

Real-World Use of Latanoprostene Bunod 0.024% in Patients with Glaucoma or Ocular Hypertension Naïve to Pharmacotherapy

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Introduction/Purpose

- Latanoprostene bunod (LBN, Vyzulta®) is a nitric oxide (NO)-donating prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) and ocular hypertension (OHT).
- Following topical ocular instillation, LBN is metabolized to two active moieties: (1) latanoprost acid and (2) NO (Fig. 1). Latanoprost acid increases aqueous humor outflow through the uveoscleral pathway whereas NO increases aqueous humor outflow through relaxation of the trabecular meshwork/Schlemm's canal.¹⁻⁴ Thus, LBN has a dual mechanism of action.

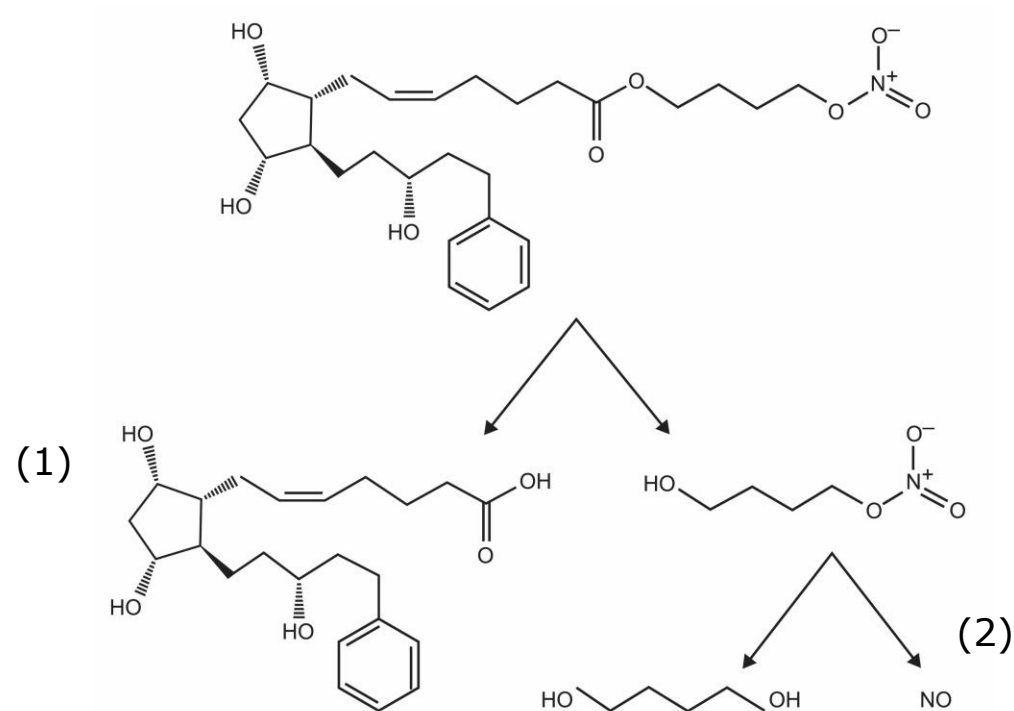


Fig 1. Metabolism of LBN

- LBN has been shown to reduce mean diurnal IOP by 32% at 3 months in OAG/OHT subjects with elevated baseline IOP (26.7 mm Hg)⁵ and by 22.0% at 4 weeks in OAG/OHT subjects with low baseline IOP (19.6 mm Hg).⁶
- In this retrospective chart review we evaluated the real-world efficacy and safety of LBN in patients with OAG and/or OHT naïve to IOP-lowering pharmacotherapy.
- Herein we present results of an analysis of interim data.

Methods

This is an ongoing, multicenter, retrospective study. The study protocol was approved by Advarra Institutional Review Board (Columbia, MD), which granted a waiver for informed consent and exemption from ongoing study oversight. All subject data were de-identified and kept confidential in accordance with the International Conference on Harmonization Guidelines for Good Clinical Practice.

Patient charts were eligible for review if the patient was ≥18 years of age with no prior IOP-lowering therapy or glaucoma surgery prior to initiation of therapy with LBN. Patients had to have at least two follow-up visits (spanning ≥2 months) prior to May 1, 2019 following initiation of LBN treatment. Data extracted from the charts included age, sex, race, cup-to-disk ratio, central corneal thickness, adverse events (AEs), IOP, visual acuity (VA), and concomitant medications. The primary outcome was the change in IOP from baseline.

