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A Comparative Study of Clinical Efficacy of Timolol0.5% AndDorzolamide 2% Eye Drops in Primary openAngle Glaucoma

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Abstract
Introduction: *Glaucoma is recognized as a major cause of ocular morbidity. About 60.5 million people are affected by glaucoma Worldwide. Raised intra-ocular pressure (IOP) remains a strong risk factor and it has been shown that the higher the IOP at presentation, the greater the risk of developing POAG (primary open angle glaucoma)Medical treatment is the first line of management and includes the use of several classes of topical agents.*
Methods: *A prospective, randomized, comparative-efficacy study included sixty patients of primary open angle glaucoma. Efficacy was assessed as the change in IOP from baseline, visual acuity and visual field analysis for every 2 weeks for six months. Safety was assessed with adverse event rates, Ocular irritation, Ocular pain, Blurring of vision.*
Results: *The mean reduction of IOP for timolol group in both the eyes was15.55 mmHg and in the dorazolamide group it was13.47 mmHg. Visual acuity and the field of vision were same as recorded at baseline visit.Patients in the Dorzolamide group had a higher incidence of adverse events compared to the timolol group.*
Conclusion: *There was no significant difference in the reduction of IOP in either of the eyes or on an average IOP with either drugs, both can be used to reduce the IOP.Both the drugs were well tolerated with 20% more of the adverse effects seen with Dorzolamide.*
Keywords:*Glaucoma, Timolol, Dorzolamide, safety and efficacy.*

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I. Introduction

Glaucoma is recognized as a major cause of ocular morbidity Worldwide. Bilateral blindness due to this disease will be present in 4.5 million people with open angle glaucoma and rise to 5.9 million in 2020. It is estimated that 8 million Indians have glaucoma.[1] Glaucoma is the leading cause of irreversible blindness worldwide, and the second most common cause of blindness after cataract.[2,3] It is responsible for 14% of blindness worldwide.[4] According to a national survey of blindness (2001-2003), glaucoma was the third most common cause of blindness (5.8%) after cataract and refractive errors. Raised intraocular pressure remains a strong risk factor, Untreated glaucoma leads to permanent damage of the optic disc and resultant visual field loss, which can progress to blindness. If the condition is detected early enough it is possible to arrest the development or slow the progress with medication.[5] There is evidence to show that the treatment of intraocular pressure has a beneficial effect on the progress of POAG and increase the time period before the onset of blindness.[6,7]Timolol is a non-selective beta adrenergic antagonist which decreases the production of aqueous humor from the ciliary body. Dorzolamide eye drops lower the secretion of aqueous humor by inhibiting carbonic anhydrase enzyme in ciliary body.

II. Methods

The aim of this study is to compare and evaluate the clinical efficacy of topically applied timolol 0.5% eye drops versus dorzolamide 2% eye drops in the management of primary open angle glaucoma. All the cases studied were attending the outpatient department of Opthalmology, Regional eye hospital, Kakatiya Medical college While selecting the cases for the study special care was taken to include only cases of primary open angle glaucoma. Sixty cases of POAG were selected and divided equally into two groups A and B based on simple random sampling. Group A was treated with 0.5% of Timolol eye drops 2 times a day daily and group B with 2% Dorzolamide eye drops 3 times a day, daily for 6 months. Ocular improvement and effect of the drug were assessed by a follow up study done once in a fortnight throughout the study period where in the intraocular

pressure was measured using Schiotz tonometer. The visual field defect was documented by octopus and visual acuity by snellen's chart both at the commencement and at the end of the study.

III. Statistical Analysis

The data collected was tabulated and analyzed using descriptive statistical tool, mean, standard deviation, and comparison between the groups by using student 't' test . Complete analysis was carried out using Statistical package for the social sciences package.

IV. Results

Demographic and baseline characteristics

There were more males (67%) than females (33%) in the study population. Thepeak prevalence age in the group A was between 41-50years and 51-60yearswhere as for the group B it was between 51-60 years and 61-70 years.

