A COMPARATIVE STUDY OF TOPICAL BETAXALOL AND TIMOLOL FOR THEIR EFFICACY AND SIDE EFFECTS

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ABSTRACT

Purpose: Primary open angle glaucoma (POAG) is one such field in Ophthalmology where ophthalmologists have failed to stop blindness due to it. All the available treatment modalities are directed towards the reduction of intraocular pressure (IOP) but without interfering the basic aetiopathogenesis. In this study we propose to study efficacy, potency and adverse effects of topical Timolol and Betaxalol in primary open angle glaucoma. **Methodology:** A comparative study of topical Betaxalol 0.5% and Timolol 0.5% in the management of POAG was conducted at Tertiary care hospital. Fifty patients of newly diagnosed POAG of different age, sex, religion from both urban and rural population attending eye OPD were included in this study. 25 patients were treated with topical Timolol maleate 0.5% ophthalmic solution BD and 25 patients were treated with topical 0.5% Betaxalol hydrochloride phthalmic solution BD. At 20 weeks follow up IOP levels n both the groups measured by applanation tonometer were compare to each other. **Results:** In this study a total of 50 patients with POAG were studied. 25 patients were treated with Timolol maleate 0.5% ophthalmic solution and 25 patients were treated with 0.5% Betaxalol hydrochloride ophthalmic solution. Out of 50 patients, 29 (58%) were male and 21(42%) were female patients. POAG was most common in the age group of 51-60 years with average age 51.50 (S.D. 9.8) years. Average age in males was 54.50 years, while in female it was 49.31 years. **Conclusion:** both Timolol and Betaxalol are effective in decreasing IOP in POAG patients. The magnitude of Timolol in decreasing IOP is more as compared to Betaxalol. The selective beta 1 adrenergic inhibition of Betaxalol provides an added benefit for those patients in whom beta 2 blockade could be harmful.

KEYWORDS: Primary open angle glaucoma; Timolol; Betaxalol; Blindness.

INTRODUCTION

Eye is that special sense of organ, which makes an individual physically, mentally, socially and economically effective. Loss of function of the eye is blindness. Blindness is a common and distressing complication of glaucoma. It accounts for blindness in 5 million population of which 3 million is due to primary open angle glaucoma (POAG) throughout the world.[1]

Primary open angle glaucoma is one such field in Ophthalmology where ophthalmologists have failed to stop blindness due to it. Despite of much experimental, clinical and even speculative work, the aetiology of primary open angle glaucoma still remains obscure and hence, treatment is just empirical.[2] All the available treatment modalities are directed towards the reduction of intraocular pressure (IOP) but without interfering the basic aetiopathogenesis. Hence at the most blindness due to primary open angle glaucoma is delayed, but not eradicated in present study. As the functional damage in glaucomatous eye is attributed to elevated intraocular pressure, the basic aim of treating glaucoma whether medical, surgical or laser is to control the intraocular pressure.[3,4,5] Primary open angle glaucoma being a slowly progressive disease remains asymptomatic in more than 50% of patients till gross diminution of vision or field occurs.1 In such a situation, to the patients laser or surgical therapy may sound high for the disease. This is one of the reasons for the acceptability of medical therapy apart from other modalities being still under long term study.[5,6] Among the available drugs, there is always a constant search for the best in terms of efficacy, safety and economy.[7] The commonly used drugs in the treatment of primary open angle glaucoma are beta adrenergic antagonists.[8,9,10] Beta blockers reduce the IOP by decreasing aqueous humor formation. The most commonly used drugs in this group are Timolol and Betaxalol.

Objectives: The effectiveness of topical Timolol 0.5% and topical Betaxalol 0.5% in controlling raised IOP in POAG as well as to observe the side effects of these

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drugs.

In this study we proposed to study efficacy, potency and adverse effects of topical Timolol and Betaxalol in primary open angle glaucoma.

MATERIALS AND METHODS

Study design: An analytical observational study

Ethics approval: Ethical clearance was taken from Institutional ethical board. For the eligible patients, written informed consent was taken.

