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# Six-month efficacy of Latanoprostene Bunod 0.024% in patients with open-angle glaucoma: Retrospective clinical observational study

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## Abstract

**Purpose:** To analyse the 6-month clinical results of latanoprostene bunod (LBN) and to compare the efficacy of LBN in the treatment of open-angle glaucoma (OAG) with other prostaglandin analogues (PGAs), latanoprost and bimatoprost.

**Methods:** This retrospective study included 193 patients with OAG. There were 63 patients in the LBN group, 57 in the bimatoprost group, and 73 in the latanoprost group. We examined the intraocular pressure (IOP) changes, retinal nerve fibre layer (RNFL) analyses, and visual field (VF) changes of each group during the 6-month treatment period. Baseline and 6-month data of the LBN group were compared. The 6-month changes of the LBN group were statistically compared with the 6-month changes of the bimatoprost and latanoprost groups.

**Results:** After six months of LBN use, there was a significant decrease in IOP compared to baseline ( $p=0.022$ ). No difference was found in terms of other parameters ( $p>0.05$  for each). In other parameters, LBN was similar to bimatoprost and latanoprost ( $p>0.05$  for each).

**Conclusion:** LBN provides a significant decrease in IOP. However, 6-month clinical effects were similar to bimatoprost and latanoprost.

**Keywords:** Bimatoprost; latanoprost; latanoprostene bunod; primary open-angle glaucoma; pseudoexfoliation glaucoma.

**G**laucoma is a group of optic neuropathies characterised by loss of visual fields (VF) and ganglion cells and is the most common cause of irreversible blindness worldwide.<sup>[1,2]</sup> Glaucoma influences over 70 million individuals globally, with the prevalence estimated to be significantly higher because it may remain asymptomatic until advanced stages.<sup>[3,4]</sup> Primary open-angle glaucoma

(POAG) is the most common type of OAG and is diagnosed with the presence of an open angle on gonioscopy, onset in adulthood, and absence of other causes to explain optic neuropathy.<sup>[5]</sup> In pseudoexfoliation glaucoma (PEG), which is the most common known cause of secondary open-angle glaucoma, proteinous material deposits in the anterior segment accompanying the open angle are remarkable.<sup>[6]</sup>



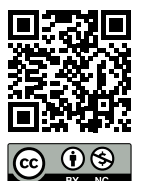
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Since IOP is still the only modifiable risk factor for glaucoma, a single topical antiglaucomatous eye drop, most commonly prostaglandin analogues (PGAs), is the first choice for the treatment of open-angle glaucoma.<sup>[7]</sup> In comparison to other classes of topical ocular antiglaucomatous agents, PGAs showed improved efficacy, safety, and tolerability, and they can substantially prevent the progression of the disease.<sup>[8]</sup> Furthermore, the once-daily regimen has been related to increased compliance in comparison to eye drops that are administered more frequently. However, patient compliance with these medications remains a challenge, with adherence and persistence rates typically falling below 50%.<sup>[9,10]</sup> Until recent years, the most commonly used topical PGAs in our clinical practice were latanoprost, bimatoprost, and travoprost.<sup>[11]</sup> A new prostaglandin F2 $\alpha$  analogue that donates nitric oxide is known as Vyzulta (latanoprostene bunod (LBN) ophthalmic solution, 0.024% w/v).<sup>[12]</sup> Clinical research (APOLLO and LUNAR studies) has thoroughly established the safety and efficacy of LBN, which exhibited superior efficacy in comparison to latanoprost and timolol.<sup>[13–15]</sup>

In this study, we aimed to analyse the 6-month clinical results of LBN and to compare the efficacy of LBN in the treatment of OAG with other PGAs, latanoprost and bimatoprost. For this reason, we examined the IOP changes, retinal nerve fibre layer analyses (RNFL), and VF changes of each group during the 6-month treatment period. We also aimed to evaluate the 6-month effects of LBN according to glaucoma type (POAG or PEG) and glaucoma stage (initial, intermediate, advanced). We consider that our study is important in terms of comparing the clinical effects and guiding our treatment choices in glaucoma polyclinics.

