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# A Prospective Comparative Study of Efficacy of Topical Anti – Glaucoma Drugs in Primary Open Angle Glaucoma.

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## ABSTRACT

**Background:** Glaucoma is an ischemic optic neuropathy comprising of raised intraocular pressure, optic disc changes and visual field defects. Due to fear of loss of vision, the therapy of Primary Open Angle Glaucoma (POAG) targets lowering the IOP by either medical or surgical means. The aim of the study is to compare the reducing efficacy of IOP using Dorzolamide and Latanoprost topical eye drops in patients with Primary open angle glaucoma. **Methods:** The study was conducted in the Department of Ophthalmology, Teerthankar Mahaveer Medical College, TMU, Moradabad. Sixty patients were recruited for the study and divided into two groups of 30 each. Group D were administered with Dorzolamide 2% eye drops thrice daily while Group L received Latanoprost 0.005%eye drops once daily. **Results:** Out of all sixty patients, 56.67% belong to 41-60 years of age group. 28.33% of the patients were of more than 61 years of age and only 9 patients i.e. 15% were of between 20-40 year of age. The mean baseline IOP in Group D was 26.60 ± 2.91 mmHg and in Group L was 26.82 ± 2.23 mmHg (P=0.22). The mean IOP gradually decreases until 12th week in both the groups and the results were comparable in between the groups. The percent change in IOP in Group D was 29.97% and in Group L was 38.82%. **Conclusion:** Although both (latanoprost and dorzolamide) drugs were well tolerated by all the patients but the efficacy in decreasing IOP is superior with latanoprost.

***Keywords:*** Dorzolamide, Glaucoma, Latanoprost.

## INTRODUCTION

An ischemic optic neuropathy consisting of three entities (raised intraocular pressure, optic disc changes and visual field defects) is known as Glaucoma. However, Intra-ocular pressure (IOP) is the most modifiable risk factor, but the aim of Anti-Glaucoma treatment is not only focussed on decreasing the IOP but also optimisation and prevention of visual function is also important during the course of therapy.

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According to The World Health Organization, "glaucoma accounted for 2 percent of visual impairment and 8 percent of global blindness in 2010, and the number of glaucoma patients is estimated to increase due to a growing population".[1] Due to fear of loss of vision, the therapy of Primary Open Angle Glaucoma (POAG) targets lowering the IOP by either medical or surgical means.[2]

Due to the introduction of newer agents for the treatment of POAG and thereby reducing IOP, controlled clinical trials are required for the assessment of relative efficacy and safety of anti-glaucoma agents.[3] Dorzolamide 2% (topical carbonic anhydrase inhibitor) is instilled three times a day thereby causing sustained reduction of the intraocular pressure (IOP) due to reduction in the flow of aqueous humor.[4]

Latanoprost 0.005% (prostaglandin analogue), a potent ocular hypotensive agent is instilled once daily and its results in the reduction of IOP is almost comparable to Timolol.[5] The mechanism of action of latanoprost is induced by increased uveoscleral outflow.[6]

The aim of the study is to compare the reducing efficacy of IOP using above mentioned drugs like Dorzolamide 2% and Latanoprost 0.005% topical eye drops in patients with Primary open angle glaucoma.

## MATERIALS AND METHODS

The study was conducted in the Department of Ophthalmology, Teerthankar Mahaveer Medical College, TMU, Moradabad from June 2016 – October 2016. The patients with the diagnosis of primary open angle glaucoma of either sex and between 30-65 years of age were included in the

study. Exclusion criteria included any patient with angle closure glaucoma, previous surgeries or laser with in preceding year, patients who had experienced severe ocular trauma, patients who had corneal infections within preceding 6 months, patients with congenital glaucoma, woman of child bearing age, patients with bronchial asthma, bronchospasm, Renal acidosis, any drug allergy and congestive pulmonary disease.

The power of the study implied 27 patients in each group and including 10% as drop out rate, 30 patients were included in the study. Randomisation was performed using chit and box method and the patients were divided into two groups of 30 each.

