ORIGINAL ARTICLE

Ocular Surface Evaluation after Switch from Latanoprost 0.005% to Latanoprostene Bunod 0.024%

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Abstract

Aim and background: To evaluate the ocular surface of patients treated with latanoprost (LT) 0.005% who switched to latanoprostene bunod (LBN) 0.024%.

Materials and methods: A prospective and nonrandomized clinical study of a case series was performed, including patients with chronic open-angle glaucoma who were on previous LT-only treatment and, after a washout period, switched to LBN, with a 3-month follow-up. The main parameter to be evaluated was the ocular surface disease index (OSDI) test. In addition, best-corrected visual acuity (BCVA), intraocular pressure (IOP), biomicroscopic aspect of the ocular surface, measuring tear breakup time, fluorescein staining (grading performed on Oxford scale) and Schirmer I test were evaluated.

Results: A total of 36 patients (72 eyes) were included, 21 women (58.3%) and 15 men (41.7%, with a mean age of 65.6 ± 10.9 years (37–86). The initial OSDI score was 17.8 ± 12.1 and improved to 11.1 ± 10.5 ($p < 0.01$). From the data evaluated at biomicroscopy, an improvement was observed in the Oxford scale from 0.6 ± 0.7 to 0.2 ± 0.8 (p: 0.01), but no statistically significant changes were observed in the break-up time (BUT) and Schirmer. BCVA remained stable, as did IOP, which was initially 13.4 ± 2.1 mm Hg and, after performing the LBN treatment change, went to 13.1 ± 1.7 mm Hg.

Conclusion: After the change of treatment from LT 0.005% to LBN 0.024%, the patients had an improvement in the ocular surface, maintaining control of their IOP. The need to investigate possible beneficial mechanisms on the ocular surface in glaucoma patients treated with LBN, potentially related to nitric oxide, is raised.

Clinical significance: Patients treated with LT 0.005% who switched to LBN 0.024% had an improvement in ocular surface symptoms and signs, keeping IOP under control.

Latanoprostene bunod (LBN) 0.024% may have beneficial effects on the ocular surface, which should be further studied.

Keywords: Glaucoma, Latanoprost, Latanoprostene bunod, Ocular surface, Ocular surface disease index-score.

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Introduction

The association between ocular surface alterations and glaucoma is well known, whether caused by medical therapy directly or as a result of some surgical techniques.[1] Regarding medical treatments, hypotensive drops can alter the ocular surface by various mechanisms, either by the side effect of the drug itself or by the effect of the preservative used.[2] Tolerance to topical treatment in glaucoma is relevant since potentially, a good drug, if poorly tolerated, will alter the patient's adherence to treatment, affecting efficacy.[3,4] To assess tolerance and ocular surface disease, in addition to the clinical observations that the physician can make, it is relevant to know the patient's opinion, for which, among the different tests that have been developed, the ocular surface disease index (OSDI) is a robust, reliable and widely validated measurement tool, based on questions aimed at detecting and grading the ocular surface involvement, in the context of a person's quality of life.[5,6]

Latanoprostene bunod (LBN) 0.024% is a drug that has been presented and approved for the treatment of glaucoma in 2017 (Vyzulta; Bausch & Lomb Argentina SRL Buenos Aires, Argentina), which is placed once a day and which has demonstrated its hypotensive efficacy.[7–12] This is achieved in a differential manner due to the fact that its formula generates, in addition to the hypotensive effect of prostaglandin analogues, an extra hypotensive effect due to its quality as a "nitric oxide donor."[5] Although the different studies already published have considered conjunctival hyperemia, irritation and ocular pain among the adverse effects, there are no publications that have specifically studied the effect of LBN on the ocular surface, prioritizing the impact on the patient's opinion. Therefore, the aim of the present work was to evaluate the patient's opinion in relation to the ocular surface tolerance of LBN 0.024%, compared to the use of latanoprost (LT) 0.005%.

Materials and Methods

A prospective, nonrandomized, nonmasked, comparative case series clinical study of patients using hypotensive monotherapy with LT 0.005% who then switched to LB 0.024% was designed at the

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Quilmes Eye Center (Buenos Aires, Argentina) between September 2021 and March 2022. The study was registered (code 23922), evaluated, and approved by the Institutional Review Board of the Quilmes Eye Center, and the participating investigators worked according to the Declaration of Helsinki. Each participating patient was previously informed and expressed his or her acceptance by means of a consent form.