## Materials and Methods

This retrospective study included 193 patients with OAG who were admitted to Sultan Abdülhamid Han Training and Research Hospital, Ophthalmology Department, Glaucoma Subspecialty Polyclinic for routine follow-up and treatment. The examination dates of the patients were between November 2022 and November 2023. The ethics committee approval of our study was granted by Haydarpaşa Numune Training and Research Hospital (HNEAH-KAEK 2024/KK/23) and is in accordance with the Declaration of Helsinki.

Patients were diagnosed with OAG based on untreated IOP >21 mmHg by Goldmann applanation tonometry, the presence of glaucomatous optic neuropathy on fundus examination, an open angle on gonioscopy, retinal nerve

fibre thinning associated with optic neuropathy, or the presence of glaucomatous defects on Swedish Interactive Thresholding Algorithm (SITA)-Faster 24-2 Humphrey automated perimetry. Patients with POAG and PEG were included in the study. Only patients who were diagnosed with glaucoma for the first time and started medication were included in this study. The examination results of the patients on the day of the first PGA initiation were considered as baseline. The examination data 6 months after this date were recorded. IOP measured by Goldmann applanation tonometry, peripapillary RNFL analyses measured in 7 quadrants with a spectral-domain optical coherence tomography (SD-OCT) (Heidelberg Engineering, Heidelberg, Germany), VF index (VFI), mean deviation (MD) value in dB, pattern standard deviation (PSD) value in dB, and glaucoma hemifield test (GHT) results in Humphrey automated visual field were retrospectively analysed and recorded. Baseline and 6-month data of the LBN (Vyzulta 0.24 mg/ml, Bausch & Lomb, Hidden River Parkway, Tampa, Florida/ABD) group were statistically compared. The difference between baseline and 6-month examination findings was compared between LBN, bimatoprost (Lumigan RC, AbbVie, Türkiye), and latanoprost (Latafree, VEM, Türkiye) groups. The LBN group was also divided into glaucoma stages according to MD values and glaucoma subtypes for the diagnosis of POAG or PEG. According to MD values in the visual field, the following definitions applied:

- 0 to -6 dB: initial stage glaucoma
- -6 to -12 dB: moderate stage glaucoma
- -12 dB: advanced stage glaucoma

There were 68 patients in the LBN group, 61 in the bimatoprost group, and 78 in the latanoprost group. The study excluded patients who were younger than 18 years of age, failed to comply with the VF test, had primary or secondary ACG, or were using antiglaucomatous drops other than LBN, bimatoprost, or latanoprost. The study excluded patients with a history of ocular trauma, those who used medications such as hydroxychloroquine that could cause VF defects, and those with additional neurological, systemic, or ocular diseases that might lead to VF defects. Patients with severe cardiovascular or diabetic conditions, patients taking drugs such as calcium channel blockers that may affect NO release, and patients receiving ozone or hyperbaric oxygen therapy were also excluded from the study. Patients who could not tolerate PGAs due to drug side effects were excluded from the study. The study did not include VF tests with a false negative or false positive rate

of over 20%, or tests with a fixation loss rate of over 30%. The study included participants who had been diagnosed with OAG and whose eyes had been treated with the PGAs mentioned. If the patients had a diagnosis of OAG in both eyes, both eyes were included in the study. Both eyes of 6 patients in the latanoprostene group, 4 patients in the bimatoprost group, and 5 patients in the latanoprost group were included in the study. All patients included in both eyes were diagnosed with POAG.

### Statistical Analysis

The NCSS (Number Cruncher Statistical System) 2020 Statistical Software (NCSS LLC, Kaysville, Utah, USA) program was used for statistical analyses when evaluating the findings obtained in the study. In the evaluation of the study data, quantitative variables were presented using descriptive statistical methods such as mean, standard deviation, median, minimum, and maximum values, while qualitative variables were presented using frequency and percentage. The Shapiro-Wilks test, skewness and kurtosis values, and Box Plot graphs were used to assess the normality of the data distribution.

For comparisons between two groups of quantitative variables showing a normal distribution, the Paired Sample t-test was used; for comparisons between three or more groups, the One-Way ANOVA test was used; and to identify the group causing the difference, the Bonferroni test was used. For two-group comparisons of variables not showing a normal distribution, the Mann-Whitney U test was used; for within-group evaluations, the Wilcoxon Signed Rank test was used; for comparisons of three or more groups, the Kruskal-Wallis test was used; and the Dunn test was used to identify the group causing the difference.