Group D (30 patients): Dorzolamide 2% eye drops thrice daily.

Group L (30 patients): Latanoprost 0.005% eye drops once daily.

All patients after due consent underwent complete examination of both eyes which included slit lamp biomicroscopy, Intraocular pressure (IOP) measurement by Goldman's applanation tonometer, Snellen's Visual acuity, Gonioscopy, B scan, Indirect Ophthalmoscopy and Humphry visual field analyser. The patients were followed up at the end of 1st, 2nd, 4 th, 8 th and 12th week.

Statistical Analysis: The data was analysed using SPSS latest version. All parametric data was analysed using Student T Test and non-parametric data using Chi-square test. A p value of less than 0.05 was taken as significant.

The data was analysed by simple statistical methods.

## RESULTS

**Age Distribution:** Out of all sixty patients, 56.67% belong to 41-60 years of age group. 28.33% of the patients were of more than 61 years of age and only 9 patients i.e. 15% were of between 20-40 year of age.

**Table 1: Age Distribution of all patients.**

| Age Distribution (years) | Group D | Group L | Total |
|---|---|---|---|
| 20-40 | 4 (13.33%) | 5 (16.67%) | 9 (15%) |
| 41-60 | 18 (60%) | 16 (53.33%) | 34 (56.67%) |
| > 61 | 8 (26.67%) | 9 (30%) | 17 (28.33%) |
| Total | 30 (100%) | 30 (100%) | 60 (100%) |

**Sex Distribution:** Group D comprises 18 patients as males and 12 patients as females whereas male to female ratio in Group L was 19 and 11 respectively. In whole, 61.67% of the patients were males and 38.33% of the patients were females.

**Table 2: Sex Distribution of all patients.**

| Sex Distribution | Group D | Group L | Total |
|---|---|---|---|
| Males | 18 (60%) | 19 (63.33%) | 37 (61.67%) |
| Females | 12 (40%) | 11 (36.67%) | 23 (38.33%) |
| Total | 30 (100 %) | 30 (100 %) | 60 (100 %) |

**Best Corrected Vison (BCVA) in 2 Groups:** The BCVA range is 6/6-6/12 to 6/60 or less. Out of 60 patients in both the groups, the maximum number of patients had BCVA of 6/6-6/12. Any of the group did not show any change in the visual acuity at the end of the study period.

**Table 3: Best corrected visual acuity in Group D.**

| BCVA | Right Eye | | Left Eye | |
|---|---|---|---|---|
| | Pre Study | Post Study | Pre Study | Post Study |
| 6/6 – 6/12 | 18 | 18 | 19 | 19 |
| 6/18 – 6/36 | 8 | 8 | 8 | 8 |
| 6/60 and less | 4 | 4 | 3 | 3 |

**Table 4: Best corrected visual acuity in Group L.**

| BCVA | Right Eye | | Left Eye | |
|---|---|---|---|---|
| | Pre Study | Post Study | Pre Study | Post Study |
| 6/6 – 6/12 | 22 | 22 | 20 | 20 |
| 6/18 – 6/36 | 8 | 8 | 9 | 9 |
| 6/60 and less | - | - | 1 | 1 |

**Mean IOP during the study period:** The mean baseline IOP in Group D was 26.60 ± 2.91 mmHg and in Group L was 26.82 ± 2.23 mmHg (P=0.22). The mean IOP gradually decreases until 12$^{th}$ week in both the groups and the results were comparable in between the groups. The percent change in IOP in Group D was 29.97% and in Group L was 38.82%.