Potential cases were recruited after reviewing the electronic database of the Quilmes Eye Center, who were over 21 years of age and were already being treated for chronic open-angle glaucoma, using monotherapy with LT 0.005%, of any brand approved in Argentina, with a previous treatment time of 6–12 months and who had no known intolerance to such treatment. Contact lens wearers and those who did not comply with the visits with a tolerance time of ±2 days for the follow-up times of the scheduled controls were excluded.

Patients who required any surgery or different topical ocular treatment during the study period or those who required it within the 6 months immediately after the start of the study were also excluded, with the exception of ocular lubricants. Previous use of lubricants or prescription of lubricants during the study was not a reason for exclusion. However, this represented one more data point to be evaluated.

During recruitment, patients were summoned, informed of the study and eligibility criteria were checked. This phase was carried out until the inclusion of a minimum of 35 patients who accepted and signed the informed consent form. After including the patient in the study, the following parameters (zero characteristics) were recorded: age, gender, commercial name of the LT used (and time of previous use), and history of treatment with lubricants or other dry eye therapy. At this baseline visit, the OSDI test and the following scans were performed: Best-corrected visual acuity (BCVA), evaluation of the ocular surface in slit lamp, measuring tear break-up time (BUT), fluorescein staining (scoring from 0 to V using the Oxford scale[13]) and the "modified Schirmer I" test (with topical anesthetic, without nasal stimulation), measurement of intraocular pressure (IOP), measured by Goldman tonometry. The same tests were performed again one and three months after starting treatment with LBN, which occurred after the patient was instructed to discontinue the previous treatment and to perform a 1-week washout period. The placement of LB was indicated once a day, in the morning (in the same manner in which his drops were administered previously). Each patient was given a new bottle per month and was asked to return it to their doctor at the end of the month, and a record of product distribution was made.

In relation to the score obtained in the OSDI test, the patients were divided into four groups: I, normal, between 0 and 12 points; II, mild dry eye syndrome, between 13 and 22; III, moderate dry eye, from 23 to 32 points; and IV, severe dry eye syndrome, from 33 to 100 points. The number of patients who were in each group, before and after the change of treatment, was evaluated, in addition to analyzing and comparing the mean total score of the series studied. To analyze the results, the values of the parametric variables were expressed as "mean, standard deviation, and range." The normality of the data was evaluated using the Kolmogorov–Smirnov test, and to compare differences between the means at the different times of the study, a one-way analysis of variance test was performed to evaluate all parameters, except for the OSDI test, where a student *t*-test for paired samples was performed, considering "$p < 0.05$" as a statistically significant value. The program used was XLMiner Analysis ToolPak software (Frontline Systems Inc.), and the data were recorded and stored under the property of "Centro de Ojos Quilmes," being available upon request.

Results

Initially, 42 patients (84 eyes) were included in the study, but six patients did not comply with the follow-up as they missed their 1st-month control visit, attending outside the tolerance range. In total, 36 patients (72 eyes) completed the study, 21 women (58.3%) and 15 men (41.7%, with a mean age of 65.6 ± 10.9 years (37–86). In relation to the previously used treatment of LT 0.005%, the different commercial brands were Louten (Poen, Argentina) in 31 patients, two Xalatan (Elea Argentina) in two patients, and one patient with each of the following products: Glaucostat (Max Vision SRL, Argentina), LT dorf (Pharmadorf SA), and Latanoflax (Sidus, Argentina). In the initial visit, before changing treatment, five patients reported using artificial tears sporadically in case of discomfort. In the subsequent visits, the patients commented that they continued to use them in the same way, without changes. The rest of the patients only used LBN topically during the entire study without adding lubricants.

Between the old and new treatment, no statistically significant changes were found between best-corrected visual acuity, IOP, and clinical ocular surface tests, where both tear breakup time and ocular surface staining assessed by the Oxford scale and Schirmer test remained stable unchanged. However, the OSDI test score, which represents the patient's opinion regarding ocular surface symptoms, decreased with a statistically significant difference ($p < 0.05$). The OSDI test score decreased after the change from LT to LBN, with a statistically significant difference, as seen in Table 1.

The OSDI score of each patient is presented in Figure 1. It can be seen that of the total number of cases, only one had no change in the OSDI score; in eight patients, the OSDI worsened, and in the rest of the 27 patients, the OSDI score improved. Of the eight patients where the score worsened, there were two cases that went from no dry eye to moderate dry eye in one case (case A in Fig. 1) and mild dry eye in the other case (case D). Cases B, C and H, although their score worsened, remained in the same range of moderate dry eye. Cases E and G, although their scores increased, remained in the normal range. In case F in Figure 1, although the score increased, the patient remained in the same range of severe dry eye.

