e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(2); 497-500

Original Research Article

Study to Evaluate the Efficacy of Reduction in Intraocular Pressure and Safety between Latanoprost and Tafluprost with Normal-Tension Glaucoma

Tamal Roy[1], Archana Kumari[2], Asif Hussain[3], Salman Shamim[4], Purnendu Kumar Singh[5]

[1]Associate Professor, Department of Ophthalmology, Raiganj Government Medical College and Hospital, Raiganj, West Bengal, India

[2]Assistant Professor, Department of Ophthalmology, Jawaharlal Nehru Medical College and Hospital, Bhagalpur, Bihar, India

[3,4]Assistant Professor, Department of Pharmacology, Katihar Medical College and Hospital, Katihar, Bihar, India

[5]Professor & HOD, Department of Community Medicine, Katihar Medical College and Hospital, Katihar, Bihar, India

Received: 25-11-2023 / Revised: 23-12-2023 / Accepted: 26-01-2024

Corresponding Author: Dr. Salman Shamim

Conflict of interest: Nil

Abstract:

Background: Normal-tension glaucoma (NTG) is a chronic eye condition characterized by optic nerve damage and visual field loss, often associated with intraocular pressure (IOP) within the normal range. The management of NTG primarily focuses on lowering IOP to slow down disease progression. Two commonly prescribed prostaglandin analogs, latanoprost and tafluprost, have been used to reduce IOP in glaucoma patients. This study aimed to compare the efficacy and safety of latanoprost and tafluprost in reducing IOP among patients with NTG over a 6-month period.

Materials and Methods: A prospective study was conducted at J.L.N. Medical College in Bhagalpur, Bihar, with a sample size of 100 patients diagnosed with NTG. Patients were randomized into two groups: one receiving latanoprost and the other receiving tafluprost. Baseline IOP measurements were obtained for all participants. The IOP was assessed at regular intervals over the 6-month study duration. Adverse events and changes in visual acuity were also monitored. Statistical analysis was performed using appropriate tests to compare IOP reduction between the two groups.

Results: After 6 months of treatment, the mean IOP reduction in the latanoprost group was found to be 3.5 ± 1.2 mm Hg, while in the tafluprost group, it was 3.8 ± 1.4 mm Hg. The difference in IOP reduction between the two groups was not statistically significant ($p > 0.05$). No serious adverse events were reported in either group, and both medications were well-tolerated. Visual acuity remained stable throughout the study in both groups.

Conclusion: In this 6-month study comparing the efficacy and safety of latanoprost and tafluprost in reducing IOP among patients with normal-tension glaucoma, both medications demonstrated similar IOP-lowering effects and were well-tolerated. These findings suggest that both latanoprost and tafluprost can be considered as effective treatment options for NTG patients, allowing clinicians to tailor the choice of medication to individual patient preferences and cost considerations.

Keywords: Normal-Tension Glaucoma, Latanoprost, Tafluprost, Intraocular Pressure, Efficacy, Safety, Visual Acuity, Prostaglandin Analogs.

Introduction

Normal-tension glaucoma (NTG) is a form of primary open-angle glaucoma characterized by optic nerve damage and visual field loss, despite intraocular pressure (IOP) consistently falling within the normal range [1, 2]. NTG poses a significant challenge in the field of ophthalmology, as its underlying mechanisms and optimal management remain subjects of on-going research and debate. The primary goal in the management of NTG is to reduce IOP, as it has been shown to slow down disease progression and preserve visual function [3]. Prostaglandin analogs are a class of ocular hypotensive agents commonly prescribed to lower IOP in glaucoma patients [4]. Two such prostaglandin analogs, latanoprost and tafluprost, have gained recognition for their IOP-lowering

efficacy in patients with primary open-angle glaucoma. However, limited studies have specifically compared these two medications in the context of NTG.

This study aims to address this gap in the literature by conducting a comparative analysis of the intraocular pressure reduction efficacy and safety profile of latanoprost and tafluprost in patients diagnosed with NTG. By evaluating these two commonly prescribed medications, we hope to provide valuable insights for clinicians and patients in choosing the most suitable treatment option for NTG management.

Materials and Methods:

Study Design and Participants: This prospective comparative study was conducted at J.L.N. Medical College, Bhagalpur, Bihar, over duration of 6 months. The study included a sample of 100 adult patients (aged 18-75 years) diagnosed with normal-tension glaucoma (NTG). The diagnosis of NTG was based on comprehensive ophthalmic evaluations, including optic disc assessment, visual field testing, and IOP measurements, which consistently fell within the normal range (defined as IOP ≤ 21 mm Hg) [1, 2].

Inclusion and Exclusion Criteria: Inclusion criteria encompassed patients with a confirmed diagnosis of NTG, willing to participate in the study, and who had not received any prostaglandin analog therapy in the past.

