

Comparison of Efficacy of Latanoprost 0.005% with Bimatoprost 0.01% in Patients with Open Angle Glaucoma

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ABSTRACT

Objective: To compare the mean change in intraocular pressure with Latanoprost 0.005% and Bimatoprost 0.01% in patients with open angle glaucoma

Study Design: Randomized open clinical trial.

Place and Duration of Study: This study was conducted at the outpatient department of Ophthalmology, Bahawal Victoria Hospital, Bahawalpur from December, 2015 to November 2016.

Materials and Methods: 60 diagnosed patients of open angle glaucoma age group 20 to 50 years were included coming to eye OPD having intraocular pressure greater than 20 millimeter of mercury at 8:00am. The patients were allotted group A or group B by the lottery method. The group A was considered as Latanoprost group while group B as Bimatoprost group. Group A was treated with Latanoprost 0.005% while the group B with Bimatoprost 0.01% as mono-therapy with one drop daily in conjunctival sac as topical administration at 05.00 p.m for 29 days, beginning on day 0 of the study. Follow up visits were conducted on day 30 at 8 am and IOP of both eyes were measured and mean reduction in IOP was noted.

Results: Difference between base line and day 30 IOP right eye of male patients in group A was 6.75+/- 0.52mmHg while in group B was 7.58 +/- 0.24mmHg (P=0.001) and the difference between base line and day 30 IOP Left eye of male patients in group A was 6.60 +/-0.70mmHg while in group B was 7.28 +/- 0.38mmHg. (P=0.0031)

The difference between base line and day 30 IOP right eye of female patients in group A was 6.18 +/- 0.01mmHg while in group B was 7.06 +/- 0.06mmHg (P=0.0001) & difference between base line and day 30 IOP Left eye of female patients in group A was 6.36 +/- 0.10 mmHg while in group B was observed 8.0 +/- 0.31mmHg. (P=0.001)

Conclusion: Current study showed that mean change in reducing the intraocular pressure with Bimatoprost 0.001% is more significant than Latanoprost 0.005%

Key Words: Glaucoma, Intraocular pressure, Latanoprost 0.005%, Bimatoprost 0.01%, Quality of Life, Health related quality of life.

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INTRODUCTION

It is difficult to define glaucoma precisely, partly because the term encompasses a diverse group of disorders. All forms of the disease have in common a characteristic potentially progressive optic neuropathy that is associated with visual field loss as damage progresses, and in which IOP is key modifiable factor¹. Three large phase-III clinical trial with Latanoprost 0.005% have been performed in Europe (Scandinavia & UK) and USA²⁻⁴ In the Scandinavian and the U.S studies Latanoprost 0.005% was significantly more effective than timolol.

The IOP lowering activity of Bimatoprost 0.01% has been evaluated in the laser-induced ocular hypertensive monkey model,⁵ and the top of the dose response curve was determined to be 0.004%.⁶ On the basis of these analysis, prostaglandin analogues are now being used as primary therapy for open angle glaucoma.

Prostaglandin analogues lower intra-ocular pressure by increasing the uveoscleral outflow of aqueous humor.⁷ Latanoprost 0.005% is phenyl-substituted prostaglandin analogue. Bimatoprost 0.01% is a topical ocular isopropyl ester prodrug, that is rapidly hydrolyzed by esterases in the cornea to the biologically active, free acid. Bimatoprost 0.01% has greater affinity for the prostaglandin F(P) receptor than either PGF2 α or Latanoprost 0.005%.⁸ Their concentration in aqueous humor peaks at 2 hours and declines over the next 24 hours. Systemically they are rapidly metabolized and have plasma half life of about 17 minutes. These pharmacokinetics are almost ideal for an ocular drug. The intraocular pressure lowering effects of prostaglandin analogue is not only well maintained but an additional effect is seen after 2-4 weeks. This delayed effects may be due to the specific mechanism

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of action of prostaglandins, which increase uveoscleral outflow, and recent studies show that they induce changes in the extra-cellular matrix of the ciliary muscle of the eye.⁹ These changes may facilitate aqueous humor outflow through the ciliary muscle (uveoscleral route). This process might possibly not to be completed in 2 weeks, which would explain the additional decrease in IOP after some months of treatment with prostaglandin analogues. An additional benefit is that monotherapy definitely improves patient compliance. There is very little national and local data available to compare the two drugs i.e latanoprost versus bimatoprost in reducing IOP in patients with primary open angle glaucoma.