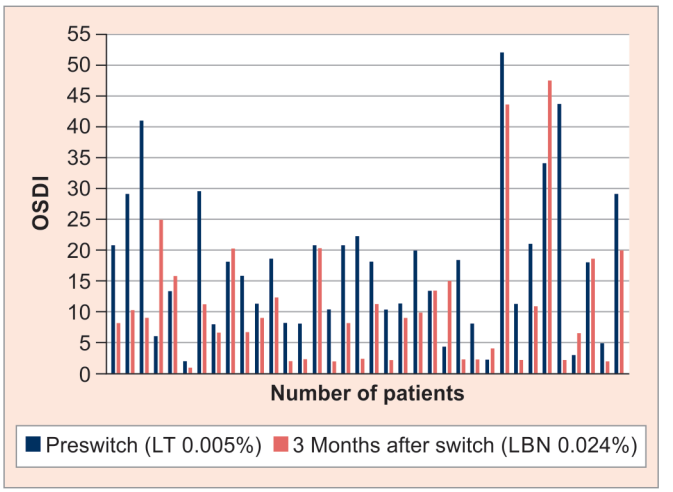

Fig. 1: Ocular surface disease index (OSDI) score of each patient preswitch and, 3 months after starting treatment with LBN 0.024%

Figure 2 shows that of the 36 patients who were on treatment with LT, only 15 had an OSDI score of <13 (normal), and the remaining 21 patients (58.4%) had OSDI scores compatible with mild, moderate or severe dry eye syndrome (12, 4, and 5 patients, respectively). After the change of treatment to LBN, the patients improved their OSDI scores, decreasing the total number of patients with dry eye to 10 (27.7%), seven of which were mild. Calculating the percentage of the observed data, we found that the number of patients who became within the normal OSDI score (0–12) without dry eye increased by 301.6% (from 41.6 to 72. 2%) while the percentage of patients with OSDI scores of 13–22 decreased by almost 14% (from 33.3 to 19.4%), as did those with moderate and severe dry eye scores, dropping 8.4% in each case (from 11.1 to 2.7% and from 13.9 to 5.5%, respectively).

Discussion

The present study evaluated the ocular surface tolerance of LBN 0.024%, a relatively new antiglaucomatous drug, compared to a previous treatment, LT 0.005%, in the same population. Likewise, hypotensive efficacy, visual acuity and biomicroscopic aspect of the ocular surface were also evaluated, parameters on which no statistically significant differences were found 3 months after starting treatment with LB, except in relation to fluorescein staining, where an improvement was observed. Regarding the patients' opinion, by means of the OSDI test, a decrease in ocular surface symptoms and the degree of severity of dry eye was found, with a statistically significant difference.

In the current practice of evidence-based medicine, measuring patient opinion using specifically designed psychometric tools has become critical.[14–16] The scientific value of the OSDI test has already been validated, where the total score obtained is positively correlated with the severity of dry eye disease and the impact on daily activities.[5,6] It asks questions aimed at detecting and grading ocular surface involvement in the context of a person's daily life, using 12 items that assess ocular pain due to problems related to dry eye syndromes and their relationship with visual function.[17] Considering the relationship between glaucoma and ocular surface, this test has also been widely used in clinical trials to evaluate pharmacological treatments and surgical procedures in glaucoma.[18–24]

In the present study, a statistically significant improvement was found in relation to the OSDI test, in favor of treatment with LBN 0.024%, compared to LT 0.005%, when evaluating the set of patients before and 3 months after the change, lowering the score from a mean value of 17.8 ± 12.1 to 11.1 ± 10.5. This expresses that the majority of the population treated with LT had a mild degree of dry eye, which resolved with the change from hypotensive to LBN. However, it is also interesting to analyze the data in relation to OSDI in another way to better understand the result. In Figure 1, where the evolution of each case is discriminated, it is observed that many patients had mild dry eye disease and that after the change of treatment, they improved. In Figure 2, the patients were grouped in relation to the OSDI group they belonged to, before and after the change, where it is observed that 72.2% were in the group without dry eye disease, while before the change, this group contained 41.6% of the patients. We can interpret that 30.6% of the cases resolved the dry eye problem after 3 months of treatment with LBN since they did not receive any other treatment that could justify this change in the OSDI test score. In relation to the ocular surface tests evaluated by biomicroscopy, no statistically significant changes were found for the BUT and Schirmer's test, but statistically significant changes were found for the Oxford scale grading of the ocular surface staining. This scale estimates the degree of damage in the ocular surface (from less to more severe) considering the score obtained between the staining observed in the cornea and also in the bulbar nasal and temporal conjunctiva. In our series, the degree of involvement in relation to this scale was low at all times, although the data express that there was a significant improvement with LBN, where the involvement of the ocular surface epithelium decreased.

