

Clinical Response to Topical Bimatoprost Therapy in Primary Open-Angle Glaucoma: A Prospective Observational Study

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ABSTRACT

Background: Primary open-angle glaucoma (POAG) is a main reason for acquiring irreversible blindness, as well as elevated intraocular pressure (IOP) is the most important correctable factor. The goal of the management of primary glaucoma is to reduce the IOP. Topical prostaglandin analogs, particularly bimatoprost, are indicated as first-line therapy because of their high efficacy in reducing IOP and convenience of once-daily dosing. The objective of the present study was to analyze the clinical response to treatment with topical bimatoprost in patients with POAG.

Methods: A total of 86 newly diagnosed POAG patients (172 eyes) were selected. All patients underwent visual acuity assessment, Goldmann applanation tonometry, gonioscopy, optical coherence tomography (OCT), and Humphrey visual field testing. Topical bimatoprost 0.03% was prescribed once nightly. The response to treatment was assessed and categorized as excellent (>30% IOP decrease), good (15–30%), and poor (<15%).

Results: The mean age of participants was 56.2 ± 9.1 years, with a male predominance of 72.1%. Mean IOP at baseline was 23.88 ± 2.35 mmHg. After the treatment, mean IOP was 18.05 ± 1.73 mmHg, which represents an overall decrease of $23.86 \pm 4.75\%$ from baseline ($p < 0.001$). An excellent response was noted in 108 eyes (62.8%), while 56 eyes (32.6%) had a good response. The remaining 8 eyes (4.6%) were considered poor responders. Overall, 95.4% of eyes had a good-to-excellent therapeutic response.

Conclusion: The use of topical bimatoprost for reducing intraocular pressure caused by POAG showed significant and sustained efficacy. The majority of eyes treated with bimatoprost therapy showed excellent or good response to therapy, illustrating the utility of bimatoprost therapy as the first line of treatment for the management of POAG. The early detection of disease and initiation of therapy helps limit the progression of the disease and protect the patient's visual capacity.

KEYWORDS: Keywords

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INTRODUCTION

Primary open-angle glaucoma (POAG) is the most common form of glaucoma and a leading cause of irreversible blindness worldwide. It is characterized by progressive optic nerve damage, retinal ganglion cell loss, and corresponding visual field defects that may ultimately result in permanent visual impairment if left untreated. The disease often remains asymptomatic during its early stages, leading to delayed diagnosis and management. Elevated intraocular pressure (IOP) is the principal modifiable risk factor for POAG, and reduction of IOP remains the only proven strategy for slowing disease progression and preserving visual function.¹⁻³

The management of POAG primarily focuses on lowering IOP through medical therapy, laser treatment, or surgical intervention. Among the available medical treatments, topical prostaglandin analogues (PGAs) are considered first-line therapy because of their potent IOP-lowering efficacy, convenient once-daily dosing, and favorable safety profile.^{2,4} These agents lower IOP primarily by enhancing aqueous humor outflow through the uveoscleral pathway and have demonstrated superior efficacy compared with several other classes of antiglaucoma medications.

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Bimatoprost, a synthetic prostamide analogue, is one of the most widely prescribed prostaglandin analogues for the treatment of POAG. Several clinical studies have demonstrated its effectiveness in achieving substantial reductions in IOP and slowing glaucomatous progression. Compared with other prostaglandin analogues, bimatoprost has been reported to provide greater IOP reduction in many patients, making it an important therapeutic option in glaucoma management.^{5,6} In addition to its efficacy, once-daily administration contributes to improved patient compliance and long-term disease control.