Sample size: Fifty patients of newly diagnosed POAG

Inclusion criteria: different age, sex, religion from both urban and rural population attending eye OPD patients with elevated IOP (IOP more than 20 mm of Hg) with or without glaucomatous disc or field damage with open anterior chamber angle were included in this study.

Exclusion criteria: Patients with hypersensitivity to components of study drugs, active ocular infection or inflammatory disorders, history of any acute or progressive retinal disorders, use of contact lenses, history of previous intraocular surgery, bronchial asthma, chronic obstructive pulmonary disease and pregnancy or lactation were excluded from the study.

Intraocular pressure was recorded with Goldman applanation tonometer under topical anaesthesia.

Group: Total 50 patients were studied. They were divided into 2 groups

Group A: 25 patients with POAG who were treated by Timolol maleate 0.5%.

Group B: 25 patients with POAG who were treated by Betaxalol hydrochloride 0.5%.

Methodology: In this study a total of 50 patients with POAG were studied. 25 patients were treated with topical Timolol maleate 0.5% ophthalmic solution BD and 25 patients were treated with topical 0.5% Betaxalol hydrochloride phthalmic solution BD. At 20 weeks follow up IOP levels n both the groups measured by applanation tonometer were compare to each other, Changes in the visual acuity, Visual field changes, optic disc changes and adverse effects were studied at every week. **Statistical analysis:** Data analysis was done by chi square test.

RESULTS

Out of 50 patients, 29 (58%) were male and 21(42%) were female patients. POAG was most common in the age group of 51-60 years with mean age of 51.50 ±9.8 S.D years. Average age in males was 54.50 years, while in female it was 49.31 years. (Table 1)

In Timolol maleate group mean baseline intraocular pressure was 28.60 (S.D. 1.75) mm Hg. These patients were treated with 0.5% Timolol maleate. The mean IOP after 20 weeks treatment was 19.96 (S.D. 1.76) mm Hg and the mean reduction in IOP was 8.64 mm Hg which is highly significant (P<0.001). (Table 2)

In Betaxalol hydrochloride group mean baseline intraocular pressure was 27.84 (S.D. 1.61) mm Hg. These patients were treated with 0.5% Betaxalol hydrochloride. The mean IOP after 20 weeks treatment was 20.28 (S.D. 1.33) mm Hg and the mean reduction in IOP was 7.56 mm Hg which is highly significant (P<0.001). (Table 2)

At 20 weeks out of 25 patients receiving Timolol maleate 2 patients showed decrease in visual acuity by one Snellen's line. In the Betaxalol hydrochloride group, only one patient showed decrease in visual acuity by one Snellen's line. (Table 3)

In our study, it was very difficult to evaluate the visual fields in the class of patients (poor and literate) studied. Also the presence of lenticular opacities interfered with correct assessment of visual fields. There was no change in the visual fields throughout the study period in either group. (Table 4) In both the study groups we found no change in the cup disc ratio in any patients. (Table 5)

Of 25 patients who received Timolol maleate, 2 patients (8%) developed mild stinging after instillation of the drug, while in the Betaxalol hydrochloride group 8 patients (32%) complained of mild to moderate stinging for few minutes after instillation of the test drug. In either group discontinuation of the drug was not required. In Timolol maleate group 4 patients (16%) complained of discomfort and tearing was seen in 3 patients (12%). Only one patient (4%) complained of photophobia. In Betaxalol hydrochloride group one patient (4%) complained of itching and 7 patients (28%) complained of discomfort. (Table 6).

Table 1. Age and sex wise distributions of 50 patients

Age in years	Sex		Total
	Male	Female	
11-20	0	1	1
21-30	0	1	1
31-40	1	2	3
41-50	9	4	13
51-60	15	11	26
61-70	4	2	6
Total	29	21	50
Percentage	58%	52%	

Table 2. Distribution of mean IOP (in mm Hg)

Observation	Timolol maleate group	Betaxalol hydro-chloride group
Baseline	28.60	27.84
1st week	20.68	21.72
2nd week	19.92	20.98
4th week	19.58	20.62
8th week	19.24	20.26
12th week	19.92	20.62
16th week	19.94	20.28
20th week	19.96	20.28