To date, there is no other study that has evaluated the patient's opinion using the OSDI test to consider aspects related to ocular surface tolerance of LBN compared to LT pretreatment. The main clinical studies recorded the presence of adverse effects associated with ocular surface problems, such as foreign body sensation, conjunctival redness, punctate keratitis, ocular dryness,

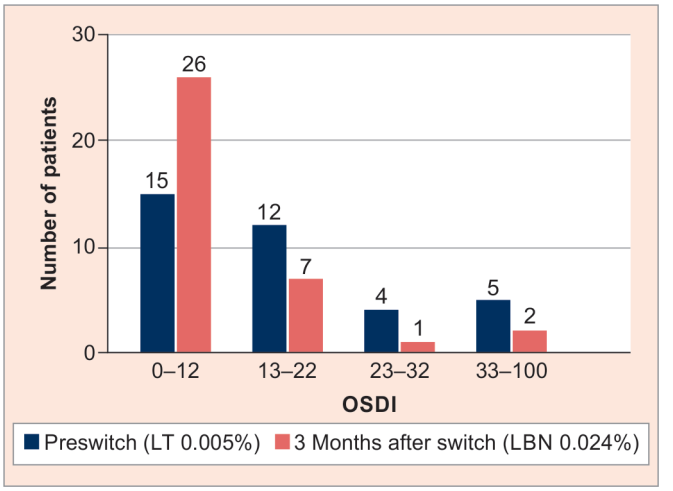

Fig. 2: Ocular surface disease index (OSDI) score, baseline and 3 months after switch to LBN 0.024%. The cases were classified according to the degree of OSDI: <13, normal; 13–22, mild; 23–32, moderate; and 33–100, severe

Table 1: Vision parameters, IOP, ocular surface tests, and OSDI test in patients treated with LBN 0.024%

Parameter	*Baseline*	*Month 1*	*Month 3*	*p*
BCVA (LogMAR)	0.1 ± 0.47 (0.05–1)	0.1 ± 0.45 (0–1.4)	0.1 ± 0.44 (0–1.4)	0.98
IOP (mm Hg)	13.4 ± 2.1 (9–18)	13.2 ± 2.0 (10–17)	13.1 ± 1.7 (9–16)	0.63
BUT (seconds)	6.6 ± 3.3 (2–15)	6.3 ± 3.0 (2–15)	6.8 ± 2.7 (3–14)	0.79
Fluorescein staining (Oxford)	0.6 ± 0.7 (0–3)	0.5 ± 0.8 (0–2)	0.2 ± 0.8 (0–2)	0.01
Schirmer (mm)	10.8 ± 9.1 (1–35)	10.2 ± 7.7 (1–35)	10.1 ± 7.1 (1–35)	0.83
OSDI	17.8 ± 12.1 (2.1–52.1)	–	11.1 ± 10.5 (1.1–47.5)	<0.01

*BCVA, visual acuity best-corrected; BUT, break-up time; IOP, intraocular pressure;

and ocular pain, in a low percentage of cases that generally ranged from 0.7 to 17.7%, as analyzed by Lo et al. in a meta-analysis.[11] Interestingly, Okeke et al.[25] published a retrospective study of 65 glaucoma patients who started using LBN without having previously received any treatment, where they found ocular surface and LBN-related adverse effects such as dryness (12.3%), ocular irritation, itching and photosensitivity (7.7% in each case), ocular pain and tearing (4.6%), and keratitis (3.1%). In another study, they found that cases treated with LT and LBN had the same percentage, 2%.[26] Radell et al.[27] retrospectively analyzed data from 56 patients treated with LBN with 2 years of follow-up, where only four patients discontinued treatment due to intolerance related to ocular pain and itching.

In our study, all the hypotensives used by patients had preservatives, benzalkonium chloride (BAK) 20 mg, and LBN. It is important to clarify this because, in Argentina, there is currently a new formulation of LT 0.005 nanoemulsion, which does not have BAK and has been shown to be better tolerated than the previous formulation of LT with BAK through cytotoxicity[28] and also clinical data.[29] Casiraghi et al.[29] found an improvement in OSDI score and also in other ocular surface tests (BUT, Schirmer and Oxford scale staining) in a group of 103 patients who switched from LT with BAK to a nanoemulsion without BAK. In our study, improvement in OSDI and ocular surface staining occurred and were statistically significant with LBN treatment at 12 weeks, but BAK was present before and after the switch. Similarly, Kim et al.[24] have shown that BAK would not be the only relevant factor, as they compared aspects of ocular surface tolerance between patients on LT treatment with and without BAK and found no statistically significant difference in OSDI score, although they did find greater adherence to treatment in the preservative-free treatment group.