Spearman's correlation analysis was performed to evaluate the relationships between variables. Pearson's Chi-Square test and Fisher-Freeman-Halton test were used to compare qualitative data. The General Linear Model (GLM) was used to examine the effect of measurement values over time in the groups. Results were evaluated at a 95% confidence interval and a significance level of  $p < 0.05$ .

### Results

This retrospective study included 63 patients in the LBN group, 57 patients in the bimatoprost group, and 73 patients in the latanoprost group. The participants included in the study were homogeneous between the groups in terms of mean age and gender ( $p = 0.069$ ,  $p = 0.524$ , respectively). Both eyes of 6 patients in the latanoprostene group, 4 patients in the bimatoprost group, and 5 patients in the latanoprost group were included in the study. The sociodemographic data of the participants are summarised in Table 1.

To examine the effect of time on changes in IOP values within groups (LBN, bimatoprost, and latanoprost groups), the General Linear Model (GLM) was used. The model obtained was found to be statistically significant [ $F = 11.998$ ;  $p < 0.01$ ]. While the effect of the group was not found to be significant in the model ( $p = 0.698$ ;  $p > 0.05$ ), the effect of time, when follow-ups were considered, was found to be significant ( $p = 0.001$ ;  $p < 0.01$ ). In particular, the significance of the group\*time interaction was reviewed and found to be insignificant ( $p = 0.434$ ;  $p > 0.05$ ). The insignificance of the interaction effect means that the groups did not affect the change in IOP values over time. The GLM models did not detect any statistical significance regarding the effect on the distribution over time of other follow-up parameters, which include the 7 quadrants of RNFL, VFI, MD, and PSD ( $p > 0.05$  for each) (Table 2).

Comparing baseline and 6-month parameters by group, the LBN group showed a substantial decrease in the 6-month mean IOP compared to baseline values ( $p = 0.022^*$ ), whereas the bimatoprost and latanoprost groups did not show any statistically significant difference ( $p > 0.05$ ). Changes in MD and PSD values and RNFL measurements from 7 quadrants did not show a significant difference ( $p > 0.05$  for each). In VFI results, there was a significant decrease in the latanoprost group at 6 months compared to baseline ( $p = 0.035^*$ ) (Table 3a).

There was no statistically significant difference in the effects of the 6-month treatment on follow-up parameters between the groups (LBN, bimatoprost, and latanoprost) ( $p > 0.05$  for each) (Table 3b).

**Table 1.** Sociodemographic data of the participants

	Latanoprostene group (n=63)	Bimatoprost group bunod (n=57)	Latanoprost group (n=73)	p
Age (min-max)	60.49±13.2 (35-89)	63.72±8 (42-77)	64.97±6.9 (39-79)	0.069
Gender, n (%)				
Female	35 (55.5)	37 (64.9)	44 (60.27)	0.524
Male	28 (44.4)	20 (35.08)	29 (39.7)	

