



MEDICAL JOURNAL OF WESTERN INDIA

THE OFFICIAL PUBLICATION OF RESEARCH SOCIETY OF BJMC AND SGH, PUNE

WEBSITE: www.mjwi.org

ISSN NO.: 0972-9798

EISSN No.: 0972-9798

CLINICAL

A COMPARATIVE STUDY OF FIXED DOSE COMBINATION OF NETARSUDIL AND LATANOPROST OPHTHALMIC SOLUTION (0.02% + 0.005% WV) VERSUS LATANOPROST OPHTHALMIC SOLUTION IN PATIENTS WITH OPEN ANGLE GLAUCOMA

[Usha nikumbh](#)^{1*}, [DR SHAILENDRA S. DESHMUKH](#)¹,

¹) B J G M C @ S G H - ASSOCIATE PROFESSOR ,DEPARTMENT OF OPHTHALMOLOGY

* means Correspondance Author

ARTICLE INFO

Article history:

Date of Web Publication 16 Feb 2022

Date of Receipt: 16 Feb 2022

Date of Acceptance: 18 Apr 2022

Date of Publication: 01 Jan 1970

Article No: 177

ABSTRACT

ABSTRACT: AIM & OBJECTIVES To compare efficacy and safety of once- daily, fix dose combination (sun pharma) of Netarsudil and Latanoprost compared with Latanoprost ophthalmic solution in patients with Open Angle Glaucoma. **METHODS** : Randomized, active controlled parallel group study conducted in two groups of 25 patients each (total 50) Group A- patients received once-daily Netarsudil 0.02%/Latanoprost 0.005% Group B- patients received Latanoprost 0.005%. Patients instilled study drug into one eye at 9.00 PM daily. **MAIN OUTCOME MEASURES:** IOP was obtained at 9.00 AM and 5.00 PM on day 1 (baseline), at weeks 2,4,8,12,16,20,24. Ocular and systemic safety were evaluated up to 6 months. **RESULTS** : Netarsudil / Latanoprost (sun pharma) maintain statistically superior IOP lowering compared to its component Latanoprost at every assessment for 6 months. Mean diurnal IOP (\pm standard error) at 6 months was 16.2 ± 0.23 mmHg for Netarsudil / Latanoprost (sun pharma) and 17.6 ± 0.18 mmHg Latanoprost, ($p < 0.05$) for Netarsudil /Latanoprost (sun pharma) versus Latanoprost. One Adverse event was conjunctival hyperemia mostly mild severity (4/25) in Netarsudil / Latanoprost Group 16% and (1/25) in Latanoprost Group 4%. **CONCLUSION:** Results of 6 months revealed superior efficacy for Netarsudil / Latanoprost (sun pharma) compared with the individual component Latanoprost. **KEY-WORDS:** (IOP- Intra ocular pressure, AE -Adverse events, OAG- Open Angle Glaucoma, TM- Trabecular Meshwork, PGA-Prostaglandin Analog, BCVA -Best Corrected Visual Acuity) • Author- Dr. Nikumbh Usha Subhash. • Corresponding Author -Dr. Deshmukh Shailendra S. • Associate Professor Department of Ophthalmology, (B.J. Govt.MedicalCollege, Pune. (Address for correspondence e-mail: dr.ushanikumbh@yahoo.com)

KEY WORDS

Acknowledgement

ACKNOWLEDGEMENT: Sun pharma for providing sponsorship of study ophthalmic solution.

Conflict of Interest

Financial Support and Sponsorship

Sun pharma for providing sponsorship of study ophthalmic solution.

Open Access Statement

The Research Society was founded for sharing and propagating the research activity and knowledge gained through it, for the betterment of the patient care and society at large.

Keeping this fundamentals in mind the journal has an open access policy.