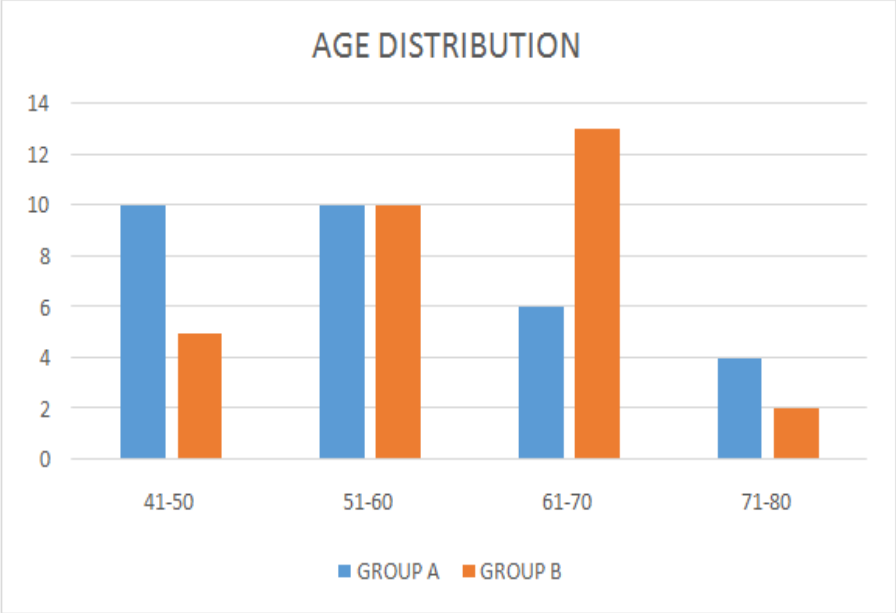

Figure 1: Graphical Representation Of The Age Distribution In The Group A And The Group B

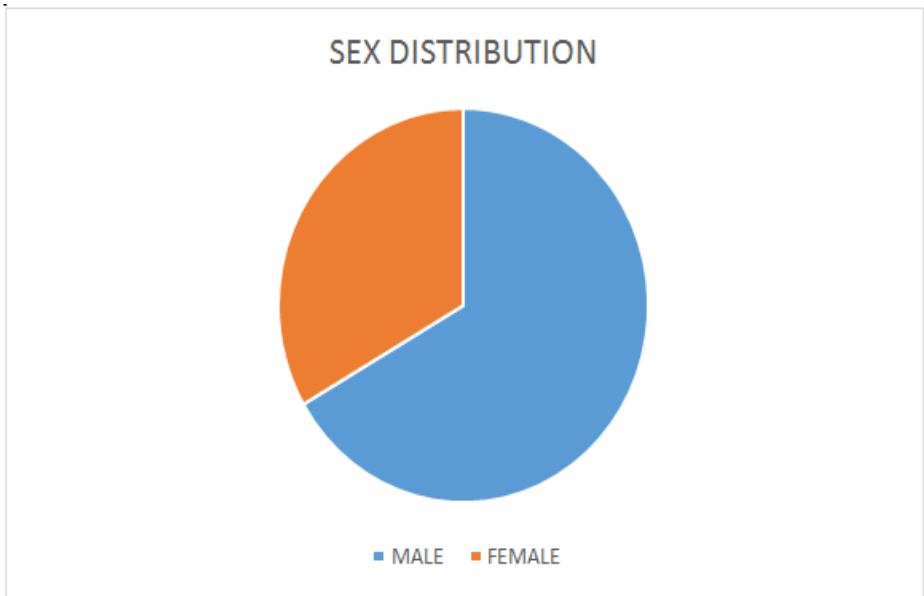

Figure 2: Graphical Representation Of The Age Distribution InBoth The Groups

Efficacy evaluation

The mean reduction of IOP for group A in both the eyes was15.55 mmHg and in the group B itwas13.47 mmHg (p 0.028).There was no significant difference in the reduction ofIOP in either of the eyes or on an average IOP with either drugs.

