

Comparative analysis of travoprost (0.004%) and bimatoprost (0.03%) on intraocular pressure in patients with open-angle glaucoma

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Abstract

Purpose: To compare the efficacy and safety of bimatoprost (0.03%) and travoprost (0.004%) in newly diagnosed cases of open angle glaucoma. **Material and Methods:** Newly diagnosed patients of open angle glaucoma were recruited in this prospective study and were randomized to receive either bimatoprost or travoprost, once daily. The Intraocular pressure (IOP) was measured at baseline and then after one week, 1 month, 3 months, 6 months and 1 year. Adverse events, if any were also noted. **Results:** Mean IOP level recorded at baseline was 21.4 mmHg in the bimatoprost and 20.6 mmHg in the travoprost group. In the bimatoprost group the reduction of IOP after one week, 1 month, 3 months, 6 months and 1 year was 17.7, 15.2, 14.8, 14.8 and 14.6 respectively. In the travoprost group the reduction of IOP after one week, 1 month, 3 months, 6 months and 1 year was 17.5, 16, 15.4, 15.3 and 15 respectively. Most commonly reported adverse event in both groups was conjunctival hyperemia which was higher in the bimatoprost group (38.1%) than in the travoprost group (26.0%). Although both bimatoprost and travoprost effectively lowered IOP, bimatoprost provided larger mean IOP reductions than travoprost. Conjunctival hyperemia was most common adverse event but the patients tolerated medications well over the study period. Findings of our study could be very useful to treat patients of open angle glaucoma in the Indian population. **Clinical significance:** Bimatoprost (0.03%) and travoprost (0.004%) provided large reduction in mean IOP from baseline in cases of primary open angle glaucoma, normal tension glaucoma and ocular hypertension; however bimatoprost could be preferred for more effectiveness. Both were equally safe for ocular use.

Key Words: Bimatoprost, Travoprost, Primary Open Angle Glaucoma, Normal Tension Glaucoma, Ocular Hypertension

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Received Date: 19/02/2018 Revised Date: 22/03/2018 Accepted Date: 10/04/2018

DOI: <https://doi.org/10.26611/1009612>

Access this article online

Quick Response Code:



Website:

www.medpulse.in

Accessed Date:
14 April 2018

INTRODUCTION

Glaucoma is estimated to have affected over 60.5 million persons worldwide and it is projected that it will increase to 79.6 million by 2020.¹ The National Blindness Survey 2001 showed that glaucoma is the third major cause of blindness in India and responsible for 5.9% of blindness.²

Glaucoma is a progressive condition and is the most common cause of irreversible blindness worldwide. Intraocular pressure (IOP) is considered the most important risk factor for the development of primary open-angle glaucoma (POAG) and IOP reduction has proven to be beneficial in halting or delaying POAG onset³ and progression.⁴ Collaborative Normal-Tension Glaucoma Study Group⁵ concluded that IOP is part of the pathogenic process in normal-tension glaucoma (NTG). Therefore therapy that is effective in lowering IOP and free of adverse effects would be expected to be most beneficial in patients who are at risk of disease progression. The once-daily prostaglandin analogues (PGA) provide significant reductions in IOP and have become the most commonly used first-line agents in glaucoma and ocular hypertension (OHT).^{6,7, 8, 9} Bimatoprost (0.03%) is a synthetic analogue of

prostaglandin and a potent ocular hypotensive agent. It acts by increasing aqueous humor outflow through both the trabecular route and the uveoscleral pathway.^{10,11,12} Travoprost 0.004%, is a synthetic prostaglandin F2 α receptor agonist and lowers IOP by increasing uveoscleral outflow.¹³ The data on clinical efficacy and safety of bimatoprost and travoprost in patients of POAG and OHT from India, especially of long study duration are few.^{14,15} This study was designed to evaluate the IOP-lowering efficacy and safety of bimatoprost and travoprost monotherapy in newly diagnosed cases of open-angle glaucoma at a tertiary care hospital.