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

How to cite the Article

<http://mjwi.org/article-detail.php?artid=177>

References

REFERENCES: 1. W.DStamer,T.S.Acott Current understanding of conventional outflow dysfunction in glaucoma *Curr Opin Ophthalmol*,23(2012), pp.135-143 2. B.E. Prum Jr, L.F. Rosenberg, S.J.Gedde,et al. Primary Open-angle glaucoma Preferred Practice Pattern Guidelines *Ophthalmology*,123(2016) pp. P41-P111 3. Collaborative Normal-Tension Glaucoma Study Group The effectiveness of intraocular pressure reduction in the treatment of normal-tension glaucoma. *Am J Ophthalmol*. 1998; 126: 498-505 4. The AGIS Investigators The Advanced Glaucoma Intervention Study (AGIS): 7. The relationship between control of intraocular pressure and visual field deterioration. *Am J Ophthalmol*. 2000; 130: 429-440 5. Kass M.A., Heuer D.K., Higginbotham E.J.et al. The Ocular Hypertension Treatment Study: a randomized trial determines that topical ocular hypotensive medication delays or prevents the onset of primary open-angle glaucoma. *Arch Ophthalmol*. 2002; 120: 701-713 6. Heijl A.Leske M.C., 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: 1268-1279 7. LeskeM.C.,HeijlA.,Hussein M.et al. Early Manifest Glaucoma Trial Group. Factors for glaucoma progression and the effect of treatment: the early manifest glaucoma trial. *Arch Ophthalmol*. 2003; 121: 48-56 8. Donegan R.K., Lieberman R.L. Discovery of molecular therapeutics for glaucoma: challenges, successes, and promising directions. *J Med Chem*. 2016; 59: 788-809 9. Rao P.V.,Pattabiraman P.P.,Kopczynski C. Role of the Rho GTPase/Rho kinase signaling pathway in pathogenesis and treatment of glaucoma: bench to bedside research. *Exp Eye Res*. 2017; 158: 23-3 10. LichterP.R.,MuschD.C.,Gillespie B.W.et al.CIGTS Study Group Interim clinical outcomes in the Collaborative Initial Glaucoma Treatment Study comparing initial treatment randomized to medications or surgery. *Ophthalmology*. 2001; 108: 1943-1953 11. Covert D.,Robin A.L. Adjunctive glaucoma therapy use associated with travoprost, bimatoprost, and latanoprost *Curr Med Res Opin*. 2006; 22: 971-976 12. Khouri A.S.,Realini T.,Fechtner R.D. Use of fixed-dose combination drugs for the treatment of glaucoma. *Drugs Aging*. 2007; 24: 1007-1016 13. RHOPRESSA® (netarsudil ophthalmic solution) 0.02% prescribing information. Aerie Pharmaceuticals, Inc., Irvine, CA2017 14. Wang R.F, Williamson J.E.,Kopczynski C.,Serle J.B. Effect of 0.04% AR-13324, a ROCK, and norepinephrine transporter inhibitor, on aqueous humor dynamics in normotensive monkey eyes. *J Glaucoma*. 2015; 24: 51-54 15. Ren R., Li G., Le T.D.et al. Netarsudil increases outflow facility in human eyes through multiple mechanisms. *Invest Ophthalmol Vis Sci*. 2016; 57: 6197-6209 16. Li G., Mukherjee D., Navarro I.et al. Visualization of conventional outflow tissue responses to netarsudil in living mouse eyes. *Eur J Pharmacol*. 2016; 787: 20-3 17. Lin C.W,ShermanB.,Moore L.A.et alDiscovery and preclinical development of netarsudil, a novel ocular hypotensive agent for the treatment of glaucoma.*J OculPharmacolTher*. 2018; 34: 40-51 18. Kiel J.W.,Kopczynski C.C. Effect of AR-13324 on episcleral venous pressure in Dutch belted rabbits. *J OculPharmacolTher*. 