Retrospective data herein were abstracted from the medical charts at 9 clinical sites. IOP outcomes were evaluated for the study eye, defined as the eye with the higher IOP at baseline. If baseline IOP was the same in both eyes, then the right eye was the designated study eye. IOP comparisons between baseline and follow-up visits were performed using paired t-tests.

Results

- Sixty three patient charts were abstracted. The mean (SD) age of patients was 59 (15) years and 52.3% were female.
- Of the 42 patients with recorded diagnosis codes, 36 were diagnosed with OAG, 4 with low-tension glaucoma, 1 with both OAG and low-tension glaucoma, and 1 with OHT.
- Mean (SD) IOP at baseline was 21.7 (6.0) mm Hg, and the median days to the 1st and 2nd follow-up visit was 29 and 130 days, respectively.
- Figure 2 presents mean (SD) IOP at baseline and the two follow-up visits; Figure 3 presents the mean IOP decrease from baseline at the two follow-up visits. Both figures present data for all patients (A) and for the subgroups of patients with high tension or elevated IOP (>21 mm Hg) at baseline (B) and low tension or normotensive IOP (≤21 mm Hg) at baseline (C).

References:

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Fig 2. Mean (SD) intraocular pressure at baseline and at the two follow-up visits following treatment with LBN

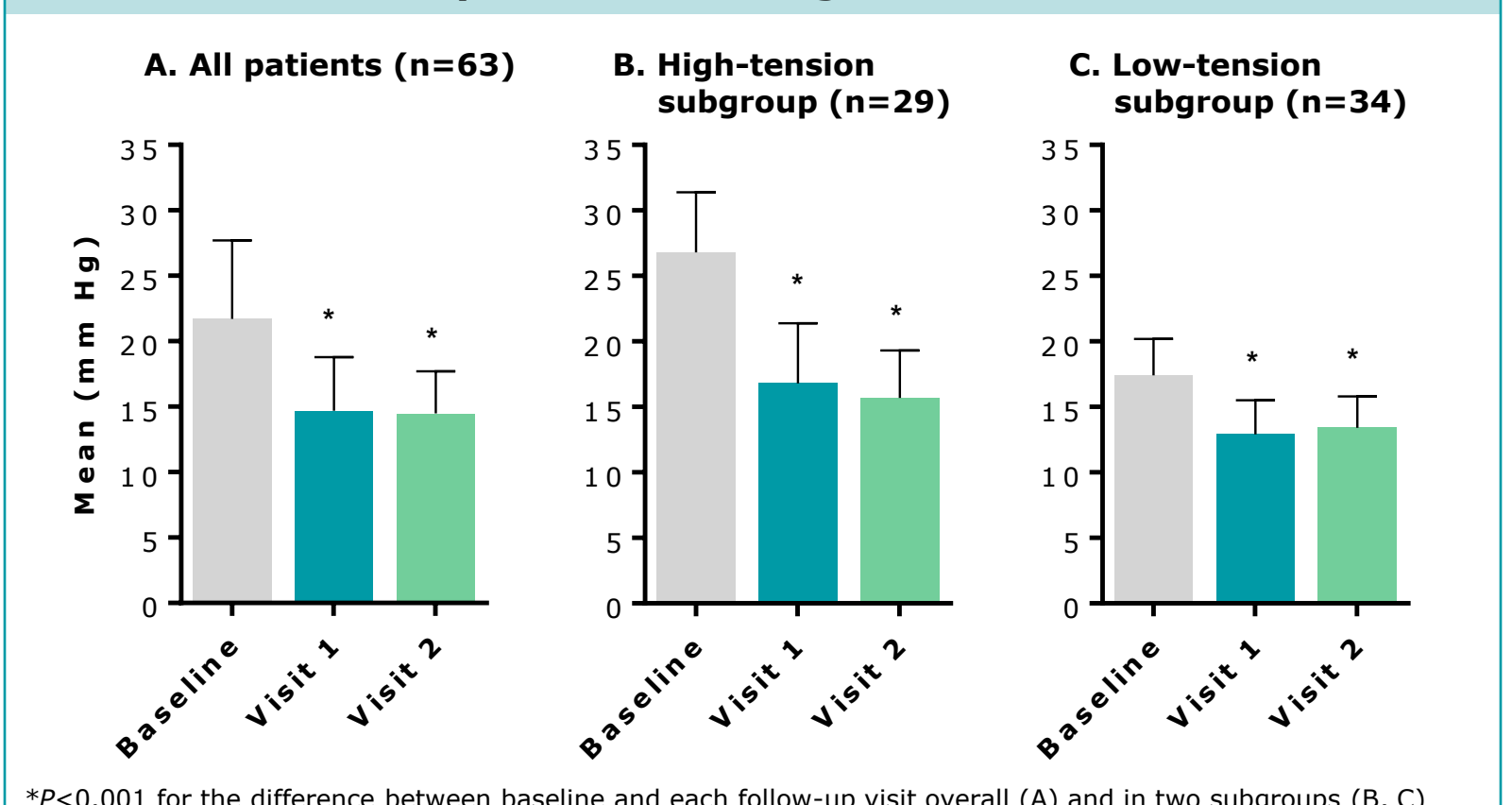
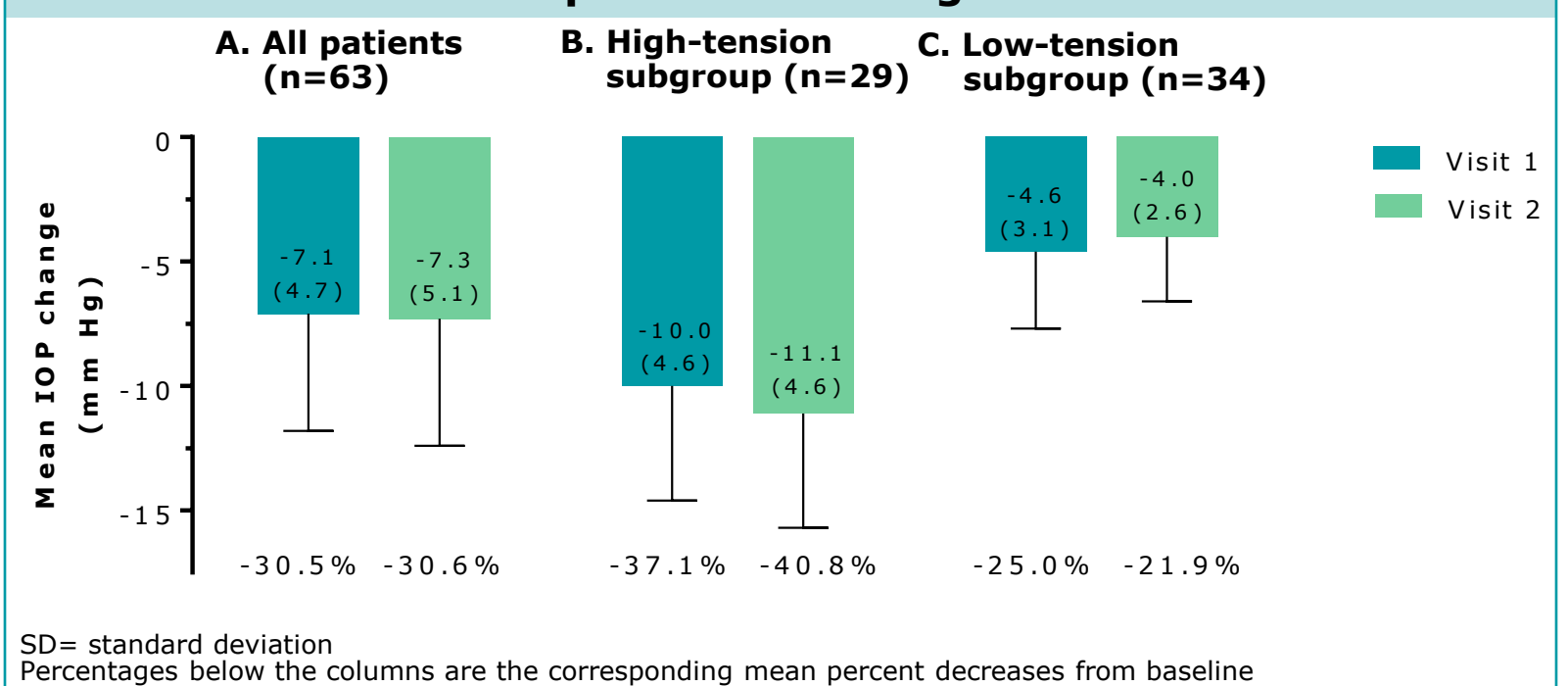
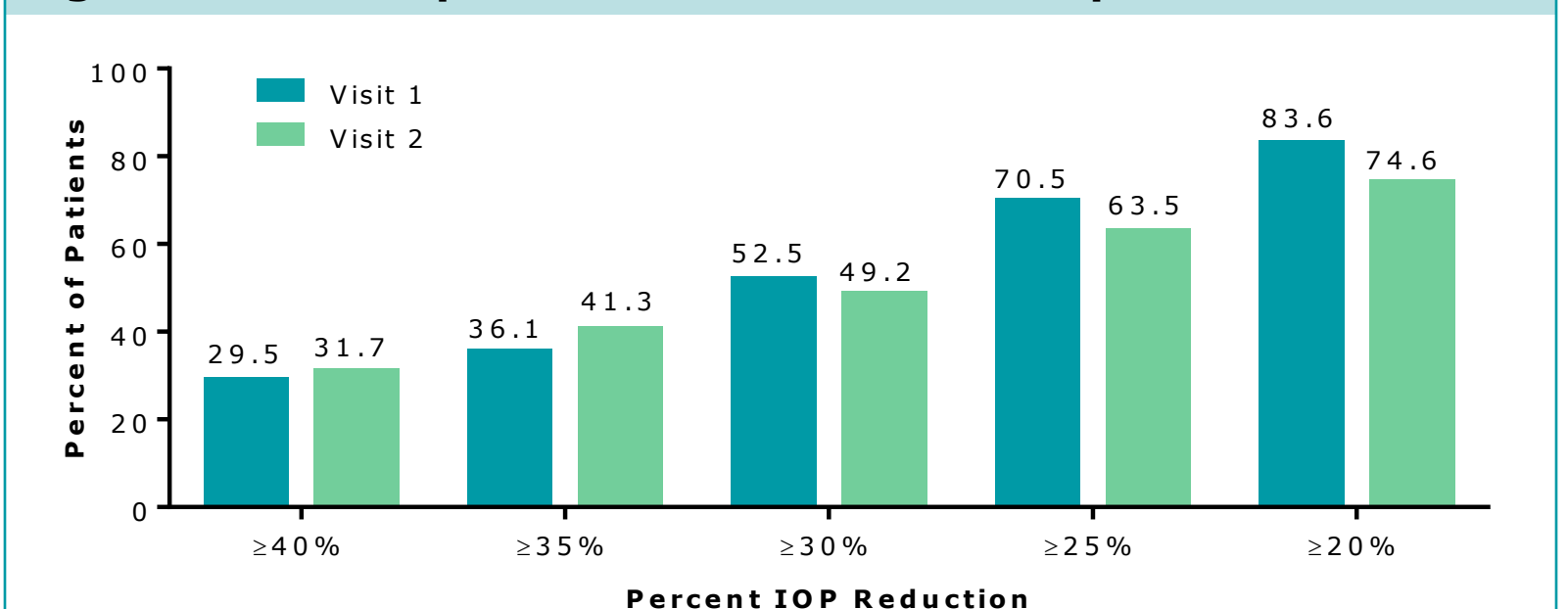


Fig 3. Mean (SD) intraocular pressure decrease from baseline at the two follow-up visits following treatment with LBN



- Figure 4 presents the percent of patients in the overall dataset achieving an IOP decrease of ≥40%, ≥35%, ≥30%, ≥25% and ≥20% from baseline by visit (i.e. percent responders for each category).

Fig 4. Percent responders at the two follow-up visits



- There were no apparent changes from baseline in VA and no serious AEs.
- The most common reported AEs were blurred vision and ocular irritation.
- Ocular redness was reported for one patient in one eye.

Conclusion

- Based on this analysis of interim data from an ongoing retrospective chart review, treatment with LBN produced a robust IOP reduction in patients with OAG or OHT naïve to pharmacotherapy, with few AEs.
- Patients with elevated IOP experienced the greatest reduction with a mean decrease of ≥10 mm Hg from baseline.

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