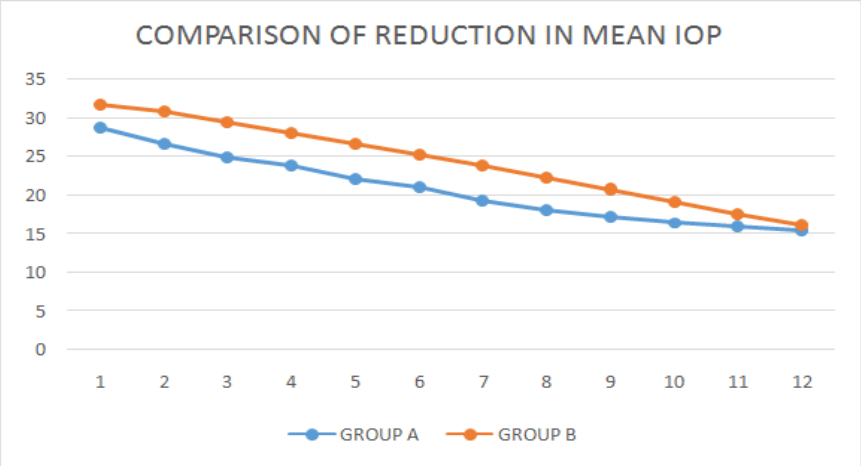

Figure 3: Graphical Representation Comparing The OverallReduction Of Iop In Timolol Group And Dorzolamide Group

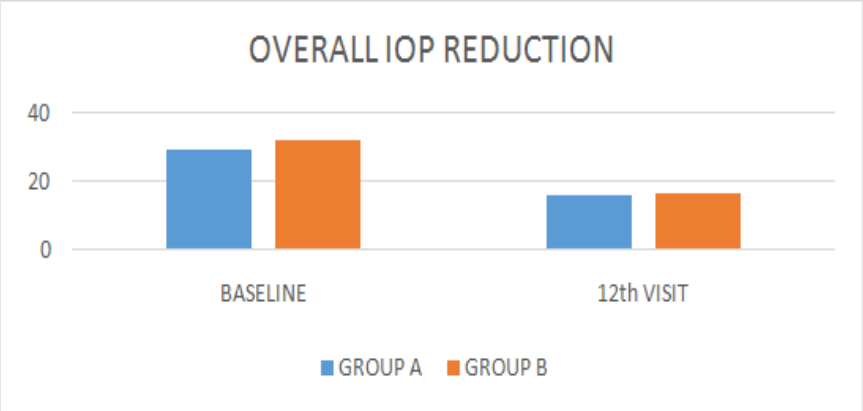

Figure 4: Shows A Graphical Representation Of TheComparative Overall Reduction In Iop From Baseline To LastVisit Between The Two Groups

Visual acuity and the field of vision at the end of 6 months; was the same inboth the groups, as what was recorded at the baseline visit

Safety evaluation

Both treatment regimens were well tolerated during the study. Patients in the group B had a higher incidence of ocular irritation (23%), pain (10%) andblurring of vision (3%) when compared to the group A which showed only ocularirritation (3%). On statistical evaluation the p value was not significant (p 0.097).

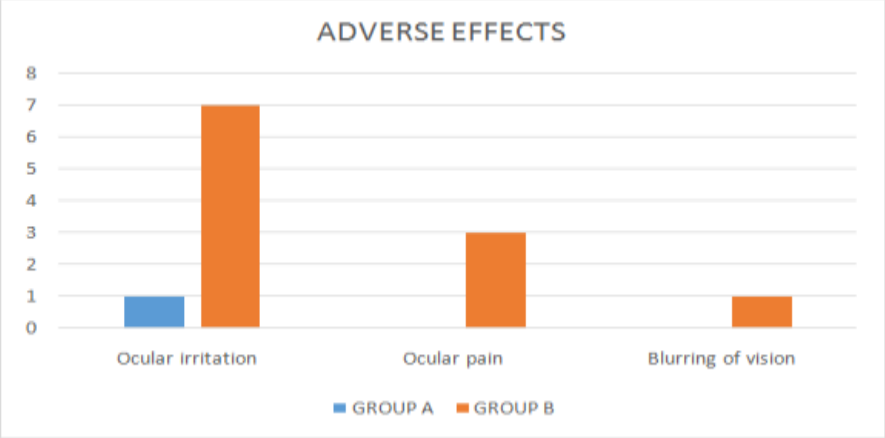

Figure 5: graphical representation of adverse effectsobserved in the two groups.