MATERIAL AND METHOD

This prospective randomized clinical study was undertaken to compare the IOP lowering efficacy of topical Bimatoprost and Travoprost in patients of POAG, NTG and OHT. The Institutional Ethical Committee approval was taken and written informed consent was obtained from each patient at the time of inclusion into the study. Cases of clinically diagnosed POAG, NTG and OHT, attending our teaching hospital from January 2014 till December 2014, were enrolled for the study. Inclusion criteria were newly-diagnosed patients of either gender, age ≥ 18 years, visual acuity $\geq 6/60$ (20 /200). Exclusion criteria were patients already on medication for glaucoma, cases of pseudo exfoliation, history of usage of any other topical drugs or systemic medications which may affect the study parameters, history of any intraocular surgery, ocular inflammation or infection in the preceding 3 months, pregnant or lactating women, and patients sensitive to any component of the drug. A detailed history, clinical examination and treatment plan were recorded for each patient. History was taken regarding migraine, Raynaud's phenomenon, episodes of shock, head injury, headache and other neurological symptoms. Use of medications including systemic steroids and antihypertensive agents was also taken into account. Detailed examination by physician was done to rule out any systemic disease. Ophthalmic examination including visual acuity, slit lamp examination of the anterior segment, Goldman applanation tonometry, pachymetry, gonioscopy, dilated fundus examination, IOP, and visual field tests were performed before patients were included in the study. A total of 88 patients were included in the study, and randomized into each study group. Patients who completed the study were only included for analysis. Baseline IOP values were recorded on the day of starting the treatment. The mean of 3 readings was recorded at the baseline value. The mean

IOP measurements for both eyes was taken and used for analysis. In patients having bilateral disease but if only one eye met the inclusion criteria that eye was included in the study. Drugs were self-administered starting the evening of the baseline visit, and one drop of bimatoprost (0.03%), or travoprost (0.004%) was applied between 8 to 9 p.m. for 1 years. At each study visit, three IOP measurements were taken at 9 am. The mean of these three measurements was used for analysis. The observations were recorded during each five visits: after 1 week, 1 month, 3 months, 6 months and 1 year. At each visit, the patients were examined for visual acuity (distance and near), evaluation of the anterior segment, fundus evaluation, applanation tonometry, and for ocular and systemic adverse events. Any complains of conjunctival hyperemia, dryness or itching was noted on each visit.

Statistical Analysis: The continuous variables in the treatment group were tested for differences using the one-way ANOVA (analysis of variance test) with treatment (bimatoprost, travoprost) as the independent variable from 0 days to 365 days. If the overall treatment effect was significant ($p < 0.05$), post-hoc analysis (Bonferroni test) was performed for multiple comparisons between this 6 parameter from 0 days to 365 days. For paired sample analysis, the Student's t-test was used (pair t test between 0 days to 3 months and 0 days to 365 days) and unpair T test done to find out if there is difference between these two drug. The primary effect outcome, as determined by a 95% confidence interval (CI) of the mean difference in IOP values between baseline and 3 months and 1 year with baseline. The data were analyzed using SPSS ver. 17.0.

RESULTS

Table 1: Patient characteristics at baseline

	Bimatoprost (n=42)	Travoprost (n=46)
Mean and (SD) of age in years,	63.4 (12.3)	62.7 (12.4)
Range	40 to 85	39 to 77
Female	14(33.3%)	16(34.8%)
male	28(66.7%)	30(65.2%)
Diagnosis		
Primary open-angle glaucoma	7 (16.0%)	8 (17.3%)
Normal tension glaucoma	31 (73.8%)	32 (69.0%)
Ocular hypertension	4 (9.5%)	6 (13%)
Cup-disc ratio	0.73 \pm 0.17	0.67 \pm 0.21