Despite the established effectiveness of prostaglandin analogue therapy, variability in treatment response has been

observed among patients with POAG. While many individuals achieve adequate IOP control, others demonstrate a suboptimal response and continue to experience disease progression. Therefore, regular assessment of treatment outcomes remains essential for optimizing therapeutic strategies. Monitoring of intraocular pressure, optic nerve status, retinal nerve fiber layer (RNFL) thickness, and visual field changes plays a crucial role in evaluating disease progression and treatment effectiveness.^{7,8}

In addition to its established intraocular pressure-lowering efficacy, the long-term therapeutic effectiveness of topical bimatoprost depends on several factors, including ocular tolerability, patient adherence, baseline intraocular pressure, and individual variability in treatment response. Although bimatoprost is generally well tolerated, ocular adverse effects such as conjunctival hyperemia, irritation, increased eyelash growth, periocular pigmentation, and changes in iris pigmentation may occur during prolonged therapy and potentially influence treatment compliance.⁹ Comparative clinical studies have demonstrated that bimatoprost provides effective IOP reduction in patients with primary open-angle glaucoma and ocular hypertension, although the magnitude of response may differ among individuals and across prostaglandin analogues.¹⁰ Furthermore, sustained IOP reduction is particularly important because fluctuations in intraocular pressure and inadequate pressure control may contribute to progressive glaucomatous optic nerve damage and visual field deterioration.¹¹⁻¹³ Therefore, regular follow-up, assessment of therapeutic efficacy, monitoring of adverse effects, and evaluation of patient adherence are essential components of long-term glaucoma management. Individualized treatment strategies based on clinical response and disease severity may help achieve optimal IOP control and preserve visual function in patients with POAG.

MATERIAL AND METHODS

Study Design and Setting

The research was carried out at the Era's Lucknow Medical College & Hospital (ELMC&H) in Lucknow, India, within the Department of Ophthalmology. It was designed to assist in the understanding of the clinical response to topical bimatoprost in POAG patients.

The research was conducted over the period of 24 months.

Study Population

The study included 86 newly diagnosed POAG patients at the ophthalmology outpatient clinic. POAG patients were diagnosed through elevated intraocular pressure (>21 mmHg), corresponding visual field defects on Humphrey visual field analysis, and an open angle on gonioscopy. Patients with active ocular inflammation or intraocular inflammation, corneal pathology, cystoid macular edema, ocular surgery, and hazy media were excluded.

Sample Size Determination

According to a study with a 90% power, and considering alpha (significance level) of 5%, the required sample size was at least 86 patients.

Clinical Evaluation

All patients underwent a comprehensive baseline evaluation which included visual acuity, slit lamp examination, gonioscopy according to Shaffer's criteria, intraocular pressure measurement, dilated fundus examination, OCT of the retina for assessment of RNFL, and Humphrey visual field analysis (HFA). Intraocular pressure and clinical response were assessed at follow up at 1 week and 1 month as well as 3 months after the initiation of therapy.

Protocol and Results Evaluation

Standard of care for primary open-angle glaucoma instructs patients to instill 1 drop of topical bimatoprost -0.03% ophthalmic solution in the affected eye(s) each night before bed. Evaluation of treatment response is conducted through analysis of the percentage change from baseline in the value of intraocular pressure (IOP). It is further divided into excellent response ($>30\%$ decrease in IOP), good response (15% – 30% decrease in IOP), and poor response ($<15\%$ change in IOP). The study notes all baseline values, including optic disc appearance, thickness of the RNFL as assessed by OCT, and the status of the visual field as assessed by the Humphrey visual field examination. The primary endpoint was the change of IOP after treatment with topical bimatoprost. The secondary endpoints were changes from baseline to follow-up visits of mean IOP, distributions of response to treatment categories, and evaluation of baseline structural and functional values in primary open-angle glaucoma.

Statistical Analysis

Data was analyzed with the help of SPSS 29. Changes of IOP in follow-up were evaluated by appropriate statistical tests. Results were considered significant at $p < 0.05$.

Protocol Approval and Consents

The study protocol was approved by the Institutional Ethics Committee (ECR/717/Inst./U.P./2015/RR-21) ELMCH Lucknow. The consent of all the participants was taken before enrollment. The study ensured the confidentiality of the participants while maintaining the integrity of the data. The study followed to the principles of Declaration of Helsinki.