MATERIALS AND METHODS

This study was conducted at the outpatient department of Ophthalmology, Bahawal Victoria Hospital, Bahawalpur from December 2015 to November 2016. Approval from the institute’s ethical and research committee was taken for this study. Informed consent was sought from all the study participants. By adopting non probability consecutive sampling technique, we enrolled a total of 60 patients newly diagnosed (within a week duration) of both gender and age 20-50 years and divided into two groups (30 in each group) having intraocular pressure greater than 20 millimeter of mercury at 8 am. Patient must be free of ocular medication at the time of enrollment and was not using any parasympathomimetics or carbonic anhydrase inhibitors for the last 4 days, adrenergic agonists for the last 2 weeks and topical beta-blockers for the last 4 weeks. Patients having previous intraocular surgery, secondary glaucomas, primary narrow angle glaucoma, known hypersensitivity to any component in the study medications, any systemic drug affecting IOP, any uncontrolled systemic disease or severe cardiovascular disease and any previous use of latanoprost / Bimatoprost, patients were excluded.

Patients were diagnosed on the basis of ocular and medical history, recording cup disc ratio, visual field examination with automated perimetry and OCT for retinal nerve fiber layer and intraocular pressure with Goldman Applanation tonometry.

The patients were allotted group A or group B by the lottery method. Their demographic data as well as brief history was taken. The group A was considered as Latanoprost group while group B as Bimatoprost group. Baseline IOP measurements were made at 8 am on day 0. IOP was measured in mm Hg with an applanation tonometer affixed to a slit lamp from both eyes and mean IOP values from both eyes were calculated. Group A was treated with Latanoprost 0.005% while group B with Bimatoprost 0.01% as mono-therapy with one drop daily in conjunctival sac as topical administration at 05.00 pm for 29 days, beginning on day 0 of the study. Follow up visits were conducted on

day 30 at 8 am and IOP of both eyes was measured and mean reduction in IOP was noted.

All the information’s were entered in the SPSS version 17.0 and analyzed through its statistical package. The mean and the standard deviation were calculated for the age and IOP at baseline and on day-30. Stratification with respect to age, gender, side of eye was done. Chi. Square test was applied to qualitative data (Gender) and t –test was applied to quantitative data (age, baseline IOP, day-30 IOP).

RESULTS

A total 60 patients were included in two study groups (each consisting of 30 patients), group A was treated with Latanoprost 0.005% and the group B was treated with Bimatoprost 0.01%.

The age varied from 20 to 50 years in group A. The mean age in group A was 32.0 +/- 4.39 years and in group B was 30.4 +/- 4.9 years (P=0.188). Among group A 16 (60%) male and 14 (40%) female and group B 14 (40%) male and 16 (60) female. (P=0.6056)

The Difference of IOP (base line and on day 30) Right Eye of Male Patients as shown in Table 1 is significant (P=0.001). Difference of IOP (base line and on day 30) Left Eye of Male Patients as shown in Table 2 is significant (P=0.0031). Difference of IOP (base line and on day 30) Right Eye of Female Patients as shown in Table 3 is significant (P=0.0001). Difference of IOP (base line and on day 30) Left Eye of Female Patients as shown in Table 4 is significant (P=0.001).

Table No.1: Difference of IOP (base line and on day 30) Right Eye of Male Patients

Group	Mean and S.D of Base Line IOP	Mean and S.D. of day 30 IOP	Difference between base line and day 30 IOP and S.D
Latanoprost 0.005%	26.09±0.75	19.34±1.27	6.75±0.52
Bimatoprost 0.01%	26.25±1.12	18.67±1.36	7.58±0.24

Table No.2: Difference of IOP (base line and on day 30) Left Eye of Male Patients

Group	Mean and S.D of Base Line IOP	Mean and S.D. of day 30 IOP	Difference between base line and day 30 IOP and S.D
Latanoprost 0.005%	25.81±1.09	19.21±1.79	6.60±0.70
Bimatoprost 0.01%	26.03±1.08	18.75±0.70	7.28±0.38

Difference of IOP (Baseline and on day 30) Rt Eye of Age Group 20-35 years as shown in Table 5 is significant (P=0.0001). Difference of IOP (Baseline and on day 30) Lt Eye of Age Group 20-35 years as shown in Table 6 is significant (P=0.0001).