2015; 31: 146-151 19. Asrani SG, Kopczynski CC, Heah T. A 3-month interim report of a prospective, double-masked, randomized, multicenter, active-controlled, parallel-group 12-month study assessing the safety and ocular hypotensive efficacy of PG324 ophthalmic solution compared to netarsudil ophthalmic solution, 0.02%, and latanoprost ophthalmic solution, 0.005%, in subjects with elevated intraocular pressure. Abstract/presentation 7. Presented at: the American Glaucoma Society Annual Meeting, Coronado, Colorado, March 2-5, 2017. 20. Kopczynski CC, Epstein DL. Emerging trabecular outflow drugs. *J OculPharmacolTher*. 2014; 30:85e87. 21. Rao PV, Pattabiraman PP, Kopczynski C. Role of the Rho GTPase/Rho kinase signaling pathway in pathogenesis and treatment of glaucoma: bench to bedside research. *Exp Eye Res*. 2017; 158:23e32. 22. Watabe H, Abe S, Yoshitomi T. Effects of Rho-associated protein kinase inhibitors Y-27632 and Y-39983 on isolated rabbit ciliary arteries. *Jpn J Ophthalmol*. 2011;55: 411e417. 23. Hu E, Lee D. Rho kinase as potential therapeutic target for cardiovascular diseases: opportunities and challenges. *Expert OpinTher Targets*. 2005; 9:715e736. 29. Kahook MY, Serle JB, Mah FS, et al. Long-term 24.Jacob W. Brubakar, MD, SavakTeymoorian, MD, Richard A. Lewis, Dale Usner, PhD, Hayley J. McKee, PhD, Nancy Ramirez, MS, Casey C. Kopczynski, MD, Theresa Heah, MD, One year of Netarsudil and Latanoprost Fix-Dose Combination for Elevated Intraocular Pressure, ISSN 2589-4196/20. 25.Ren R, Li G, LI TD, et al. Netarsudil increases outflow facility in human eyes through multiple mechanisms. *Invest Ophthalmol Vis Sci*. 2016; 5:6197-6209. REFERENCES: 1. W.DStamer,T.S.Acott Current understanding of conventional outflow dysfunction in glaucoma *Curr Opin Ophthalmol*,23(2012), pp.135-143 2. B.E. Prum Jr, L.F. Rosenberg, S.J.Gedde,et al. Primary Open-angle glaucoma Preferred Practice Pattern Guidelines *Ophthalmology*,123(2016) pp. P41-P111 3. Collaborative Normal-Tension Glaucoma Study Group The effectiveness of intraocular pressure reduction in the treatment of normal-tension glaucoma. *Am J Ophthalmol*. 1998; 126: 498-505 4. The AGIS Investigators The Advanced Glaucoma Intervention Study (AGIS): 7. The relationship between control of intraocular pressure and visual field deterioration. *Am J Ophthalmol*. 2000; 130: 429-440 5. Kass M.A., Heuer D.K., Higginbotham E.J.et al. The Ocular Hypertension Treatment Study: a randomized trial determines that topical ocular hypotensive medication delays or prevents the onset of primary open-angle glaucoma. *Arch Ophthalmol*. 2002; 120: 701-713 6. Heijl A.Leske M.C., 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: 1268-1279 7. LeskeM.C.,HeijlA.,Hussein M.et al. Early Manifest Glaucoma Trial Group. Factors for glaucoma progression and the effect of treatment: the early manifest glaucoma trial. *Arch Ophthalmol*. 2003; 121: 48-56 8. Donegan R.K., Lieberman R.L. Discovery of molecular therapeutics for glaucoma: challenges, successes, and promising directions. *J Med Chem*. 2016; 59: 788-809 9. Rao P.V.,Pattabiraman P.P.,Kopczynski C. Role of the Rho GTPase/Rho kinase signaling pathway in pathogenesis and treatment of glaucoma: bench to bedside research. *Exp Eye Res*. 