RESULTS

This study includes 86 patients with newly diagnosed POAG representing 172 eyes. Participants had a mean age of 56.2 years with a range of 40 to 72 years and a median of 57 years with an interquartile range of 48 to 64 years. There was a majority of male participants making up 72.1% of

the participants. The mean IOP at first baseline was found to be 23.88 ± 2.35 mmHg. Visual acuity was generally good, and the anterior chamber angles were open on gonioscopy. Also, a majority of patients presented with open angles on gonioscopy and glaucomatous visual field defects of moderate to severe level. Post treatment, topical bimatoprost showed a tremendous therapeutic response resulting in a drop in IOP for a majority of the patients.

This study analyzed 86 newly diagnosed cases of POAG. The study analysis was based on 172 eyes. The participants' mean age was 56.2 years (SD = 9.1), with age range from 40 to 72 years and median age of 57 years (IQR = 48-64). This shows that POAG affect middle-aged and older adults. The male participants were 72.1% of the study population. Female participants made up 27.9% of study population. The mean baseline intraocular pressure (IOP) was 23.88 mmHg (SD = 2.35), showing that the majority of the participants had high IOP when they presented for care. A complete gonioscopic evaluation was performed in all participants of the study and confirmed that all of the participants had open anterior chamber angle with grade 4 anterior chamber angle in 93.0% of eyes and grade 3 anterior chamber angle in 7.0% of eyes, which confirmed the diagnosis of POAG. The mean cupping to disc ratio was 0.65 (SD = 0.15) indicating that the participants had moderate level of glaucoma. The baseline findings show that the study participants were mostly an advanced cases of glaucoma that needed immediate treatment to lower their IOP.

Baseline functional and structural characteristics of the study eyes are summarized in Table 2. Most (64.0%) eyes had 'good' vision with a BCVA of ≤ 0.3 logMAR. Relatively conserved vision was also seen in 20.9% of eyes, but with mild-to-moderate visual impairment. Approximately 10.5% of the eyes had more severe visual impairment. Severe visual impairment or light perception impairment was observed in a minority of eyes. When we analyzed the visual field, moderate damage of the glaucomatous field was evident in 40.2% of the eyes and severe damage of the glaucomatous field was evident in 39.0% of the eyes. In 17.1% of the eyes advanced visual field loss was present, while early damage was present in 3.7% of the eyes. This suggests that, in the majority of the cases, the patients sought medical attention after a considerable degree of disease progression had occurred. Based on optic coherence tomography (OCT), the mean thickness of the RNFL was 75.9 ± 13.2 μ m and therefore damage of the glaucomatous optic nerve was present. The combination of visual field defects and RNFL thinning demonstrated the chronic and progressive nature of primary open-angle glaucoma (POAG), thus underscoring the need for early intervention.

Table 3 reports on the results of the use of topical bimatoprost during follow-up on intraocular pressure (IOP). Mean baseline IOP was 23.88 ± 2.35 mmHg. It significantly decreased by one week to a mean of 20.16 ± 1.95 mmHg

and a mean reduction of $15.47 \pm 6.32\%$ from baseline. IOP decreased to a mean of 18.77 ± 1.68 mmHg at the end of the month, a mean reduction of $20.78 \pm 5.06\%$ from baseline. At the end of the three-month follow-up, the mean IOP was 18.05 ± 1.73 mmHg representing a mean reduction of $23.86 \pm 4.75\%$ from baseline. These decreases were all statistically significant ($p < 0.001$). A progressive decrease in IOP was seen with successive follow-up visits and demonstrates bimatoprost's ability to control intraocular pressure and maintain adequate control in patients with primary open angle glaucoma. These results support that bimatoprost is a first-line medical therapy to address the major modifiable risk factor in glaucoma progression.