Table No.3: Difference of IOP (base line and on day 30) Right Eye of Female Patients

Group	Mean and S.D of Base Line IOP	Mean and S.D. of day 30 IOP	Difference between base line and day 30 IOP and S.D
Latanoprost 0.005%	25.78±1.41	19.06±1.40	6.18±0.01
Bimatoprost 0.01%	25.75±1.42	18.09±1.36	7.06±0.06

Table No.4: Difference of IOP (base line and on day 30) Left Eye of Female Patients

Group	Mean and S.D of Base Line IOP	Mean and S.D. of day 30 IOP	Difference between base line and day 30 IOP and S.D
Latanoprost 0.005%	26.07±1.07	19.71±0.97	6.36±0.10
Bimatoprost 0.01%	26.18±1.42	18.18±1.73	8.0±0.31

Table No.5: Difference of IOP (Baseline and on day 30) Rt Eye of Age Group 20-35 years

Group	Mean and S.D of Base Line IOP	Mean and S.D. of day 30 IOP	Difference between base line and day 30 IOP and S.D
Latanoprost 0.005%	25.59±1.06	19.29±1.30	6.30±0.24
Bimatoprost 0.01%	26.04±1.13	18.31±1.46	7.73±0.33

Table No.6: Difference of IOP (Baseline and on day 30) Lt Eye of Age Group 20-35 years

Group	Mean and S.D of Base Line IOP	Mean and S.D. of day 30 IOP	Difference between base line and day 30 IOP and S.D
Latanoprost 0.005%	25.72±1.03	19.18±1.58	6.54±0.55
Bimatoprost 0.01%	26.33±1.23	17.93±1.30	8.40±0.07

Table No.7: Difference of IOP (Baseline and on day 30) Rt Eye of Age Group 36-50 years

Group	Mean and S.D of Base Line IOP	Mean and S.D. of day 30 IOP	Difference between base line and day 30 IOP and S.D
Latanoprost 0.005%	25.59±1.22	18.62±1.27	6.97±0.05
Bimatoprost 0.01%	26.00±0.89	18.00±0.89	8.00±0.00

Difference of IOP (Baseline and on day 30) Rt Eye of Age Group 36-50 years as shown in Table 7 is significant (P=0.0001). Difference of IOP (Baseline and

on day 30) Lt Eye of Age Group 36-50 years as shown in Table 8 is significant (P=0.0001).

Table No.8: Difference of IOP (Baseline and on day 30) Lt Eye of Age Group 36-50 years

Group	Mean and S.D of Base Line IOP	Mean and S.D. of day 30 IOP	Difference between base line and day 30 IOP and S.D
Latanoprost 0.005%	25.37±0.95	19.25±1.00	6.12±0.05
Bimatoprost 0.01%	26.50±0.44	18.00±0.89	8.50±0.45

DISCUSSION

Glaucoma is a group of eye diseases which result in damage to the optic nerve and cause vision loss. The most common type is open-angle glaucoma with less common types including closed-angle glaucoma and normal-tension glaucoma. Risk factors for glaucoma include increased intraocular pressure in the eye, a family history of the condition, and high blood pressure.^[10] but intraocular pressure is the only factor can be modified at present. If treated early it is possible to slow or stop the progression of disease with medication,^{[10][12]}

The goal of this treatment is to decrease eye pressure¹¹. Worldwide, glaucoma is the second-leading cause of blindness after Cataract^{11,13}.