**Table 2.** GLM Model Results for Measurement Values

	F	p	Effect sizes
IOP* (mm Hg)			
Model	11.998	0.001**	0.106
Group	0.360	0.698	0.007
Time	2655.339	0.001**	0.963
Group * Time	0.842	0.434	0.016
RNFL** (µm) Central			
Model	0.728	0.396	0.007
Group	0.144	0.866	0,003
Time	4571.807	0.001**	0.978
Group* Time	0.500	0.608	0.010
Temporo-superior (TS)			
Model	0.112	0.739	0.001
Group	0.074	0.929	0.001
Time	3672.530	0.001**	0.973
Group * Time	0.338	0.714	0.007
Naso-superior (NS)			
Model	0.581	0.448	0.006
Group	1.201	0.305	0.023
Time	2482.635	0.001**	0.961
Group * Time	1,123	0,329	0,022
Nasal (N)			
Model	0.003	0.953	0.000
Group	0.056	0.945	0.001
Time	2672.844	0.001**	0.964
Group * Time	0,120	0,887	0,002
Naso-inferior (NI)			
Model	2.057	0.155	0.020
Group	0.508	0.603	0.010
Time	1966.895	0.001**	0.952
Group* Time	0.249	0.780	0.005
Temporo-inferior (TI)			
Model	0.062	0.803	0.001
Group	0.409	0.666	0.008
Time	2698.145	0.001**	0.964
Group * Time	0.942	0.393	0.018
Temporal (T)			
Model	3.280	0.073	0.032
Group	0.818	0.444	0.016
Time	3300.991	0.001**	0.971
Group* Time	0.110	0.896	0.002
Visual Field Index (VFI) (%)			
Model	1.486	0.226	0.017
Group	0.667	0.516	0.015
Time	4534.280	0.001**	0.981
Group* Time	0.112	0.895	0.003
Mean Deviation (MD) (dB)			
Model	2.846	0.095	0.029
Group	0.917	0.403	0.019
Time	52.520	0.001**	0.358
Group * Time	1.666	0.195	0.034
Pattern Standard deviation (PSD)(dB)			
Model	0.115	0.735	0.001
Group	2.043	0.135	0.042
Time	351.167	0.001**	0.789
Group * Time	1.669	0.194	0.034

F: GLM model value \*\*p<0,01; \*p<0,05; IOP\*: Intra-ocular pressure; RNFL\*\*: Retinal nerve fiber layer.

The LBN group was divided into two groups based on the glaucoma subtypes PEG and POAG. After six months of drug treatment, the follow-up parameters were compared, and no significant differences were observed in IOP, RNFL in the central, naso-superior (NS), nasal (N), naso-inferior (NI), and temporal (T) quadrants, VFI, and MD values (p>0.05 for each). Compared to the POAG group, the PEG group exhibited a significantly higher 6-month change in the temporo-superior (TS) quadrant of the RNFL (p=0.016\*); the POAG group exhibited a significantly higher 6-month change in the temporo-inferior (TI) quadrant of the RNFL than the PEG group (p=0.009\*). Compared to the POAG group, the PSD alterations in the PEG group were substantially greater over the duration of six months (p=0.038\*) (Table 4).

Based on MD values, the LBN group was classified into early, intermediate, and advanced phases. However, no statistically significant relationship was observed between changes in IOP, the central, TS, NS, N, NI, and T quadrants of the RNFL, VFI, and PSD by stage (p>0.05 for each). Significantly negative correlations were observed between alterations in the R TI quadrant of RNFL and the stages. As the stage progressed, the difference reduced (r=0.0449, p=0.013\*) (Table 5).

### Discussion

In this study, in which we analysed the 6-month clinical results of LBN, it was observed that it significantly decreased IOP; however, it did not produce a statistically significant difference in terms of RNFL and visual field parameters. When LBN was compared with other PGAs, similar results were observed in all parameters.

The LUNAR<sup>[13]</sup> and APOLLO<sup>[16]</sup> studies aimed to compare the results of LBN and timolol 0.5% drops in patients with OAG. A 3-month follow-up was performed in the LUNAR study and a 9-month follow-up was performed in the APOLLO study. In both studies, LBN was not found to be inferior to timolol. Moreover, LBN was found to be superior to timolol in the APOLLO study. The mean IOP decrease in LUNAR and APOLLO compared to baseline is higher in the LBN group than in the timolol group. In APOLLO, mean diurnal IOP was lower in LBN users compared to timolol.<sup>[13,16]</sup> In our study, a significant decrease in IOP was observed at the end of 6 months of LBN treatment compared to the baseline IOP average; however, this change level showed no significant difference between groups when compared to other PGAs such as bimatoprost and latanoprost. According to our study, LBN demonstrated similar efficacy to bimatoprost