Table 4 shows the response to treatment with topical bimatoprost. Response was evaluated based on the change in intraocular pressure (IOP) from baseline. 62.8% showed an excellent response (greater than 30% decrease in IOP). 15-30% decrease in IOP was considered a good response, and was shown in 32.6%. Only 4.6% showed a poor response, with less than 15% decrease in IOP. 95.4% of eyes achieved either excellent or good response. This illustrates the high effectiveness of the study therapy. Excellent response to treatment indicates a high level of effectiveness for the majority of the population of the study. There was a high percentage of excellent responders. Poor response to treatment was low. This further supports the use of bimatoprost as the primary treatment. The results show the high reliability and increase largely the overall effectiveness of prostaglandin analogues in the management of glaucoma. This update confirms the existing evidence of the effectiveness of prostaglandin analogues and supports their continued use as first-line therapy for achieving target intraocular pressure.

DISCUSSION

This study analyzes the clinical features of patients with POAG and the response to topical bimatoprost treatment. The participants of this study had a mean age of 56.2 ± 9.1 years with a predominance of male participants (72.1%). These findings are in accordance with the previously published literature, where POAG was observed in the older adult and middle-aged population. The mean age was reported as 43.9 years by Cui et al.¹¹ and as 46.5 ± 14.1 in the study of Opazo-Toro et al.¹⁰ and as 58.0 ± 13.1 years by Sakurai et al.¹⁴ The preference of male participants observed in the present study mirrors findings from several hospital-based studies and may speak to the demographic and health care seeking behaviors of the study participants.

The mean baseline intraocular pressure (IOP) in our study was 23.88 ± 2.35 mmHg and is consistent with the baseline IOP values reported in studies examining prostaglandin analogue therapy. Opazo-Toro et al.¹⁰ reported a baseline IOP of 26.55 ± 8.19 mmHg, while Inoue et al.¹⁵ reported baseline IOP values of 15.3 to 22.6 mmHg in patients

Table 1. Baseline Sociodemographic and Ocular Characteristics of the Study Population (n = 86 patients, 172 eyes)

Characteristic	Value
Age (years), mean $\pm$ SD	56.2 $\pm$ 9.1
Age range (years)	40–72
Median age (IQR)	57 (48–64)
Male sex, n (%)	62 (72.1)
Female sex, n (%)	24 (27.9)
Baseline IOP (mmHg), mean $\pm$ SD	23.88 $\pm$ 2.35
Cup-disc ratio, mean $\pm$ SD	0.65 $\pm$ 0.15
Grade 4 angles, n (%)	160 (93.0)
Grade 3 angles, n (%)	12 (7.0)

Table 2. Visual Acuity, Visual Field Status and RNFL Thickness at Baseline

Parameter	n (%) / Mean $\pm$ SD
BCVA $\leq$ 0.3 logMAR	110 (64.0)
BCVA 0.3–0.5 logMAR	36 (20.9)
BCVA 0.5–1.0 logMAR	18 (10.5)
BCVA $>$ 1.0 logMAR	4 (2.3)
PL Negative	4 (2.3)
Early visual field defect	6 (3.7)
Moderate defect	66 (40.2)
Severe defect	64 (39.0)
Advanced defect	28 (17.1)
RNFL thickness (μ m), mean $\pm$ SD	75.9 $\pm$ 13.2

Table 3. Change in Intraocular Pressure Following Topical Bimatoprost Therapy (n = 172 eyes)

Follow-up Visit	Mean IOP $\pm$ SD (mmHg)	Mean % Reduction from Baseline	p-value
Baseline	23.88 $\pm$ 2.35	—	—
1 Week	20.16 $\pm$ 1.95	15.47 $\pm$ 6.32	$<$ 0.001
1 Month	18.77 $\pm$ 1.68	20.78 $\pm$ 5.06	$<$ 0.001
3 Months	18.05 $\pm$ 1.73	23.86 $\pm$ 4.75	$<$ 0.001

Table 4. Treatment Response to Topical Bimatoprost Therapy (n = 172 eyes)

