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Efficiency of Bimatoprost 0.03% versus Bimatoprost 0.01% in cases of Primary Open Angle Glaucoma and Ocular Hypertension

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ABSTRACT

Objective – A prospective, open, randomized, parallel group, comparative study to evaluate the efficacy and side effect profile of bimatoprost 0.03% versus bimatoprost 0.01% in cases of primary open angle glaucoma (POAG) and ocular hypertension. Materials and Methods – 60 patients of POAG or ocular hypertension were selected. Patients were then randomized into two groups (group I, II) and received bimatoprost 0.03% and bimatoprost 0.01% respectively. Side effect profile was monitored in patients. At the end of a period of 3 months, effectiveness of the drugs was calculated in terms of mm Hg fall in mean intraocular pressure. Observations thus made were subjected to appropriate statistical tests.
Results – In group I, the mean pre-treatment IOP, mean post-treatment IOP and mean reduction in IOP were 26.78±2.01, 17.46±1.36 and 9.32 (34.31%). In group II the mean pre-treatment IOP, mean post-treatment IOP and mean reduction in IOP were 25.66±1.44, 16.47±1.40 and 9.19 (33.13%). Conclusion – From the study we concluded that there is no significant difference in IOP lowering efficacy between the two groups but bimatoprost 0.01% was associated with less side effects than bimatoprost 0.03%.

KEYWORDS IOP; glaucoma; prostaglandin analogues; bimatoprost

Introduction

Glaucoma is an eye disorder in which the intraocular pressure (IOP) is too high for the health of the eye as a result of which the optic disc becomes atrophic and visual fields develop characteristic nerve fibre defects. [1] It affects more than 67 million people worldwide, out of which approximately 10% or 6.6 million are estimated to be blind, making it the foremost cause of irreversible blindness worldwide, second only to cataract as the most common overall cause of blindness. [2]

The normal value of IOP ranges from 10-21mmHg. In glaucoma, there is sustained increase in IOP, which can be due to an increase in the formation of the aqueous humour, a difficulty in its drainage or higher pressure in the episcleral veins of the eye. [3] Primary open angle glaucoma (POAG) by definition is, IOP consistently over 21 mmHg in at least one eye, with an open anterior chamber angle and typical glaucomatous visual field and/or optic nerve head alterations. Ocular hypertension is an IOP consistently above 21 mmHg in the absence of the other two findings of POAG. [3] Due to its lack of symptoms and slow course, POAG is an often under-diagnosed disease. Because the visual deterioration in POAG may be slowed but not completely halted by treatment, it is important that this condition is appropriately diagnosed early in its course. [4]

The risk of damage to the nerve fibres and resulting visual loss for the affected patient can be decreased by timely reduction of IOP to the normal range, and in many cases may even prevent further damage. [5] Any therapeutic intervention that controls the IOP will thus be an effective treatment for glaucoma and currently, medical treatment is the first approach. [6]

Prostaglandin (PG) analogues, as a class of drugs, lower IOP by increasing the uveoscleral outflow of aqueous humour in the eye. [7] They are effective in lowering IOP and have the added advantage of requiring only once a day administration. Currently available drugs in this class include bimatoprost, latanoprost and travoprost. [8] Bimatoprost is a new ocular hypotensive prostaglandin derivative that lowers IOP in glaucomatous, ocular hypertensive and even normal eyes. Its mechanism of action is through enhancement of the trabecular outflow pathway and additionally, an increase in the uveoscleral outflow and lowering of pressure in episcleral veins. [9]

As bimatoprost is available in various concentrations in the market currently, such as bimatoprost 0.01% and bimatoprost 0.03% among others, our study was undertaken to compare the efficacy of the two commonly available drug concentrations and their side – effects profile in an Indian population.

Materials and Methods

In this prospective, open, randomized, parallel group, comparative study, 60 patients of POAG or ocular hypertension visiting the Department of Ophthalmology, Govt. Medical College, Patiala were selected. Due permission from the ethical committee of the institute was obtained. Patients having diagnosed unilateral/bilateral primary open angle glaucoma or ocular hypertension, IOP >21mm Hg and less than 32mmHg, and over 18 years of age were included after obtaining a written informed consent. Exclusion criteria were history of angle closure glaucoma, intraocular surgery within 6 months prior to study, closed anterior chamber angle, secondary glaucoma, ocular inflammation, ocular infection, pregnant and lactating females, patient unable to attend follow up, and any known sensitivity to drugs. Patients already on any other anti-glaucoma treatment were made to undergo an appropriate washout period. Patients having bilateral disease were treated for both their eyes but only their right eyes were taken up for study.

Patients once selected were then randomised into two groups of 30 patients each with group I given bimatoprost 0.03% (Lumigan 0.03%) once daily at 8:00 pm and group II using bimatoprost 0.01% (Lumigan 0.01%) once daily at 8:00 pm.The baseline visit was recorded as day 0 after which patients came for follow up visits on week 4, week 8, and week 12. IOP was measured on day 0 and on subse-

quent visits at 8:00 am, 12:00 pm and 4:00 pm by Goldman applanation tonometry. Examination and investigations for baseline data and each follow – up visit included medical history, history of drug allergy, ocular history, complete ocular examination including visual acuity, IOP under treatment, optic disc examination, gonioscopy and tonometry.

Results

In the patients included in our study, the mean age was 59.4 years. From the total patients in the study, in both groups, 60% of the patients were male and 40% were female. There were no statistically significant differences between the two groups regarding all the demographic parameters.

In group I the IOP at baseline was 26.78±2.01 mmHg, while IOP at week 4, week 8 and week 12 was 17.59±1.15, 16.89±1.16, and 17.46±1.36 mmHg, respectively. The mean reduction in IOP in group I was 9.32 mmHg (34.31%). The change in IOP at each follow – up visit was statistically significant as compared with baseline value.