Exclusion criteria included patients with contraindications to either latanoprost or tafluprost, previous history of intolerance or allergy to prostaglandin analogs, secondary glaucoma, or any other ocular pathology that might interfere with the assessment of treatment outcomes.

Randomization and Treatment: Patients were randomly assigned to one of two groups: the latanoprost group and the tafluprost group. Randomization was performed using a computer-generated random number sequence. The latanoprost group received latanoprost 0.005% eye drops, and the tafluprost group received tafluprost 0.0015% eye drops. Both medications were administered once daily in the evening.

Outcome Measures: Baseline measurements included IOP assessment, best-corrected visual acuity (BCVA) using the Snellen chart, and a comprehensive ophthalmic examination. IOP was measured using a Goldmann applanation tonometer. BCVA was recorded in Snellen fractions and subsequently converted to log MAR for statistical analysis.

Follow-up Visits: Participants were followed up at 1 month, 3 months, and 6 months from the initiation of treatment. At each visit, IOP measurements, BCVA assessments, and adverse events monitoring were performed. Compliance with medication was also assessed.

Statistical Analysis: The primary outcome measure was the change in IOP from baseline to the 6-month follow-up. Secondary outcome measures included changes in BCVA and the occurrence of adverse events. Statistical analysis was conducted using appropriate tests, including the paired t-test for within-group comparisons and the independent t-test for between-group comparisons. A p-value less than 0.05 were considered statistically significant.

Results

Table 1: Baseline Characteristics of Study Participants

Characteristic	Latanoprost Group (n=50)	Tafluprost Group (n=50)
Age (years), Mean ± SD	62.4 ± 8.1	63.1 ± 7.5
Gender (Male/Female)	27/23	28/22
Baseline IOP (mm Hg), Mean ± SD	17.8 ± 2.3	17.6 ± 2.2
Baseline BCVA (logMAR), Mean ± SD	0.25 ± 0.12	0.26 ± 0.14

Table 1 summarizes the baseline characteristics of the study participants in both the latanoprost and tafluprost groups. There were no significant differences between the groups in terms of age, gender distribution, baseline IOP, or baseline best-corrected visual acuity (BCVA).

Table 2: Intraocular Pressure (IOP) Reduction from Baseline at Follow-up Time Points

Time Point (Months)	Latanoprost Group (mm Hg), Mean ± SD	Tafluprost Group (mm Hg), Mean ± SD
Baseline	17.8 ± 2.3	17.6 ± 2.2
1	15.3 ± 2.1	15.2 ± 2.0
3	14.2 ± 1.9	14.1 ± 1.8
6	14.0 ± 1.8	13.9 ± 1.7

Table 2 illustrates the changes in intraocular pressure (IOP) from baseline to different follow-up time points in both the latanoprost and tafluprost groups. Both medications resulted in a progressive reduction in IOP over the 6-month study period, with no statistically significant difference observed between the two groups at any time point.

Table 3: Changes in Best-Corrected Visual Acuity (BCVA) from Baseline

Time Point (Months)	Latanoprost Group (logMAR), Mean ± SD	Tafluprost Group (logMAR), Mean ± SD
Baseline	0.25 ± 0.12	0.26 ± 0.14
1	0.26 ± 0.13	0.27 ± 0.15
3	0.27 ± 0.14	0.28 ± 0.16
6	0.28 ± 0.15	0.29 ± 0.17

Table 3 presents the changes in best-corrected visual acuity (BCVA) from baseline to different follow-up time points in both the latanoprost and tafluprost groups. No significant deterioration in BCVA was observed in either group throughout the study, indicating that both medications were well-tolerated with regard to visual function.

Table 4: Adverse Events

Adverse Event	Latanoprost Group (n)	Tafluprost Group (n)
Ocular irritation	3	2
Conjunctival hyperemia	2	1
Headache	1	0
Foreign body sensation	1	1
Other (specify)	0	1

Table 4 summarizes the adverse events reported during the study. Ocular irritation and conjunctival hyperemia were the most common adverse events, with similar frequencies in both the latanoprost and tafluprost groups. Other adverse events were infrequent, and no serious adverse events were reported in either group.

Overall, the results demonstrate that both latanoprost and tafluprost effectively reduced intraocular pressure in patients with normal-tension glaucoma over the 6-month study period, with comparable safety profiles and no significant impact on best-corrected visual acuity. These findings suggest that both medications can be considered suitable options for the management of NTG, allowing clinicians to make informed treatment decisions based on patient preferences and individual factors.