**Table 3a.** Comparison of Baseline and 6-Month Measurement Values of Groups

	<b>Latanoprostene bunod n=68 Mean±SD</b>	<b>Bimatoprost n=61 Mean±SD</b>	<b>Latanoprost n=78 Mean±SD</b>	<b>Test value/p</b>	<b>Cohen'd</b>
IOP* baseline (mmHg)	17.27±4.21	17.39±2.79	16.68±3.69	0.394/ F0.675	0.087
IOP 6th month	15.77±3.80	16.62±3.42	15.97±3.22	0.511/F0.605	0.101
p	2.402/ t0.022*	1.687/t0.102	1.901/t0.065		
Cohen'd (95% CI)	0.406 (0.058-0.748)	0.308(-0.061-0.672)	0.304 (-0.019-0.624)		
RNFL**(µm)Central baseline	88.64±14.29	90.69±11.83	89.09±13.77	0.210/F0.811	0.063
RNFL Central 6.th month	88.79±14.00	90.11±11.61	88.89±14.60	0.096/ F0.909	0.043
p	-0.380/t0.706	0.875/t0.389	0.656/t0.516		
Cohen'd (95% CI)	-0.064 (-0.35-0.268)	0.157 (-0.198-0.510)	0.106 (-0.213-0.425)		
Temporo-superior(µm) (TS) baseline	119.96±19.72	122.40±19.04	119.77±22.58	0.394/F0.675	0.056
TS 6th month	119.67±19.17	121.02±21.60	120.78±22.21	0.511/F0.601	0.027
p	0.217/t0.830	0.498/t0.622	-0.662/t0.512		
Cohen'd (95 %CI)	0.037 (-0.295-0.368)	0.089(-0.264-0.441)	-0.107(-0.425-0.212)		
Naso-superior (µm) (NS) baseline	101.40±19.47	104.87±19.62	96.95±21.32	1.351 /F0.264	0.159
NS 6.ay	103.93±20.57	103.97±20.51	97.37±24.46	1.072/F0.346	0.144
p	-1.287/t0.207	0.539/t0.594	-0.444/t0.660		
Cohen'd (95 %CI)	-0.217 (-0.551-0.119)	0.097(-0.257-0.449)	-0.072(-0.390-0.247)		
Nasal (µm) (N) baseline	66.71±15.04	66.95±12.63	68.35±13.39	0.152 /F0.859	0.054
N 6th month	66.80±13.80	67.15±12.93	67.58±12.76	0.032/F0.968	0.025
p	-0.121/t0.905	-0.283/t0.779	0.342/t0.734		
Cohen'd (95% CI)	-0.020 (-0.352-0.311)	-0.051(-0.403-0.302)	0.055(-0.263-0.373)		
Naso-inferior(µm)(NI )başseline	99.04±23.83	100.00±21.40	102.89±25.94	0.256 /F0.774	0.070
NI 6th month	96.68±20.60	97.97±19.06	102.42±26.43	0.557/F0.576	0.112
p	0.986/t0.331	1.116/t0.273	0.316/t0.754		
Cohen'd (95% CI)	0.169 (-0.171-0.506)	0.200(-0.157-0.554)	0.051(-0.267-0.369)		
Temporo-inferior(µm) (TI) baseline	124.3±22.68	129.97±20.76	123.17±29.99	0.696 /F0.501	0.115
TI 6th month	125.29±23.06	127.60±21.61	123.58±29.98	0.213/F0.809	0.064
p	-1.558/t0.129	1.193/t0.242	0.156/t0.877		
Cohen'd (95% CI)	-0.267 (-0.607-0.077)	0.214(-0.144-0.569)	0.025(-0.293-0.343)		
Temporal(µm)(T) baseline	64.76±13.27	67.32±11.04	68.56±12.59	0.892/F0.413	0.130
T 6th month	65.06±14.10	68.35±10.9	68.18±10.74	0.813/F0.446	0.125
p	-1.030/t0.310	-1.490/t0.147	-0.723/t0.474		
Cohen'd (95% CI)	-0.177 (-0.514-0.163)	-0.268(-0.624-0.093)	-0.117(-0.435-0.203)		
	<b>Median (Min-Max)</b>	<b>Median (Min-Max)</b>	<b>Median (Min-Max)</b>		
Visual field index(VFI)% baseline	95.5 (46-100)	97 (29-100)	92.5 (20-100)	5.468/H0.065	0.138
VFI 6th month	96 (32-100)	96.5 (60-100)	95.5 (39.5-100)	0.331/H0.848	0.129
p	-1.037/w0.300	-0.430/w0.667	-2.106/w0.035*		
Cohen'd (95% CI)	-0.198 (-0.558-0.165)	-0.054(-0.425-0.317)	-0.147(-0.494-0.203)		
Mean deviation (dB)(MD )baseline	-3.1 (-18.2-1.7)	-1.1 (-23.2-1.9)	-3.3 (-26.5-13.7)	6.946/H0.031*	0.179
MD 6th month	-1.8 (-22.1-2.4)	-1.5 (-13.3-1.8)	-2.4 (-19.8-5.9)	0.374/H0.830	0.126
p	-1.697/w0.090	-1.003 /w0.316	-1.778/w0.075		
Cohen'd (95% CI)	-0.356 (-0.717-0.010)	0.105(-0.255-0.463)	-0.242(-0.572-0.091)		
Pattern standard deviation (dB) (PSD) baseline	3.1 (1.3-9.4)	2.2 (1.3-10.2)	3.8 (0.1-10)	6.958/H0.031*	0.274
PSD 6th month	2,8 (1-9,5)	2,6 (1,2-8,6)	3,2 (1,3-11)	4.597/H0,100	0,182
p	-0.339/w0.734	-1.410/w0.159	-1.974/w0.048*		
Cohen'd (95% CI)	0.169 (-0.187-0.522)	-0.310(-0.674-0.059)	0.141(-0.189-0.468)		

