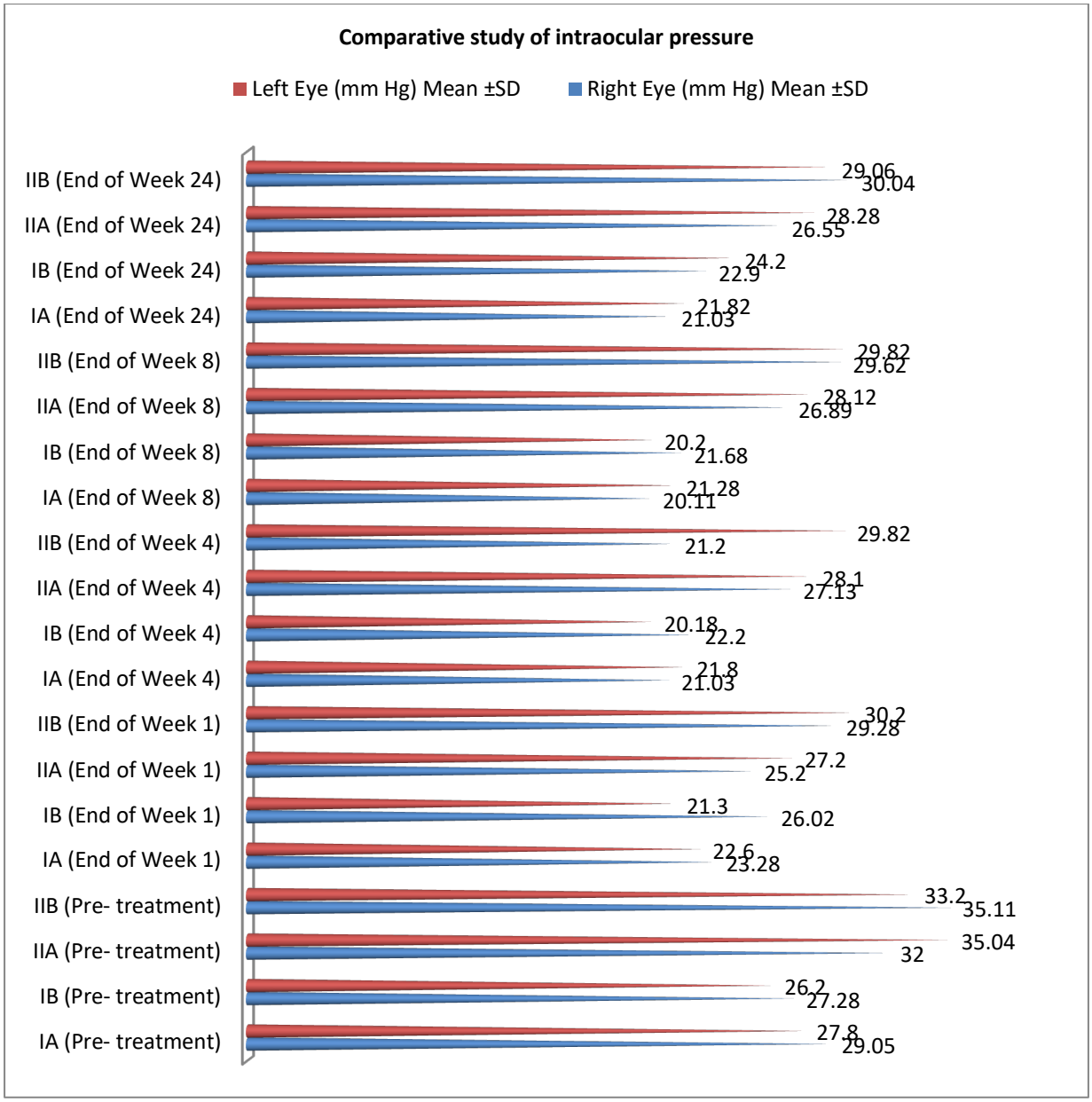

Figure 1: Comparative study of intraocular pressure

Table 2: Comparison of IOP reduction by different drugs in same groups IOP Reduction (mm Hg) (Means ±SD)