Table 3. Changes in the visual acuity in this study

Visual acuity	Timolol maleate group		Betaxalol hydro-chloride group	
	On admis-sion	20th week	On admis-sion	20th week
6/6	2	2	3	3
6/9	6	6	5	5
6/12	2	2	4	4
6/18	4	4	3	3
6/24	3	3	2	1
6/36	2	2	1	2
6/60	2	2	4	4
FC 5 meter	1	0	1	1
FC 4 meter	0	1	1	1
FC 3 meter	1	0	0	0
FC 2 meter	1	1	1	1
FC 1 meter	0	1	0	0
PL PR (+)	1	1	0	0
Total	25	25	25	25

Table 4. Observation showing visual field changes in this study

Observa-tion	Timolol maleate group	Betaxalol hydro-chloride group
1st week	No changes	No changes
2nd week	No changes	No changes
4th week	No changes	No changes
8th week	No changes	No changes
12th week	No changes	No changes
16th week	No changes	No changes
20th week	No changes	No changes

Table 5. Observation showing optic disc changes in this study

Observa-tion	Timolol maleate group	Betaxalol hydro-chloride group
1st week	No changes	No changes
2nd week	No changes	No changes
4th week	No changes	No changes
8th week	No changes	No changes
12th week	No changes	No changes
16th week	No changes	No changes
20th week	No changes	No changes

Table 6. Ocular adverse effects in this study

Adverse effect	Timolol male-ate group	Betaxalol hydro-chloride group
Stinging or	2	8
Discomfort	4	7
Itching	0	1
Tearing	3	0
Photophobia	1	0

DISCUSSION

Medical therapy is usually the first line of approach in POAG. The mainly used drugs in the treatment of POAG are beta adrenergic blockers.[3] Beta adrenergic blockers reduce IOP by decreasing aqueous formation.[4] In this study a total of 50 patients with POAG were studied. 25 patients were treated with 0.5% Timolol maleate ophthalmic solution and 25 patients were treated with 0.5% Betaxalol hydrochloride solution.

In the follow up after 20 week, the decrease in IOP were highly significant (P<0.001) with Timolol. The decrease in IOP was 30.21%. David P. Berry et al compared topical Timolol and Betaxalol in 46 patients for 26 weeks. They found the percentage reduction of IOP was 33.2% in Timolol group.5 Robert H. Stewart et al, in their study of comparison of Timolol and Betaxalol in 29 patients found reduction of IOP by 8.4 mm Hg (29%).[6,7] These results are similar to our study.

In the follow up after 20 week, the decrease in IOP were highly significant (P<0.001) with betaxalol. The decrease in IOP was 7.56 mm Hg (27.15%). Our findings are nearer to previous studies by David P. Berry et al, who showed 28.9% reduction in IOP5 and Robert H. Stewart et al, who showed 7.6 mm Hg (26%) average reduction in Betaxalol group.[6]

At 20 weeks out of 25 patients receiving Timolol maleate 2 patients showed decrease in visual acuity by one

snellen's line. In the Betaxalol group hudrochloride group, only one patient showed decrease in visual acuity by one snellens line. Decrease in visual acuity could be attributed to progressive lenticular changes in all 3 patients. Not even a single case showed sudden loss of vision. David P. Berry et al compared 0.5% Timolol and 0.5% Betaxalol in 46 patients with POAG.[5] They did not find any visual acuity changes in both these groups. According to Robert H. Stewart et al no change in visual acuity was seen in either group in their six-month double blind comparative study of Betaxalol and timolol involving 29 patients.[6] These observations are similar to our findings. In our study there was no change in the visual fields throughout the study period in either group. Our findings are similar to other studies.

In both the study groups we found no change in the cup disc ratio in any patients. Our findings are in accordance with the previous studies.

CONCLUSION

In the light of these results, we conclude that both Timolol and Betaxalol are effective in decreasing IOP in POAG patients. The magnitude of Timolol in decreasing IOP is more as compared to Betaxalol. The selective beta 1 adrenergic inhibition of Betaxalol provides an added benefit for those patients in whom beta 2 blockade could be harmful.

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