<sup>F</sup>One Way Anova Test; <sup>H</sup>Kruskal Wallis Test; <sup>t</sup>Paired Samples t Test; <sup>W</sup>Wilcoxon Signed Rank Test IOP\*: Intra-ocular pressure; RNFL\*\*: Retinal nerve fiber layer.

**Table 3b.** Comparison of 6-month changes  $\Delta$  between latanoprostene bunod, bimatoprost and latanoprost groups

Change $\Delta$	Latanoprost n=68	Bimatoprost n=61	Latanoprost n=78	Test value/p	Cohen'd
	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD		
IOP*(mmHg)	-1.50 $\pm$ 3.69	-0.75 $\pm$ 2,43	-0.71 $\pm$ 2,32	1.008/ H0.604	0.126
RNFL** central( $\mu$ m)	0.14 $\pm$ 2.22	-0.58 $\pm$ 3,69	-0.32 $\pm$ 2,97	2.470/H0.291	0.097
Temporo-superior ( $\mu$ m) (TS)	-0.29 $\pm$ 7.80	-1.39 $\pm$ 15.50	0.66 $\pm$ 6.13	0.098/H0.952	0.081
Naso-superior ( $\mu$ m) (NS)	2.53 $\pm$ 11.63	-0.90 $\pm$ 9.33	0.49 $\pm$ 6.77	1.380/H0.501	0.146
Nasal ( $\mu$ m) (N)	0.09 $\pm$ 4.20	0.19 $\pm$ 3.81	-0.37 $\pm$ 6.64	2.419/H0.298	0.048
Naso-inferior ( $\mu$ m) (NI)	-1.47 $\pm$ 8.70	-2.03 $\pm$ 10.14	-0.47 $\pm$ 9.24	1.186/H0.553	0.070
Temporo-inferior ( $\mu$ m) (TI)	1.87 $\pm$ 6.99	-2.37 $\pm$ 11.06	-0.42 $\pm$ 16.66	0.345/H0.137	0.135
T	0.68 $\pm$ 3.83	1.03 $\pm$ 3.86	0.57 $\pm$ 4.83	0.345/H0.841	0.045
VFI	1.78 $\pm$ 8.99	0.59 $\pm$ 10.83	1.44 $\pm$ 9.78	2.708/H0.258	0.049
MD	1.24 $\pm$ 3.49	-0.34 $\pm$ 3.27	0.98 $\pm$ 4.07	4.400/H0.111	0.181
PSD	-0.43 $\pm$ 2.56	0.56 $\pm$ 1.8	-0.38 $\pm$ 2.68	4.597/H0.100	0.182

HKruskal Wallis Test; IOP\*: Intra-ocular pressure; RNFL\*\*: Retinal nerve fiber layer.