Group	Drug	Rt. Eye	Lt. Eye	t test	p value
IA	Dorzolamide HCL 2%	6.6 (± 1.20)	5.42 (±1.3)	3.65	P<0.05 *
IB	Timolol Maleate 2%	5.02 (±1.06)	4.34 (± 1.89)	2.54	P<0.001
IIA	Dorzolamide HCL 2%	4.60 (± 1.90)	5.90 (± 2.18)	2.46	P<0.001
IIB	Timolol Maleate 0.5%	4.82 (± 1.20)	4.14 (±1.02)	2.36	P<0.001

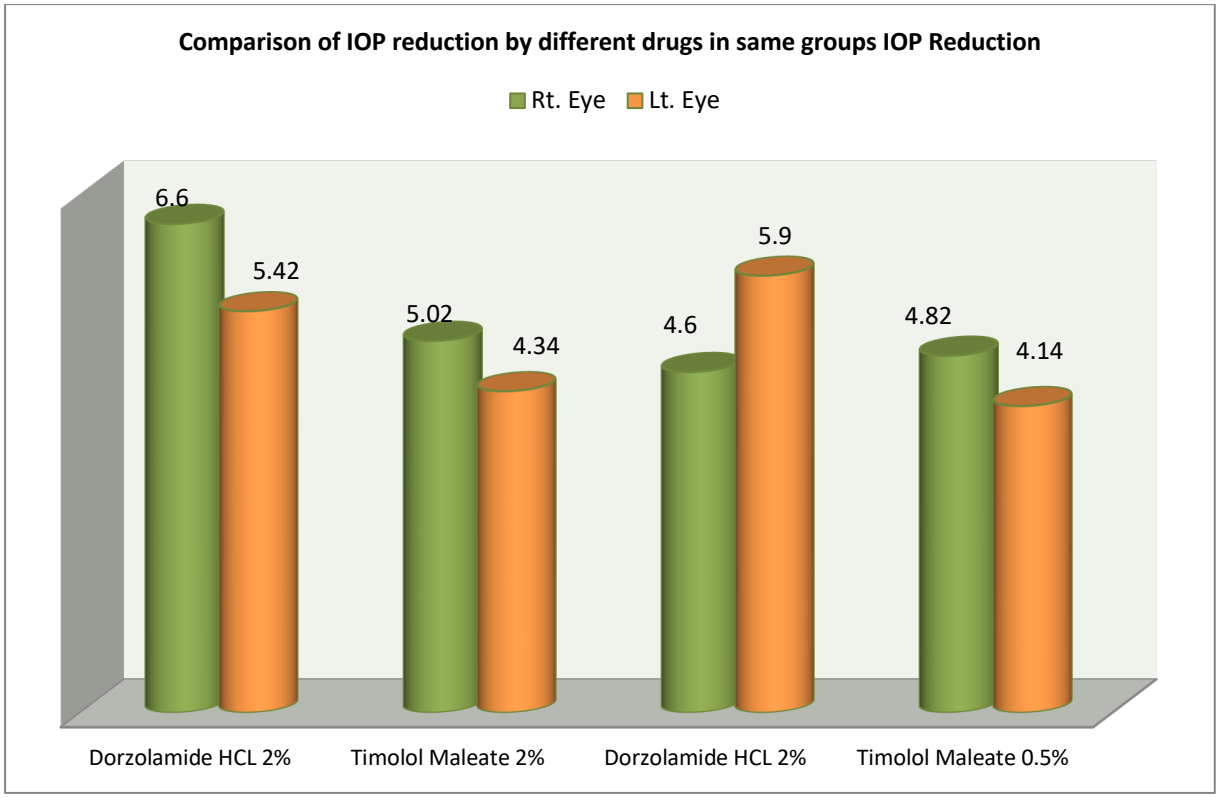

Figure 2: Comparison of IOP reduction by different drugs in same groups IOP Reduction