In our case, the observed improvement seems to be related to the active principles of LBN, specifically with the NO donor agent. In relation to the hypotensive mechanism, NO and its second messenger, cyclic guanosine monophosphate, mediate smooth muscle relaxation and vasodilation and reduce the cell volume of trabecular meshwork cells, in addition to relaxing the inner wall of Schlemm's canal and altering intercellular adherens junctions, thus improving outflow from the trabecular meshwork.[7] The effect of NO on the ocular surface is currently not fully understood. In our study, the change of treatment from LT to LBN induced an improvement in the ocular surface, observed by the OSDI test, where slightly more than 30% of patients went from having a score compatible with dry eye to having a normal score, in addition to having improved the degree of staining of the corneal and conjunctival epithelium, assessed by the Oxford test. Our results can be explained and supported by the information published by Tummanapalli et al.[30] where, after an extensive review of the subject, they proposed that NO donors may be a new therapeutic option for dry eye disease since they promote the secretion of proteins from the acinar cells of the lacrimal gland. They also raised the relevance of NO in corneal healing and its potential antimicrobial effect, beneficial effects observed with NO concentrations 1.5–2.5 times higher than physiological ones, by inducing ocular surface cell survival and defensive mechanisms. But they also highlighted a dangerous dual effect, as higher NO concentrations (3–10 times higher) can cause negative proinflammatory effects.

Although it was not the main objective of the study, since it is a hypotensive drug, it is necessary to discuss the results obtained in relation to this aspect. What we have found is that blood pressure was maintained under control with LBN without statistically significant changes in relation to previous treatment with LT. In principle, considering its mechanism of action and data from other publications,[11,12] we might have expected to observe a statistically significant improvement. But in our study, the population already had their IOP levels previously controlled with LT, with a mean value of 13.4 ± 2.1 mm Hg (9–18). After making the treatment change with LBN, it remained statistically unchanged at 13.1 ± 1.7 mm Hg (9–16). Likewise, we believe that this is a real way of evaluating treatments and that the design was appropriate for our main purpose since it is something that happens in routine clinical practice, where patients with glaucoma that are well controlled with one drug require switching to another, often due to ocular surface problems. Considering the improvement we have observed in relation to the ocular surface, perhaps there could also be a benefit in IOP values in patients who changed from LT to LBN, but we would have to extend the follow-up times to observe if it really influences adherence and finally IOP values.

Our work has limitations in relation to the number of participants and to the fact that the main parameter to evaluate tolerance and degree of ocular surface involvement is a subjective tool based on the patient's opinion; although it is the most solid test, as has already been mentioned and cited above. In turn, the improvement found in relation to the OSDI score was not accompanied by an improvement of all data observed at biomicroscopy, except for fluorescein staining of the ocular surface epithelium. This could be justified by the high dissociation that exists between signs and symptoms in ocular surface diseases.[31] It would be interesting in future studies to add objective tests, such as impression cytology or cytokine test in tears, in order to confirm our results.

However, the current work brings the originality of evaluating the effect of LBN in a different way, emphasizing ocular surface tolerance and the patient's opinion. We believe this is interesting, emphasizing the importance of treatment adherence in the management of the glaucoma patient and the close relationship between glaucoma treatment and the development or worsening of ocular surface disease. Our work, therefore, provides a clinical observation where a series of glaucoma patients who had a dry eye in relation to the OSDI test and were on LT treatment improved after being treated with LBN. The NO donor feature seems to be the reason, but this is a hypothesis that we put forward so that future lines of research can confirm it.

Conclusion

After discontinuing treatment with LT and starting treatment with LBN, it was observed that patients had an improvement in the ocular surface, in addition to maintaining control of their IOP. The OSDI test score showed that after 3 months of LBN treatment, most of the patients went from moderate to normal dry eye syndrome and also decreased their degree of corneal and conjunctival epitheliopathy. The present clinical data encourage us to expand this area of research and to further investigate the possible beneficial mechanisms at the ocular surface in glaucoma patients treated with LBN, potentially related to nitric oxide.

Clinical Significance

Patients treated with LT 0.005% who switched to LBN 0.024% had an improvement in ocular surface symptoms. They also improved ocular surface signs, keeping IOP under control.

The present work highlights that in addition to its hypotensive effect, LBN 0.024% may have beneficial effects on the ocular surface, which should be further studied.

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