

Editorial

Roclatan: The Next Revolution in the Medical Management of Glaucoma

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Glaucoma is a group of progressive optic neuropathies that is characterized by a degeneration of retinal ganglion cells (RGC) [1]. It is a heterogeneous disease and its pathophysiology is assumed to be multifactorial. An elevated intraocular pressure (IOP) and vascular dysregulation contribute mainly to the initial insult of glaucomatous atrophy. There are other factors such as obstruction of axoplasmic transport within the RGC axons at the lamina cribrosa, altered microcirculation of the optic nerve at the level of lamina cribrosa and further modifications inside the lamina glial and connective tissues. The secondary factors include toxic insult caused by glutamate or glycine from injured neurons and oxidative injury due to overproduction of nitric oxide (NO). Therefore, if the injury because of a primary or secondary factor is, it leads to dysfunction and death of RGCs leading to irreversible visual loss, as a result of complicated combination interaction of multiple elements and factors more than one factor individually [2].

Glaucoma management is aimed at reducing IOP because it is the only modifiable risk factor. One of the most promising medication is Roclatan.

Roclatan (netarsudil/latanoprost ophthalmic solution), a combination product containing netarsudil and the prostaglandin analog latanoprost, is produced by Aerie Pharmaceuticals. It is only administered as one daily eye drop at night and is formulated as a netarsudil/latanoprost 0.02%/0.005% solution. The IOP-reducing results of netarsudil are anticipated to be complemented by increasing the outflow of the uveoscleral pathway facilitated by latanoprost [3].

The aim of combining two materials is to combine the best individual properties; therefore, the final drug will become closer to the ideal of both the functional and quality criteria. Netarsudil and latanoprost are proven to be very effective in the treatment of glaucoma. To illustrate, Netarsudil ophthalmic solution 0.02% [Rhopressa®] is a Rho-associated protein kinase (ROCK) inhibitor that primarily reduces intraocular pressure (IOP) by increasing the outflow of aqueous humor through the trabecular meshwork pathway. It is recently approved for the reduction of elevated IOP in patients with open-angle glaucoma and ocular hypertension in the United States. The recommended dosage is

once daily in the evening in the affected eye(s) [4]. Latanoprost has been widely studied. 17 initial reviews confirmed a daily dose of topical latanoprost (0.005%) to be very safe and effective within the short- and long-term duration therapy of glaucoma or ocular hypertension. A review of 3 masked multicenter Phase III studies in 829 patients with IOP in Scandinavia, America, and the UK confirmed that 6 months' treatment with latanoprost reduced IOP via 35%, if it is prescribed within the nighttime, and by 31% if used in the morning [5].

There are 3 Clinical trials which are carried out to ensure the efficacy of Roclatan. The Mercury 1 was randomized trial and participated by 718 categorized in 3 treatment groups: netarsudil monotherapy, latanoprost monotherapy, or netarsudil/latanoprost combination therapy, each drug was prescribed once daily. The primary efficacy outcome was the mean IOP at three months; patients were observed for 12 months for ocular and systemic safety outcomes. At 90 days, patients who received the combination therapy achieved 1.3-2.5 mmHg lower mean IOP than patients who received latanoprost monotherapy, and 1.8-3.0 mmHg lower mean IOP than patients who received netarsudil monotherapy. Patients who received the combination therapy showed 20% or greater IOP reduction and achieved an IOP of < 18 mmHg. While no serious side effects were reported, a higher percentage of patients discontinued therapy at three months in the combination (15.5%) and netarsudil monotherapy (17.6%) groups versus latanoprost monotherapy (5.5%), with adverse effects being reported mainly because of discontinuation of the drug therapy. Mild Conjunctival hyperemia was reported in approximately 50% of patients. Approximately 5% to 11% of patients reported experiencing conjunctival hemorrhage, pruritus, increased lacrimation, and cornea verticillata [6].

The Mercury 2 trial evaluated the modifications and changes in IOP at 90 days in 750 participants obtaining netarsudil/latanoprost, netarsudil monotherapy, or latanoprost monotherapy. The findings were similar to the Mercury 1, the combined agent reduced IOP further 1.5-2.4 mmHg in comparison with latanoprost monotherapy and an additional 2.2-3.3 mmHg whilst compared with netarsudil monotherapy. 56% of patients receiving netarsudil/latanoprost were capable to achieve diurnal IOP of < 16 mmHg [7].

The Mercury three is an additional trial which is underway to evaluate and compare the efficacy and safety of netarsudil/latanoprost with the combination of bimatoprost/timolol 0.03%/0.5%. 472 participants will be enrolled and it aims to evaluate the changes in IOP at six months similarly to clinical safety endpoints. Currently, no additional information is available regarding this trial [8]. Mercury 3 is only performed for the approval and commercialization in Europe.

On 03/12/2019, Aerie Pharmaceuticals Announces U.S. FDA Approval of Rocklatan™ (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% for the Reduction of Intraocular Pressure in Patients with Open-Angle Glaucoma or Ocular Hypertension

The introduction of well-tolerated and potent medications such as Roclatan allows the ophthalmologists to choose the best treatment options for the patients thereby treat this disorder more effectively. It showed significant IOP-lowering effects with minimum safety concerns. Thus, Roclatan could be an evolutionary and revolutionary medication in the treatment for open-angle glaucoma or ocular hypertension.

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