Table 3: Comparison of IOP reduction by same drug in different group

Drug	Group	Right Eye	Left Eye	t test	p value
Dorzolamide HCL %	G. IA	6.86 (± 2.20)	5.55 (±1.60)	2.63	P<0.001 *
	G. IIA	4.23 (±1.90)	5.62 (±2.22)	2.60	P<0.001 *
Timolol Maleate 0.5	G. IB	5.14 (±1.20)	4.42 (±1.02)	2.50	P<0.001 *
	G. IIB	4.31 (±1.40)	4.14 (±2.06)	0.38	p>0.75

*** p value is highly significant**

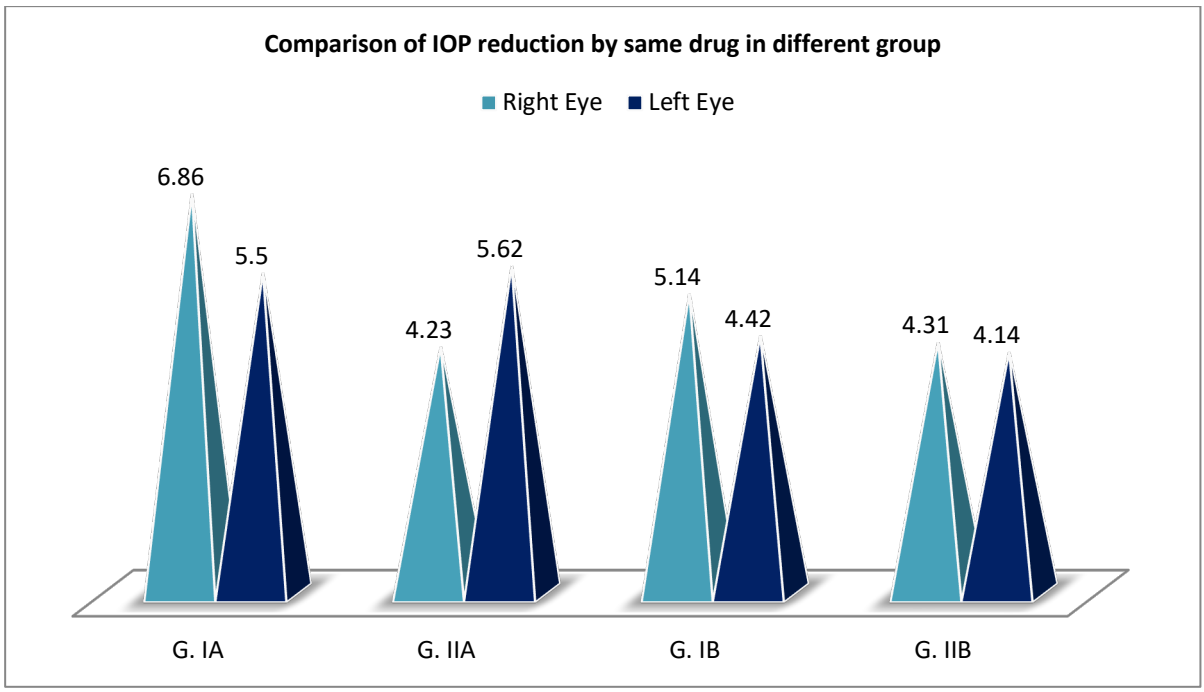

Figure 3: Comparison of IOP reduction by same drug in different group

Table 4: Effect of Dorzolamide and Timolol HCL on Blood pressure

Group	Dorzolamide HCL 2%		Timolol 0.5%	
Pre treatment	128.70 (±5.20)	82.20 (±3.10)	132 (±10.50)	86 (±5.50)
End of 24th week	123 (±4.70)	78.70 (±3.5)	124 (±5.0)	82.55 (±3.03)
t test	4.45	4.10	3.76	2.85
p value	P<0.001	P<0.001	P<0.001	P<0.001

P value are highly significant (P<0.001)