2017; 158: 23-3 10. LichterP.R.,MuschD.C.,Gillespie B.W.et al.CIGTS Study Group Interim clinical outcomes in the Collaborative Initial Glaucoma Treatment Study comparing initial treatment randomized to medications or surgery. *Ophthalmology*. 2001; 108: 1943-1953 11. Covert D.,Robin A.L. Adjunctive glaucoma therapy use associated with travoprost, bimatoprost, and latanoprost *Curr Med Res Opin*. 2006; 22: 971-976 12. Khouri A.S.,Realini T.,Fechtner R.D. Use of fixed-dose combination drugs for the treatment of glaucoma. *Drugs Aging*. 2007; 24: 1007-1016 13. RHOPRESSA® (netarsudil ophthalmic solution) 0.02% prescribing information. Aerie Pharmaceuticals, Inc., Irvine, CA2017 14. Wang R.F, Williamson J.E.,Kopczynski C.,Serle J.B. Effect of 0.04% AR-13324, a ROCK, and norepinephrine transporter inhibitor, on aqueous humor dynamics in normotensive monkey eyes. *J Glaucoma*. 2015; 24: 51-54 15. Ren R., Li G., Le T.D.et al. Netarsudil increases outflow facility in human eyes through multiple mechanisms. *Invest Ophthalmol Vis Sci*. 2016; 57: 6197-6209 16. Li G., Mukherjee D., Navarro I.et al. Visualization of conventional outflow tissue responses to netarsudil in living mouse eyes. *Eur J Pharmacol*. 2016; 787: 20-3 17. Lin C.W,ShermanB.,Moore L.A.et alDiscovery and preclinical development of netarsudil, a novel ocular hypotensive agent for the treatment of glaucoma.*J OculPharmacolTher*. 2018; 34: 40-51 18. Kiel J.W.,Kopczynski C.C. Effect of AR-13324 on episcleral venous pressure in Dutch belted rabbits. *J OculPharmacolTher*. 2015; 31: 146-151 19. Asrani SG, Kopczynski CC, Heah T. A 3-month interim report of a prospective, double-masked, randomized, multicenter, active-controlled, parallel-group 12-month study assessing the safety and ocular hypotensive efficacy of PG324 ophthalmic solution compared to netarsudil ophthalmic solution, 0.02%, and latanoprost ophthalmic solution, 0.005%, in subjects with elevated intraocular pressure. Abstract/presentation 7. Presented at: the American Glaucoma Society Annual Meeting, Coronado, Colorado, March 2-5, 2017. 20. Kopczynski CC, Epstein DL. Emerging trabecular outflow drugs. *J OculPharmacolTher*. 2014; 30:85e87. 21. Rao PV, Pattabiraman PP, Kopczynski C. Role of the Rho GTPase/Rho kinase signaling pathway in pathogenesis and treatment of glaucoma: bench to bedside research. *Exp Eye Res*. 2017; 158:23e32. 22. Watabe H, Abe S, Yoshitomi T. Effects of Rho-associated protein kinase inhibitors Y-27632 and Y-39983 on isolated rabbit ciliary arteries. *Jpn J Ophthalmol*. 2011;55: 411e417. 23. Hu E, Lee D. Rho kinase as potential therapeutic target for cardiovascular diseases: opportunities and challenges. *Expert OpinTher Targets*. 2005; 9:715e736. 29. Kahook MY, Serle JB, Mah FS, et al. Long-term 24.Jacob W. Brubakar, MD, SavakTeymoorian, MD, Richard A. Lewis, Dale Usner, PhD, Hayley J. McKee, PhD, Nancy Ramirez, MS, Casey C. Kopczynski, MD, Theresa Heah, MD, One year of Netarsudil and Latanoprost Fix-Dose Combination for Elevated Intraocular Pressure, ISSN 2589-4196/20. 25.Ren R, Li G, LI TD, et al. Netarsudil increases outflow facility in human eyes through multiple mechanisms. *Invest Ophthalmol Vis Sci*. 2016; 5:6197-6209.