Response Category	Number of Eyes	Percentage (%)
Excellent responders ($>$ 30% IOP reduction)	108	62.8
Good responders (15–30% IOP reduction)	56	32.6
Poor responders ($<$ 15% IOP reduction)	8	4.6
Total	172	100

prescribed different prostaglandin analogues. Structural and functional evaluations documented a mean cup-disc ratio of 0.65 ± 0.15 , moderate visual field defects in 40.2% of eyes, severe defects in 39.0% and advanced defects in 17.1%, as well as a mean RNFL thickness of 75.9 ± 13.2 μ m. The data indicate that most patients presented with moderate-to-severe stage glaucomatous damage at the time of presentation. Similar findings have been reported by Opazo-Toro et al.¹⁰ who reported more severe visual field loss in glaucoma patients with established disease.

This study examined the effectiveness of topical bimatoprost for treating glaucoma. Over the period of the study, topical bimatoprost therapy showed a significant and sustained decrease in intraocular pressure (IOP). The mean IOP at baseline was 23.88 ± 2.35 mmHg and at the end of the study was 18.05 ± 1.73 mmHg, which represents a decrease of 23.96% ($p < 0.001$). The results of this study showed that bimatoprost is effective in lowering IOP, which is consistent with previous reports that investigated the analogs of prostaglandin in IOP lowering. Inoue et al. (2009) reported that bimatoprost significantly lowered IOP and Chander et al. (2013) demonstrated superior IOP

lowering efficacy of bimatoprost compared with travoprost in primary open-angle glaucoma patients. Opazo-Toro et al. (2016) demonstrated significant reductions in treated IOP with prostaglandin analogue therapy in glaucoma patients, which further solidifies the efficacy and important role of topical bimatoprost as an ocular hypotensive agent.

The assessment of treatment response revealed that 108 eyes (62.8%) had an excellent response with an IOP reduction of greater than 30%, and 56 eyes (32.6%) had a good response with an IOP reduction of 15 to 30%. Poor responders accounted for only 8 eyes (4.6%). 95.4% of eyes had good or excellent responses to treatment. These results show that the treatment had a high level of success in terms of therapeutic outcomes, and these results are consistent with other studies which had similar outcomes on prostaglandin analogue therapy. Inoue et al.¹⁵ stated that the group that showed the least response to treatment with bimatoprost was very small, therefore, stating that bimatoprost has a high level of success in comparison to the prostaglandin analogues. These results support the use of bimatoprost as the first treatment for POAG because of the high success rate of treatment.

Outcomes in this study may be explained by the pharmacological effects of bimatoprost. Through increasing aqueous humor outflow via the uveoscleral and the trabecular pathways, intraocular pressure is reduced. Due to its pharmacological effects and a once daily administration, bimatoprost may also improve patient compliance and prolong the therapeutic effect. Since increased intraocular pressure is the most significant and modifiable risk factor associated with the progression of glaucoma, visual function is preserved and further optic nerve injury may be prevented.¹⁻³ Thus, the strong reduction of intraocular pressure and high responder rate in this study, demonstrate the role of bimatoprost as first line treatment for primary open angle glaucoma.

The results of this study are positive. However, there are some study restrictions. This study was a 3 month follow-up period. It was not feasible to assess visual fields, the optic nerve, or treatment adherence. Therefore, to really understand the long-term effects and safety of topical bimatoprost on POAG patients, larger multicentric studies with longer follow-up periods are required.

CONCLUSION

In summary, the use of topical bimatoprost in patients with primary open-angle glaucoma reduced intraocular pressure. The study subjects were primarily middle-aged and older adults with severe glaucomatous damage. After the subjects received bimatoprost, there was a progressive, statistically significant decrease in intraocular pressure which was on average 23.86% from baseline. From this study, it is clear that the vast majority of the subjects (95.4%) had great or satisfactory therapeutic response. Because of these results, one can confirm that an initial treatment with bimatoprost is safe and effective for primary open-angle glaucoma. The early diagnosis and frequent monitoring of glaucoma patients is necessary because bimatoprost, as a prostaglandin analogue, can be effective in retarding the progression of glaucoma and limiting damage to the visual field.

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