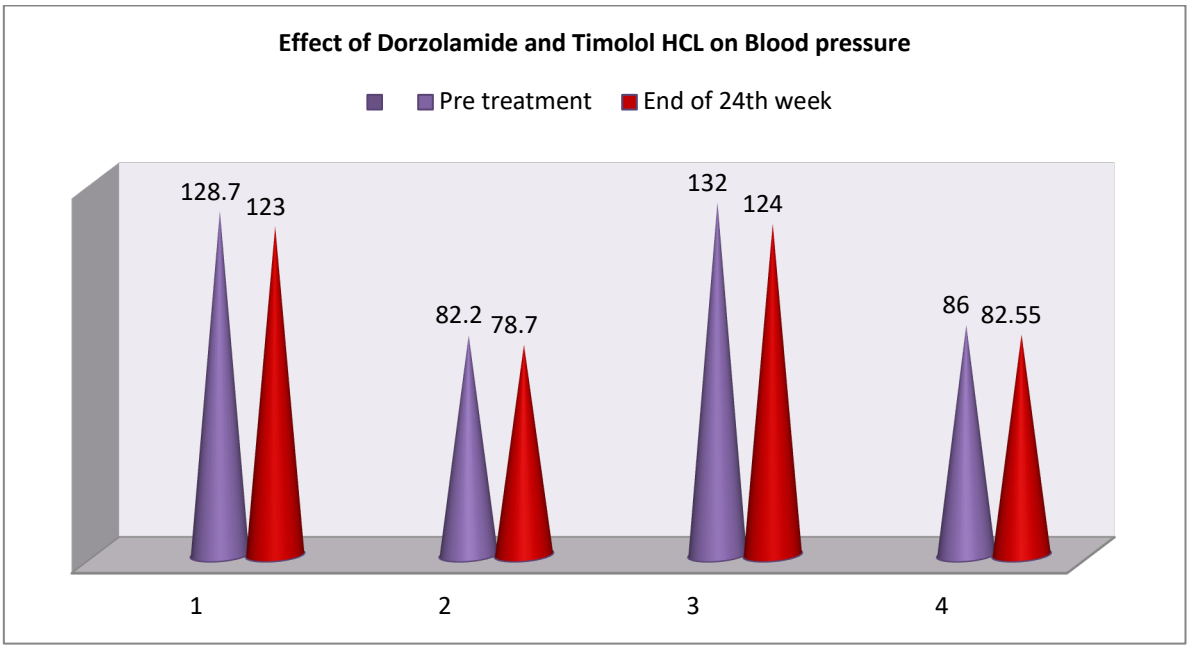

Figure 4: Effect of Dorzolamide and Timolol HCL on Blood pressure

Table 5: Effect of both drugs on Heart rate (Mean ± SD)

	Dorzolamide HCL (2%) (Beats/ minute) Mean ± SD	Timolol Maleate 0.5% (Beats/ minute) Mean ± SD
Pretreatment	78.32 (±5.0)	80.7 (±3.12)
End of 24th week	75.3 (±4.2)	76.2 (±3.60)
t test	2.53	5.17
p value	P<0.02	P<0.001

P value are highly significant (p<0.001)