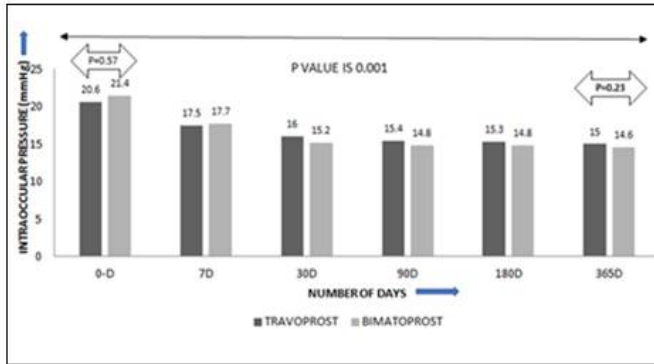


Figure 1

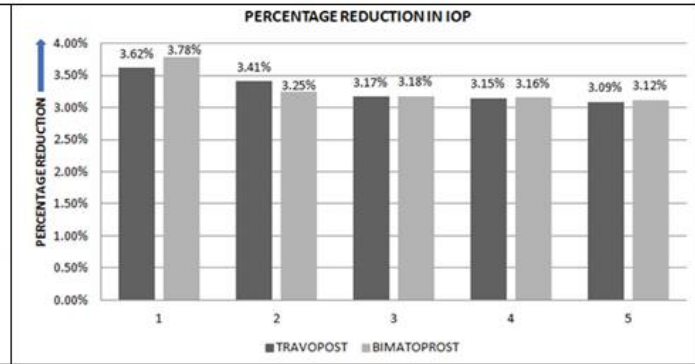


Figure 2

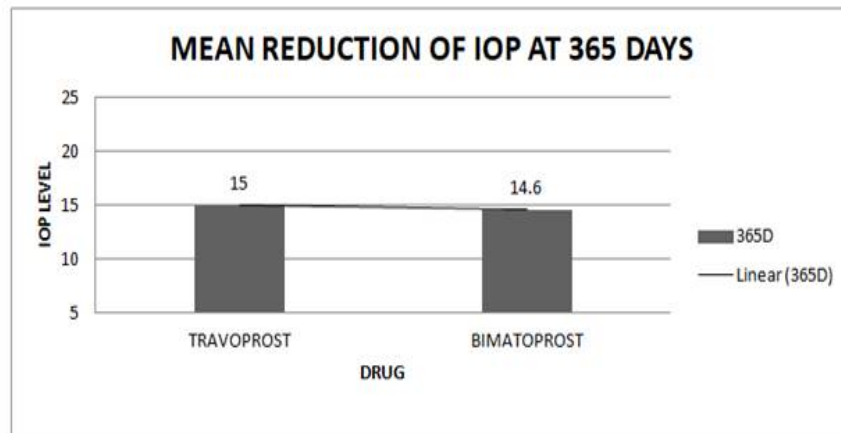


Figure 3

Figure 1: Mean intraocular pressure at different time points in each study group; **Figure 2:** Percent reduction of mean intraocular pressure at each time point in each study group; **Figure 3:** Mean intraocular pressure reduction at 1 year in each study group

Table 2: Adverse drug events

Adverse drug events	Bimatoprost (n=42)	Travoprost (n=46)
Conjunctival hyperemia	16(38.1 %)	12(26.0%)
Itching	2 (4.8%)	3 (6.5%)
Dryness	2(4.8%)	5(10.9%)
burning	2(4.8%)	4(8.7%)
Total	22(52.4%)	24(52.2%)

Values are presented as n (%)

In this study 88 patients were enrolled and randomised to either bimatoprost (0.03%) or travoprost (0.004%) monotherapy. Out of the 88 patients, 23 cases had disease in one eye and 65 cases had disease in both eyes. There were 42 cases in bimatoprost (0.03%) and 46 in travoprost (0.004%) group. Patient characteristics at baseline are listed in Table 1. Male patients were more in both the treatment groups. The mean age was comparable in each group. The mean IOP values in the different study groups that were recorded at baseline (day 0), 1 week, 1 month, 3 month, 6 month and 1 year are shown in Fig. 1. The mean IOP values did not differ significantly among the groups at each individual time point, nor were the overall IOP values different. The following mean IOP levels were recorded at baseline: 21.5 mmHg in the

bimatoprost groups and 20.7 mmHg in the travoprost group. There was no significant difference between travoprost and bimatoprost group at 0 day ($T=0.543$ and $P=0.570$). There was a significant reduction in values from baseline at each of the time points ($p < 0.0001$), and the amount of reduction was different among groups ($p < 0.0001$). At 3 months the mean reduction in IOP was 30.1 % (6.1 ± 5.4) in Bimatoprost group and 25.2 % (5.2 ± 6.3) in travoprost group (figure 2). The mean reduction in IOP (mmHg) at 3 months in the travoprost group shows significant difference and IOP reduced. ($T=5.66$ $P=0.0001$) Similarly the mean reduction in IOP (mmHg) at 3 months in the bimatoprost group shows significant difference and IOP reduced. ($T=7.81$ $P=0.0001$) from baseline. The mean reduction in IOP (mmHg) at 3 months compared to baseline ($p < 0.001$) was not significant between the two groups.