In group II the mean baseline IOP was 25.66±1.44 mmHg, while IOP at week 4, week 8 and week 12 was 18.54±1.65, 17.53±1.38, 16.47±1.40 mmHg, respectively. The mean IOP reduction was 9.19 mmHg (33.13%). IOP lowering at each follow – up visit was significant statistically when compared to the baseline visit.

The side effects recorded with bimatoprost 0.01% were less than with bimatoprost 0.03% with conjuctival hyperaemia occurring in 26.70% cases in group I versus 36.70% cases in group II.

The difference between mean IOP of the two drugs is within ± 1 mmHg. So the two concentrations are equally effective as per lowering of IOP is concerned. The difference in IOP lowering in both the groups was statistically non-significant. The study was carried out for 12 weeks, so some of the side effects like eyelash growth were not seen in these patients. A longer study is required to comment on such variables of the drugs.

Discussion

In glaucoma, IOP levels once considered to be safe now have been shown not to prevent progressive visual loss in many patients. This supports increasingly aggressive efforts to reduce IOP levels to as low as safely possible, especially in patients with severe or rapidly progressing disease. [10]

Katz et al [11] found that bimatoprost 0.01%, was equivalent in efficacy to bimatoprost 0.03% based on predetermined criteria and that the overall incidence of treatment-related adverse events was reduced significantly in the bimatoprost 0.01% group as compared with the bimatoprost 0.03% group (P < or =.034). Yucela et al [12] in their study found that the mean IOP reduction seen in bimatoprost group was 8.50±5.3 mm of Hg i.e. 34.46%. Chander et al [13] (2013) concluded that the mean IOP reduction seen in bimatoprost group was 9.07 mm of Hg i.e.34.94%. Thus the findings of previously conducted studies reflect a trend similar to the observations of our study.

IOP reductions of bimatoprost 0.03% and bimatoprost 0.01% both were clinically significant at 4, 8 and 12 weeks which were 9.32 mm Hg (34.31%) and 9.19 mm Hg (33.13%), respectively at the end of the study period. Between the two study groups, there was no significant difference in IOP lowering amongst the two concentrations of bimatoprost. Percentage of ocular hyperemia was higher in patients on bimatoprost 0.03% (36.7%) as compared to bimatoprost 0.01% (26.7%). Other side effects like eye irritation and eyelid erythema were also more. Thus to conclude, there is no significant difference in IOP lowering efficacy between the two groups but bimatoprost 0.01% is associated with lesser side effects than bimatoprost 0.03%.

The authors reveal no conflict of interest.

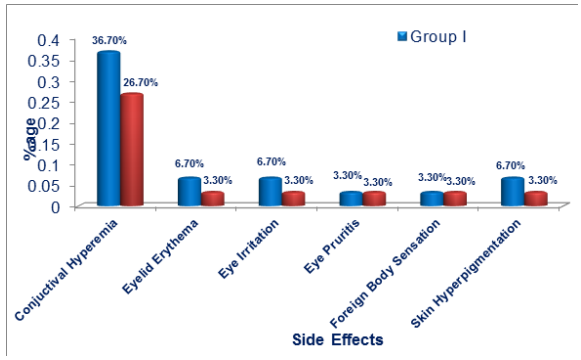

FIG 1 - SIDE EFFECTS IN GROUP I (BIMATOPROST 0.03%) AND GROUP II (BIMATOPROST 0.01%)

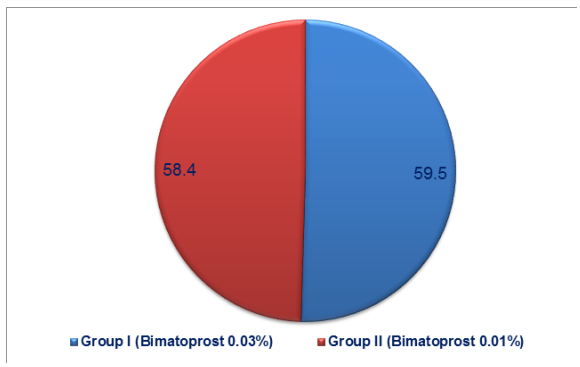

FIG 2 – BAR DIAGRAM SHOWING AGE DISTRIBUTION IN THE GROUPS

TABLE 1 - MEAN IOP IN GROUP I (BIMATOPROST 0.03%) AT DIFFERENT POINT OF TIME

Visit	At 8:00 am Mean±SD (mmHg)	At 12:00 pm Mean±SD (mmHg)	At 4:00 pm Mean±SD (mmHg)	Average of Visit (mmHg)
Baseline	27.90±2.02	26.87±2.01	25.73±1.96	26.78±2.00
Week 4	18.20±1.12	17.30±1.21	17.27±1.14	17.59±1.15
Week 8	17.53±1.17	16.60±1.22	16.53±1.14	16.89±1.16
Week 12	18.13±1.36	17.23±1.38	17.03±1.40	17.47±1.36

TABLE-2 MEAN IOP IN GROUP II (BIMATOPROST 0.01%) AT DIFFERENT POINT OF TIME

Visit	At 8:00 am Mean±SD (mmHg)	At 12:00 pm Mean±SD (mmHg)	At 4:00 pm Mean±SD (mmHg)	Average of Visit (mmHg)
Baseline	26.07±1.44	25.23±1.54	25.44±1.52	25.66±1.44
Week 4	19.00±1.76	18.20±1.69	18.43±1.63	18.54±1.65
Week 8	17.97±1.38	17.17±1.55	17.47±1.38	17.53±1.38
Week 12	16.67±1.37	16.57±1.43	16.67±1.46	16.47±1.40

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