**Table 5: Mean IOP during the study period.**

| Study Period | Group D | | Group L | | P value |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| Baseline | 26.60 | 2.91 | 26.82 | 2.23 | 0.22 |
| 1$^{st}$ week | 23.45 | 1.87 | 24.19 | 2.06 | 0.15 |
| 2$^{nd}$ week | 20.95 | 2.11 | 19.18 | 1.93 | 0.67 |
| 4$^{th}$ week | 18.83 | 2.03 | 17.07 | 1.93 | 0.14 |
| 8$^{th}$ week | 17.71 | 1.79 | 16.62 | 2.01 | 0.86 |
| 12$^{th}$ week | 17.48 | 1.83 | 16.77 | 1.82 | 0.54 |
| Percent Change in IOP | 29.97% | | 38.82% | | - |

**Outcome in Both Eyes:** 90% of the patients had complete success in Group D in both the eyes while 86.67% of the patients had the same in Group L. Partial Success and Partial failure was observed in 6.67% and 3.33% of the patients in Group D while the same was observed in Group L IN 6.67% And 6.67% respectively. Complete failure is not seen in any Group.

## DISCUSSION

The present study was conducted to compare the efficacy/side effects of two recently introduced drugs for treatment of open angle glaucoma. Blinding could not be possible as the eye drops used in the study has different viscosity and different regimes of administration.

**Table 6: Outcome in Both Eyes.**

| Outcome | Group D | | Group L | |
|---|---|---|---|---|
| | Right Eye | Left Eye | Right Eye | Left Eye |
| Complete Success | 27 (90%) | 27 (90%) | 26 (86.67%) | 26 (86.67%) |
| Partial Success | 2 (6.67%) | 2 (6.67%) | 2 (6.67%) | 2 (6.67%) |
| Partial Failure | 1 (3.33%) | 1 (3.33%) | 2 (6.67%) | 2 (6.67%) |
| Complete Failure | - | - | - | - |

The commonest age of presentation of POAG is in the patients above 40 years of age group. This supports our study as we encountered 56.67% of the patients between 41-60 year of age group. "The local derived prevalence estimate for POAG was 978 per 100 000 people aged 40–89 years compared with the expected prevalence from a published model of 1230 people per 100 000 people aged 40–89 years." [7,8]

Out of 60 patients, 61.67% were males and 38.33% were females. This is also supported by the previous data as the prevalence of POAG was higher in men than in women.5,6

The Best corrected Vision Acuity was also observed pre and post study and our study revealed no change in any of the patients.[9]

In this study highest reduction of IOP (38.82%) is seen in Group L (Latanoprost), when compared to 29.97% in Group D (Dorzolamide). Once daily administration of Latanoprost was found to be safe and effective.[10] We observed maximal IOP reduction within 8-12 hours after the administration of Latanoprost 0.005%. The IOP remained below the pretreatment level for at least 24 hours post administartion. In previous studies, comparison of the efficacy of latanoprost with 0.5% timolol had revealed that the reduction of diurnal IOP by Latanoprost was significantly larger that Timolol.[11-13] However, reduction of IOP by Dorzolamide is less than that of Timolol and it can be explained by the fact that the above mentioned drug has weaker aqueous suppressive effect compared with timolol.[14] Thus, it can be expected beforehand that latanoprost should be the more effective drug than dorzolamide/timolol in terms of IOP reduction and this assumption which is confirmed in the present study.

Upon diurnal measurements of IOP, administration of Latanoprost at the evening induces a sustained reduction of IOP.[15] During our study period, almost all of the patients has some kind of visual field defects during the inclusion and period of study and we observed no change in the field of vision at the end of the study. In 24 hour IOP measurements, Latanoprost administered once a day in the evening induces a constant IOP reduction, although the hypotensive effect seems to be greatest during the day.

No significant ocular complications were observed in any of the study groups during the study period. None of the patients experienced iris pigmentation during the study based on slit lamp examination.

Although we observed good compliance among the patients of both the groups, but the patients were more comfortable by the instillation of Latanoprost eye drops as they had to administer it only once a day.

## CONCLUSION

From our study we concluded that although both (latanoprost and dorzolamide) drugs were well tolerated by all the patients but the efficacy in decreasing IOP is superior with latanoprost.

Moreover, nature and progression of the disease is to be educated to all patients by ophthalmologists. To prolong useful vision and for the prevention of blindness, regular follow up to ophthalmologists are advised.

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