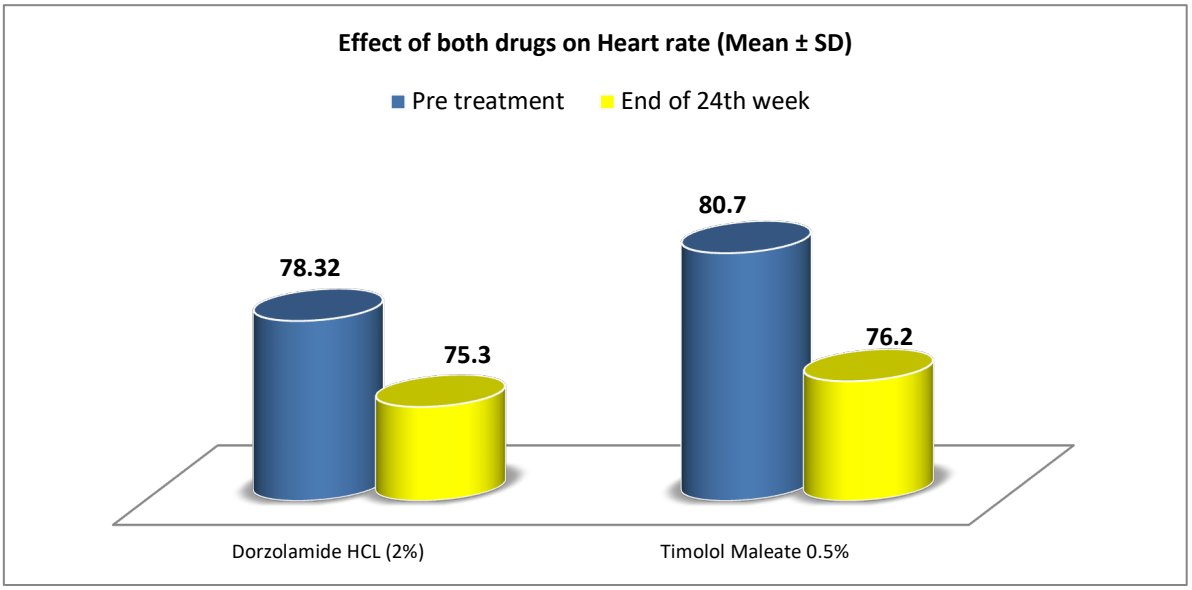

Figure 5: Effect of both drugs on Heart rate (Mean ± SD)

Discussion

Present study of efficacy and safety of topical 2% Dorzolamide and 0.5% Timolol in open-angle glaucoma in the Jharkhand population. In the comparison, IOP in both groups with different ocular pressures was significant for the study ($p<0.001$) (table 1).

In a comparison of IOP by different drugs (i.e., Dorzolamide and Timolol), Dorzolamide had a significant p-value ($p<0.001$) (Table 2). In the comparison study of IOP reduction by the same drugs in different groups, Dorzalamide had a significant p-value ($p<0.001$).

The effects of dorzolamide and timolol had a significant value in the study of blood pressure ($p<0.001$) (Table 4). The effect of both drugs on heart rate had a significant p-value ($p<0.001$) (Table 5). These findings are more or less in agreement with previous studies [5,6,7].

It is reported that in patients with open-angle glaucoma or ocular hypertension, dorzolamide hydrochloride 2% administered three times daily lowers the IOP by approximately 4-6 mm Hg at peak (2 hours post-dosage) and 3-4.5 mm Hg at peak (8 hours post-dosage) [8]. It is also confirmed that there is a 20% reduction in IOP after administration of 2% Dorzolamide hydrochloride three times daily into the conjunctival sac of affected eyes [9].

It is also reported that mean IOP reductions ranging from 3.8 to 5.1 mm Hg were achieved by Timolol maleate 0.5% administered for 4 weeks [10]. In another study, it was confirmed that Timolol maleate 0.5% reduced 5.8 to 6 mm Hg at 2 hours. At 12 hours, Timolol maleate had a mean IOP lowering ranging from 3.8 to 4.8 mm Hg [11].

After systemic absorption, dorzolamide is preferentially taken up by erythrocytes as a result of binding to CA-II in patients with glaucoma or ocular hypertension.

The terminal elimination half-life of dorzolamide in erythrocytes is <120 days, so there is potential for systemic accumulation during long-term administration. However, in patients with glaucoma treated with Dorzolamide 2% three times daily, plasma concentrations after 12 months were similar to those after 6 months [12].

Both drug regimens were well tolerated, and no serious drug-related adverse effects were reported in the present study.

Summary and Conclusion

Although both drugs were safe without any adverse reactions, Dorzolamide had an edge over Timolol in terms of reduction in intraocular pressure. Dorzolamide is well tolerated, has a low allergic response, and has a favorable ocular and systemic safety profile. Such a comparative study has to be carried out in a large number of patients where all super-specialized techniques are available to combat any adverse reactions to confirm these significant and positive findings.

Limitation of Study: Owing to the remote location of the research center, the small number of patients, and the lack of the latest techniques, we have limited findings and results.

This research paper has been approved by the ethical committee of the Sadar hospital Dumka cum upgraded phulo Jhano Medical College hospital, Dumka, Jharkhand-814101.

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