At 1 year the mean reduction in IOP was 31.25 % (6.5 ± 5.9) in bimatoprost group and (27.2 %) (5.6 ± 6.7) in travoprost group (Fig 2, 3). The mean reduction in IOP (mmHg) in the travoprost group shows significant difference and IOP reduced ($T=5.66$ $P=0.0001$). Similarly the mean reduction in IOP (mmHg) in the bimatoprost

group shows significant difference and IOP reduction ($T=7.65$ $P=0.0001$) from baseline. The mean reduction in IOP (mmHg) at 1 year compared to baseline ($p < 0.001$) was not significant between the two groups ($T=0.947$ and $P=0.235$). So it indicates that there is no significant difference between travoprost and bimatoprost after 1 year of treatment. The adverse events observed over the study period for each drug are presented in table 2. The most commonly reported adverse event in both groups was conjunctival hyperemia, which occurred in 16 (38.1%) patients of the bimatoprost group and in 12 (26.0%) patients in the travoprost group ($p=0.260$). Conjunctival hyperemia peaked at 1 week in both groups. The incidence of hyperemia was higher in the bimatoprost group than in the travoprost group, but this difference was not statistically significant. Ocular itching was reported more often in the travoprost group (6.5%) than in the bimatoprost group (4.8%), but was not significant. Ocular Dryness was noted in 2 (4.8%) cases in bimatoprost and in 5 (10.9%) cases in travoprost group. Burning was noted in 2 (4.8%) in bimatoprost and in 4 (8.7%) travoprost group. The study patients tolerated medications well, as was evident during the follow-up visits. No significant changes were found in visual acuity in either group.

DISCUSSION

Glaucoma ultimately leads to optic nerve atrophy and thus visual field loss. Hence, early detection and treatment prevents the disease from further progression. The objective of the management of glaucoma today is the preservation of the visual field through the reduction of IOP. Pharmacotherapy is usually the first line of treatment and thus, prostaglandins have become the first choice for treatment of elevated IOP. We undertook this study to evaluate the IOP-lowering efficacy and safety of bimatoprost 0.03% and travoprost monotherapy in OHT and POAG in patients attending our OPD. In our study, there was no significant difference in IOP between travoprost and bimatoprost at baseline. There was a significant reduction in values from baseline at each of the time points of 1 week, week 4, week 12, 6 month and 1 year ($p < 0.0001$), and the amount of reduction was different among both groups ($p < 0.0001$). Bimatoprost reduced IOP more than travoprost but difference was not significant after 3 months or 1 year. The majority of the studies comparing the efficacy of travoprost against other PGs have shown no significant differences in IOP-lowering ability.^{7,13,16} Similar mechanism of action and comparable effects on uveoscleral outflow and trabecular meshwork are probably the basis of this finding. Our findings support other studies that reported bimatoprost having superior efficacy relative to travoprost. In a study