**Table 4.** Comparison of 6-month changes in the latanoprostene bunod group according to glaucoma types

Latanoprostene bunod=68 Change	PEG* n=16		POAG** n=52		Test value/Zp
	Mean $\pm$ SD	Median (Min-Max)	Mean $\pm$ SD	Median (Min-Max)	
IOP*** (mmHg)	0.28 $\pm$ 2.81	0 (-4.5-5)	-2.12 $\pm$ 3.81	-0.8 (-15-5.5)	-1.841/Z0.067
RNFL <sup>2</sup> ( $\mu$ m) Central	1.06 $\pm$ 2.79	0 (-2-6.5)	-0.17 $\pm$ 1.96	0 (-4-4.5)	-0.796/Z0.446
Temporo-superior ( $\mu$ m)TS	4.94 $\pm$ 6.25	5.5 (-4-12.5)	-2.10 $\pm$ 7.56	-1.3 (-25-9)	-2.360/Z0.016*
Naso-superior ( $\mu$ m) NS	5.17 $\pm$ 7.64	3 (0-24)	1.62 $\pm$ 12.72	1.5 (-14-53)	-1.361/Z0.184
Nasal ( $\mu$ m) (N)	1.67 $\pm$ 5.51	0.5 (-3.5-15)	-0.46 $\pm$ 3.61	0.3 (-9.5-6.5)	-0.890/Z0.382
Naso-inferior( $\mu$ m)(NI)	-2.94 $\pm$ 4.34	-2.5 (-12.5-1.5)	-0.94 $\pm$ 9.83	0 (-34-17.5)	-1.329/Z0.188
Temporo-inferior ( $\mu$ m)(TI)	-3.06 $\pm$ 5.28	-3 (-11-3.5)	3.64 $\pm$ 6.75	3 (-6-21.5)	-2.541/Z0.009**
Temporal( $\mu$ m)(T)	1.22 $\pm$ 5.42	0 (-3.5-14.5)	0.48 $\pm$ 3.20	0 (-5-8.5)	-0.137/Z0.908
Visual Field Index % (VFI)	1.1 $\pm$ 9.39	-2 (-8.5-16.5)	1.92 $\pm$ 9.1	0.5 (-18.5-27)	-0.613/Z0.552
Mean Deviation (dB) MD	2.75 $\pm$ 4.22	2.4 (-2.9-7.9)	0.88 $\pm$ 3.28	0.2 (-6.2-8.4)	-0.750/Z0.478
Pattern Standard Deviation (dB) PSD	-1.60 $\pm$ 3.53	-0.9 (-7.3-2.1)	-0.15 $\pm$ 2.28	0 (-5.8-3.3)	-2.076/Z0.038*

ZMann Whitney U Test; \*\*\*p<0,01; \*p<0,05; PEG\*: Pseudoexfoliation glaucoma; POAG\*\*: Primary open angle glaucoma; IOP\*\*\*: Intra-ocular pressure; RNFL<sup>2</sup>: Retinal nerve fiber layer.

and latanoprost in reducing IOP during 6 months of clinical use. Likewise, no significant difference was observed between LBN, bimatoprost, and latanoprost users in the RNFL and visual field findings after 6 months of treatment. In the JUPITER study, results of 12 months of LBN use in Japanese patients over 20 years of age with OAG (PEG, normotensive or pigmentary glaucoma) or ocular hypertension were published. Statistically significant IOP decreases were found from the 1<sup>st</sup> month of LBN use compared to baseline values.<sup>[17]</sup> Our study also supports these results of JUPITER. In patients with POAG or PEG, there was a significant decrease in the mean IOP compared to baseline after 6 months of regular use of LBN. However, in

contrast to this study, in our study, LBN users were divided into two subgroups based on their diagnosis of PEG and POAG, and the differences in the follow-up parameters of the 6-month treatment were compared between the groups. No significant difference was observed between the two groups in terms of IOP, the five quadrants of RNFL, MD, and VFI values. However, 6-month changes in the TS and TI quadrants of the RNFL were found to differ between the two groups. It was thought that this difference could be due to deviations in the peripapillary area related to image quality. The 6-month PSD change was found to be significantly higher in the PEG group compared to the POAG group. This difference may be interpreted as indicating that