V. Discussion

This prospective, randomized, open labelled, study was conducted on 60 patients of POAG; 30 patients were on timolol 0.5% eye drops administered twice a day and the other 30 patients were on dorzolamide 2% eye drops administered thrice a day. The reduction of IOP with timolol was from 28.83 to 15.37 mmHg and for dorzolamide it was from 31.67 to 16.12 mmHg. The mean overall reduction in IOP for timolol was 15.55 mmHg whereas for dorzolamide, it was 13.47 mmHg (p 0.028). The difference in reduction of IOP is not statistically significant. The reduction in IOP with timolol is more consistent ; dorzolamide shows an inconsistent reduction. This inconsistency may be attributed to noncompliance. There were three reasons for noncompliance with dorzolamide in this study: (i) adverse effects, which are more with dorzolamide, (ii) multiple dosing regimen and

(iii) cost of dorzolamide.

Safety evaluation was another important object of this study. There were no serious side-effects observed in this study. Both the drugs were well tolerated. Dorzolamide has a higher incidence of adverse effects. Ocular irritation with timolol is 3% and with dorzolamide, it is 23%. There is no ocular pain with timolol, in contrast to the dorzolamide group where 10% of the patients suffered from ocular pain. Blurring of vision was seen in 3% of patients on dorzolamide. Although from our observations dorzolamide appears to have more adverse effects, it is statistically not significantStudies demonstrated comparable amounts of dorzolamide and timolol in the iris-ciliary body of pigmented rabbits when comparing the topical application of the fixed combination of the two drugs versus the separate dosing of the drugs. Several clinical trials have demonstrated that the fixed combination of 2% dorzolamide and 0.5% timolol is comparable to the IOP-lowering effect of these drugs dosed separately.[8]

When medical therapy has been chosen as initial treatment for open-angle glaucoma, prostaglandins are generally considered first-line therapy. Most[9,10] ,but not all[11], meta-analyses have found prostaglandins to be more effective than beta blockers, carbonic anhydrase inhibitors, and alpha adrenergic agonists for the treatment of open-angle glaucoma. In addition, initial therapy with prostaglandins has been suggested by consensus panels, in part due to the low side effect profile. Beta blockers may be more appropriate as initial therapy for those patients who cannot afford a topical prostaglandin.Combining drops from different classes (ie, beta blocker plus prostaglandin, or beta blocker plus carbonic anhydrase inhibitor) can cause a greater reduction in the intraocular pressure than monotherapy, and several drugs are available as fixed combination products. Adding a second medication is reasonable if initial monotherapy is not effectiveGlaucoma requires long term therapy, failing which there is gradual loss of vision. Loss of vision becomes a handicap for glaucoma patients, who commonly belong to the elderly age group, with a weak financial background. Treatment also has a negative impact on the cost-factor which is one of the important factors of noncompliance. Hence monotherapy with either timolol or dorzolamide would be economically effective and compliance would also be better with these drugs in a developing country like India.

VI. Conclusion

The difference of overall reduction in IOP between the two drug groups is not statistically significant. The reduction in IOP with Timolol 0.5% eye drops 2 times daily was more Gradual and consistent. The reduction in IOP with Dorzolamide 2% eye drops 3 times a day was inconsistent in comparison to Timolol. Both the drugs were well tolerated with 20% more of the adverse effects seen with Dorzolamide, although this was not statistically significant. Both the drugs can be used to reduce the IOP efficiently in patients with POAG, keeping in mind that the ultimate goal in POAG is to reduce the IOP, to prevent further damage to the optic nerve causing loss of vision.

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