Prostaglandin analogs, such as latanoprost and bimatoprost increase uveoscleral outflow of aqueous humor. Bimatoprost also increases trabecular outflow.^[14] However, outcome data have been lacking that there is an unequivocally link between lowering of intraocular pressure and preserving vision¹⁵. A recent randomized trial¹⁶ showed that topical ocular hypotensive medication was effective in delaying or preventing the onset of open-angle glaucoma in patients with elevated intraocular pressure. Two recent trials^{17,18} showed that lowering of intraocular pressure decreased glaucoma progression. The current study was designed to compare the effects of drugs Latanoprost 0.005% and Bimatoprost 0.01% as primary monotherapy for open angle glaucoma. The results of this study showed that Bimatoprost 0.01% is better than Latanoprost 0.005% in lowering of intraocular pressure in follow up visits of all patients with open angle glaucoma. The results are similar with international studies as per statistical data analysis.

In this study, a total 60 patients were included in two study groups (each consisting of 30 patients), group A was treated with Latanoprost 0.005% and the Group B was treated with Bimatoprost 0.01%. The mean age in group A was found 32.0 years and in group B was 30.4 years. Difference between base line and day 30 IOP right eye of male patients in group A was 6.75+/-

0.52mmHg while in group B was 7.58 +/- 0.24mmHg (P=0.001) and the difference between base line and day 30 IOP Left eye of male patients in group A was 6.60 +/-0.70mmHg while in group B was 7.28 +/- 0.38mmHg. (P=0.0031)

The difference between base line and day 30 IOP right eye of female patients in group A was 6.18 +/- 0.01mmHg while in group B was 7.06 +/- 0.06mmHg (P=0.0001) and the difference between base line and day 30 IOP Left eye of female patients in group A was 6.36 +/- 0.10 mmHg while in group B was observed 8.0 +/- 0.31mmHg. (P=0.001).

The difference between baseline and day 30 IOP Rt Eye of age group 20-35 years in group A was 6.30 +/- 0.24mmHg while in group B was 7.73 +/- 0.33mmHg (P=0.0001) and the difference between baseline and day 30 IOP Lt Eye of age group 20-35 years in group A was 6.54 +/- 0.55mmHg) while in group B was 8.40 +/- 0.07mmHg (P=0.0001).

The difference between baseline and day 30 IOP Rt Eye of age group 36-50 years in group A was 6.97 +/- 0.05mmHg) while in group B was 8.00 +/- 0.00mmHg) and the difference between baseline and day 30 IOP Lt Eye of age group 36-50 years in the group A was 6.12 +/- 0.05mmHg) while in group B was 8.50 +/- 0.45mmHg) (P=0.0001).

The same results are highly comparable with the study conducted by Wang K et al,¹⁹ in which 8.0 ± 3.7 mmHg (32.0%) reduction in IOP was observed in treatment-naive patients after Bimatoprost 0.01% monotherapy.

In another randomized trials done by DuBiner H et al²⁰, it was seen that both Bimatoprost 0.01% and latanoprost 0.005% significantly lowered IOP from baseline (p <.001) but Bimatoprost 0.01% lowered IOP more than latanoprost 0.005% at every time point measured (Bimatoprost 0.01%: 25-34% reduction, 5.9-8.9 mm Hg; latanoprost 0.005%: 20-31% reduction, 4.4-7.9 mm Hg).

Faridi and associates found a 9.45 mmHg (36%) IOP reduction at 2 months and a 9.23 mmHg (35%) IOP reduction at 6 months after Bimatoprost 0.01% 0.03% monotherapy in newly diagnosed ocular hypertension and POAG patients.²¹ Since previous clinical evaluations suggest that glaucoma or ocular hypertension patients are rarely troubled by temporary ocular side effects, specifically ocular redness,²² the mild hyperemia after Bimatoprost 0.01% treatment did not represent a clinical safety concern.

The anticipated introduction in China of the new Bimatoprost 0.01% formulation with the same efficacy and improved tolerability as the original Bimatoprost 0.03% formulation, as well as education of patients explaining the importance of IOP lowering and drug efficacy, may further improve their acceptance and compliance.²³

CONCLUSION

Current study showed that mean change in reducing the intraocular pressure with Bimatoprost 0.001% is more significant than Latanoprost 0.005%.

Author's Contribution:

Concept & Design of Study: Nadia Nazir
 Drafting: Zulfiqar Ali
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Conflict of Interest: The study has no conflict of interest to declare by any author.

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