**Table 5.** The relationship between 6-month changes in the Latanoprost bunod group according to the stage of glaucoma (initial, moderate, advanced)

	Glaucoma Stage	
	r	P
IOP* (mmHg)	0.134	0.474
RNFL** ( $\mu\text{m}$ ) Central	0.113	0.545
Temporo-superior ( $\mu\text{m}$ ) (TS)	0.101	0.588
Naso-superior ( $\mu\text{m}$ ) (NS)	-0.122	0.512
Nasal ( $\mu\text{m}$ ) (N)	0.251	0.173
Naso-inferior ( $\mu\text{m}$ ) (NI)	-0.048	0.803
Temporo-inferior ( $\mu\text{m}$ ) (TI)	-0.449	0.013*
Temporal ( $\mu\text{m}$ ) (T)	-0.262	0.163
Visual Field Index % (VFI)	0.145	0.446
Pattern Standard Deviation (dB) (PSD)	0.116	0.535

r: Spearman's Correlation Coefficient; \*p<0,05.

NO-containing LBN could be a more effective treatment agent due to its anti-inflammatory efficacy in patients diagnosed with PEG.

In a retrospective study of the results of 12 months of LBN use in patients with OAG who were switched from tafluprost, travoprost, or latanoprost to LBN, a significant extra decrease in IOP was observed after switching to LBN. In VFI, MD, and PSD values, and peripapillary RNFL values, no significant decrease was observed after switching to LBN.<sup>[18]</sup> The study group consisted of patients with POAG and normotensive glaucoma. This study, in which we evaluated our 6-month results, also supports these results. There was no worsening in the mean RNFL or visual field VFI, MD, or PSD values after 6 months of LBN use. In our study, we classified patients in the LBN group as initial, moderate, and advanced glaucoma based on their MD values and evaluated the relationship between glaucoma stage and the 6-month change in follow-up parameters. We found no significant relationship between glaucoma stage and IOP, the central, TS, NS, N, NI, and T quadrants of the RNFL, VFI, or PSD. Only a significant negative correlation was found between the stage of glaucoma and the change in the RNFL in the TI quadrant. To confirm the validity of this finding, further studies with a longer follow-up period and a larger number of patients should be conducted.

In a retrospective study evaluating the findings of patients with POAG (POAG, PEG, or pigmentary glaucoma) or ocular hypertension who switched from current treatment to LBN, an additional 25% reduction was achieved after switching to LBN.<sup>[19]</sup> Before switching to LBN, patients were using a different PGA, or timolol, brimonidine, brinzolamide, or

different combinations of them. In our study, we compared the 6-month outcomes of patients who used LBN or other PGAs, bimatoprost and latanoprost, as the initial treatment agent, not patients who were switched from another drug. Comparison of the 6-month effects of LBN, bimatoprost, and latanoprost in patients with OAG showed that LBN has similar efficacy in all parameters compared to bimatoprost and latanoprost.

The study has limitations. The first is the retrospective character of our study. Since the inability to mask patient information is due to the retrospective design, it is not possible to completely rule out potential bias in the selection process. Secondly, we divided the LBN group into PEG and POAG subgroups and evaluated the findings; however, the number of patients in the subgroups was not comparable and was limited. Therefore, to evaluate the efficacy of LBN according to glaucoma type in more detail, it is necessary to include a larger number of patients. Another limitation is that, because it was not possible to standardise the IOP measurement times for the patients, we could not track the diurnal IOP changes for the same reason. And the last one is the 6-month follow-up period of the patients. A study with a prospective design that has a longer follow-up period will provide more data.

## Conclusion

In conclusion, after six months of LBN use, there was a significant decrease in IOP compared to baseline, and RNFL and VF parameters did not worsen over the 6 months. However, LBN showed similar efficacy to bimatoprost and latanoprost in terms of IOP-lowering effect and stabilisation of VF parameters. These findings need to be supported by further studies with longer follow-up and a larger number of patients.

**Ethics Committee Approval:** The Haydarpaşa Numune Training and Research Hospital Ethics Committee granted approval for this study (Date: 12.02.2024, number: HNEAH-KAEK 2024/KK/23).

**Informed Consent:** Informed consent was obtained.

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