by Parrish *et al*^[13] the IOP-lowering efficacy of latanoprost, bimatoprost and travoprost was evaluated. In this 12-week clinical study, there were no significant differences in mean IOP among-group, but bimatoprost provided lower mean IOP than travoprost. Berenson *et al*^[17] demonstrated that greater IOP reduction from bimatoprost is associated with increased cost savings compared to travoprost. Cantor^[18] noted that more patients achieved low target pressures with bimatoprost than with travoprost at each time point. In a study by Holmstrom *et al*^[19] it was observed in direct comparisons (head-to-head studies) that bimatoprost is the most efficacious treatment compared to other prostaglandins. According to Chander *et al*,^[14] bimatoprost provided greater mean IOP reductions from baseline than travoprost at the end of the study period of 12 weeks. Similarly according to Noecker *et al*,^[20] both drugs comparably lowered IOP, but bimatoprost was more likely than travoprost to allow achievement of every target pressure from 12 to 19 mm Hg at month 3. Deepak *et al*^[15] and Aptel *et al*^[21] findings suggest a greater efficacy of bimatoprost compared with travoprost. However, a meta-analysis done by Li *et al*^[22] failed to find significant differences in hypotensive efficacy between travoprost and bimatoprost (weighted mean difference: -0.08 mmHg in favor of bimatoprost, $P=0.8$). In contrast, the amount of IOP reduction seen at 8 and 10 a.m. in the travoprost group (31%) was significantly higher when compared to patients treated with bimatoprost (21.6%), as reported by Yildirim *et al*^[23] during an 8-week trial period. Faridi *et al*^[24] in their study noted that at 2 months, there was a significant difference between the three PGA treatment groups with bimatoprost achieving a greater reduction in IOP than the other two drops. Bimatoprost was found to be most effective in the initial phase of the trial, and there was no statistically significant difference in the efficacy, among the three prostaglandin analogue eye drops after 6 months of treatment. Özlem^[25] determined significant IOP reductions with latanoprost, travoprost and bimatoprost monotherapy in patients with POAG and OHT after follow-up for 6 months. There was no significant difference between the three groups in terms of effectiveness on reducing the IOP. Cantor *et al* randomized 157 patients affected by POAG or OHT to treatment with travoprost or bimatoprost, in a double-blind, parallel-group clinical trial.^[26] At the 6-month visit, patients were more likely to achieve clinically relevant IOP reductions $\geq 20\%$, 25% , or 30% with bimatoprost than travoprost at the 9 am time-point. Bimatoprost lowers IOP by increasing aqueous outflow through a pressure sensitive mechanism as well as a pressure insensitive mechanism.^[19] This explains why bimatoprost possibly has a better IOP lowering effect than travoprost.

Comparison of long term of 1 year efficacy between the groups was not possible because of lack of similar studies. In our study the most commonly reported adverse event in both groups was conjunctival hyperemia with the incidence of hyperemia higher in the bimatoprost group (16; 38.1 %) than in the travoprost group (12; 6.0%), but this difference was not statistically significant. Conjunctival hyperemia peaked at 1 week in both groups and resolved with time, with or without lubricants. Similar to our study Chander *et al*,¹⁴ Deepak *et al*,¹⁵ Cantor *et al*,¹⁸ DuBiner H *et al*,²⁷ Quinones R,²⁸ Alagöz G *et al*²⁹ also noted that the most common side effect was conjunctival hyperemia. Similar to our study Chander¹⁵ also noted that mild ocular redness was the commonest side effect in both the groups but was not significant in either group. Netland *et al*⁷ found clinically significant changes in ocular hyperemia in 49.5% of patients treated with travoprost 0.004%,⁷ however, the majority of patients experienced none/trace to mild hyperemia. In his study hyperemia was evident since the first follow-up visit, at week 2. Cantor *et al*¹⁸ observed that the incidence of hyperemia was higher in the bimatoprost group than in the travoprost group, but this difference was not statistically significant. Aptel²¹ observed that the incidence of hyperemia was lower with travoprost. In our study ocular itching was reported more often in the travoprost group (6.5%) than in the bimatoprost group 4.8% (6.5%) but was not significant between-group. Cantor *et al*²⁶ also reported ocular itching was more often in the travoprost group than in the bimatoprost group (7.4% of patients treated with travoprost compared with 2.3% of those treated with bimatoprost). Ocular Dryness was noted in 2 cases (4.8%) in bimatoprost and in 5 cases (10.9%) in travoprost group, in our study. Burning was noted in 2 cases (4.8%) in bimatoprost and in 4 cases (8.7%) in travoprost group. The study patients tolerated medications well during the study period. Limitations of our study is the small sample size. Thus, the findings of IOP lowering and adverse events between-group were not statistically significant. Similar studies of longer observation period were not available for comparison.

CONCLUSION

The results of our 1 year study demonstrates clinically important and statistically significant IOP-lowering efficacy of bimatoprost 0.03% and travoprost 0.004% in newly diagnosed cases of POAG, NTG and OHT. Although both bimatoprost and travoprost effectively lowered IOP in patients with glaucoma, bimatoprost provided larger mean IOP reductions than travoprost. Conjunctival hyperemia was most common adverse event but the patients tolerated medications well over the study

period. Findings of our study could be very useful to treat patients of OHT, NT and POAG in the Indian population.

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Source of Support: None Declared
Conflict of Interest: None Declared