Discussion:

Normal-tension glaucoma (NTG) presents a unique challenge in ophthalmology due to its characteristic optic nerve damage and visual field loss, despite intraocular pressure (IOP) levels consistently within the normal range [1, 2]. The primary objective in managing NTG is to reduce IOP, as it has been shown to slow disease progression and preserve visual function [3].

Prostaglandin analogs, including latanoprost and tafluprost, are frequently used to achieve this goal [4]. This study aimed to compare the efficacy and safety of latanoprost and tafluprost in NTG management over a 6-month period. In this study, both latanoprost and tafluprost demonstrated significant reductions in IOP from baseline values. These IOP reductions were consistent with those reported in previous studies evaluating prostaglandin analogs in glaucoma patients [5, 6]. Importantly, no statistically significant difference in IOP reduction was observed between the two treatment groups at any of the study's time points. This suggests that both latanoprost and tafluprost are equally effective in lowering IOP in NTG patients.

Another critical aspect of glaucoma treatment is the preservation of visual function. In this study, changes in best-corrected visual acuity (BCVA) from baseline were assessed. Both treatment groups demonstrated minimal changes in BCVA over the 6-month period, and these changes were not statistically significant. These findings are consistent with previous research suggesting that prostaglandin analogs are generally well-tolerated and have a low risk of causing visual deterioration [7,8]. Thus, both latanoprost and tafluprost appear to be safe with respect to visual function in NTG patients.

The safety profile of the two medications was also assessed in this study. Adverse events reported were primarily mild and transient, such as ocular irritation and conjunctival hyperemia. These side effects are commonly associated with prostaglandin analogs and are generally well-tolerated by patients [9, 10]. No serious adverse events were reported in either treatment group. These findings are in line with the safety profiles established in clinical trials and real-world clinical practice. It is worth noting that patient preferences, cost considerations, and individual responses to treatment may influence the choice of medication in clinical practice. This study provides valuable information to clinicians by confirming that both latanoprost and tafluprost are effective and well-tolerated options for managing NTG.

Limitations of this study include its relatively short duration of 6 months and the absence of long-term

follow-up. Future research with extended follow-up periods may provide insights into the sustained efficacy and safety of these medications. Additionally, factors such as patient adherence and quality of life were not addressed in this study but should be considered in clinical decision-making.

Conclusion

In conclusion, the results of this study suggest that both latanoprost and tafluprost are effective in reducing IOP and preserving visual function in patients with normal-tension glaucoma. Both medications have a favorable safety profile, with minimal and transient adverse events. The choice between these two prostaglandin analogs should be individualized, taking into account patient preferences and cost considerations. Further research is warranted to evaluate the long-term outcomes and patient-reported outcomes associated with these treatments.

References:

1. Anderson DR, Drance SM, Schulzer M; Collaborative Normal-Tension Glaucoma Study Group. Natural history of normal-tension glaucoma. Ophthalmology. 2001;108(2):247-253.
2. Heijl A, Leske MC, Bengtsson B, et al; Early Manifest Glaucoma Trial Group. Reduction of intraocular pressure and glaucoma progression: results from the Early Manifest Glaucoma Trial. Arch Ophthalmol. 2002; 120(10):1268-1279.
3. Quigley HA. Glaucoma. Lancet. 2011; 377(9774):1367-1377.
4. Denis P. Adverse effects, adherence, and cost efficacy in glaucoma treatment. J Fr Ophtalmol. 2007; 30(1 Suppl 1):S1-S6.
5. Leung EW, Medeiros FA, Weinreb RN. Prevalence of ocular surface disease in glaucoma patients. J Glaucoma. 2008; 17(5):350-355.
6. Parrish RK, Palmberg P, Sheu WP; XLT Study Group. A comparison of latanoprost, bimatoprost, and travoprost in patients with elevated intraocular pressure: a 12-week, randomized, masked-evaluator multicenter study. Am J Ophthalmol. 2003; 135(5):688-703.
7. Konstas AG, Quaranta L, Katsanos A, et al. Twenty-four hour efficacy with preservative free tafluprost compared with latanoprost in patients with primary open angle glaucoma or ocular hypertension. Br J Ophthalmol. 2013; 97(12):1510-1515.
8. Baudouin C, Labbé A, Liang H, Pauly A, Brignole-Baudouin F. Preservatives in eyedrops: the good, the bad and the ugly. Prog Retin Eye Res. 2010; 29(4):312-334.
9. Simmons ST, Dirks MS, Noecker RJ. Comparison of the ocular hypotensive efficacy of adjunctive brimonidine 0.15% or brinzolamide 1% in combination with travoprost 0.004%. Ophthalmology. 2009; 116(3):449-455.
10. 10. Alm A, Grierson I, Shields MB. Side effects associated with prostaglandin analog therapy. Surv Ophthalmol. 2008; 53 Suppl1: S93-105.