International Journal of Research in Medical Sciences
Kaur A et al. Int J Res Med Sci. 2018 Jul;6(7):2495-2498
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: http://dx.doi.org/10.18203/2320-6012.ijrms20182842

Original Research Article

Effect of benzalkonium chloride-preserved latanoprost and benzalkonium chloride-free latanoprost on intraocular pressure in patients of primary open angle glaucoma

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Received: 15 April 2018
Accepted: 04 May 2018

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ABSTRACT

Background: To evaluate the change in mean IOP with BKC-preserved latanoprost versus BKC-free latanoprost in patients of primary open angle glaucoma (POAG).
Methods: This was an open-label, randomized, interventional, switch trial. Thirty patients of primary open angle glaucoma (POAG) who were already on benzalkonium chloride (BKC)-preserved latanoprost for a minimum of three months were recruited. Their intraocular pressure (IOP) was recorded at the baseline. Then, they were switched over to benzalkonium chloride (BKC)-free latanoprost for another three months. Their intraocular pressure (IOP) was recorded at both 6 and 12 weeks of follow-up.
Results: IOP decreased from 15.57±0.85mm Hg at baseline to 15.40±0.89mm Hg at 6 weeks to 15.30±0.70mm Hg at 12 weeks. p value was found to be 0.209 and 0.115 at 6 and 12 weeks respectively. No statistically significant change was observed between mean IOP at both 6 and 12 weeks as compared to the baseline.
Conclusions: BKC-free medications have equal IOP lowering effect as BKC-preserved medications in glaucoma patients.

Keywords: Benzalkonium chloride-preserved latanoprost, Benzalkonium chloride-free latanoprost, Glaucoma, Latanoprost, Ocular surface disease

INTRODUCTION

Glaucoma is a chronic and progressive ocular disorder characterized by damage of optic nerve and retinal ganglion cells leading to blindness if not treated.[1] Medical therapy is the essence of glaucoma treatment and is the first line of management in open angle glaucoma.[2] These topical medications contain preservatives for increasing their shelf-lives and to prevent them from any kind of contamination.[3] One such commonly used preservative is benzalkonium-chloride (BKC).[4] Regular use of preserved therapies has led to the emergence of ocular surface disease (OSD) in glaucoma patients.[5] Burning or stinging sensation, discharge, pain, irritation, dryness and foreign body sensation are some of the common complaints.[6] BKC is the major etiological agent behind OSD which has been proved in various in vivo and in vitro studies.[7-12] BKC-free therapies have been observed to be healthy and safe for ocular surface health of glaucoma patients but are they equally effective in IOP lowering too?.[13-15] The major objective of this study was thus to evaluate the change in mean IOP with BKC-preserved latanoprost versus BKC-free latanoprost in patients of primary open angle glaucoma (POAG).

METHODS

The present study was done at Ophthalmology outpatient department, Rajindra hospital, Patiala. It was an open-label, randomized, interventional, switch trial. The study

was registered at Clinical Trial Registry- India (CTRI.nic.in identifier: CTRI/2016/06/007001) and the World Health Organization (Universal Trial Number: U1111-1165-4913). After approval of the institutional ethics committee (IEC) and written informed consent, thirty patients of primary open angle glaucoma (POAG) who were already on benzalkonium chloride (BKC)-preserved latanoprost for a minimum of three months were recruited. Complete patient history was taken and ocular examination was done. The patients who had a history of ocular surgery or trauma in the previous year, concurrent conjunctivitis, keratitis or uveitis, any clinically significant systemic disease was excluded from the study. The patients who fulfilled the inclusion criteria were enrolled in the study. Their IOP was recorded at the baseline using Goldmann applanation tonometer. The patients were then switched to BKC-free latanoprost. At 6 and 12 weeks of follow-up, their IOP was recorded again. Statistical analysis was done by SPSS software version 20.0. Paired t test was used for quantitative variables and chi square test for qualitative variables. p value less than 0.05 was taken as statistically significant.

RESULTS

In the present study, thirty patients of primary open angle glaucoma (POAG) who were already on benzalkonium chloride (BKC)-preserved latanoprost for a minimum of three months were enrolled. The age of patients ranged from 47 years to 88 years. Majority of the POAG patients were in the range of 61 to 70 years (Figure 1). The mean age was 66.9±10.56 years. Out of the 30 subjects enrolled in this study, 23 were males (76.67%) and 7 were females (23.33%) indicating a male to female ratio of about 3:1 (Figure 2).

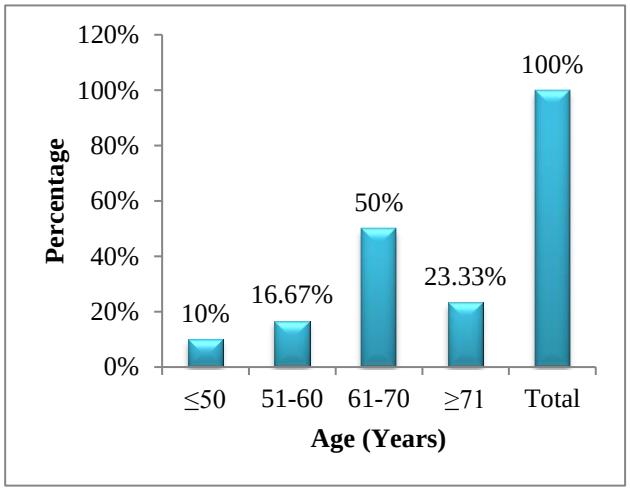

Figure 1: Age wise distribution (n=30).

At baseline, the mean IOP in POAG patients who were on treatment with BKC-preserved latanoprost was 15.57±0.85mmHg. The patients were then switched to BKC-free latanoprost. At 6 and 12 weeks of follow-up, their IOP was recorded again. Mean IOP at 6 weeks and 12 weeks in POAG patients after starting treatment with BKC-free latanoprost was 15.40±0.89mmHg and 15.30±0.70mmHg respectively (Figure 3).

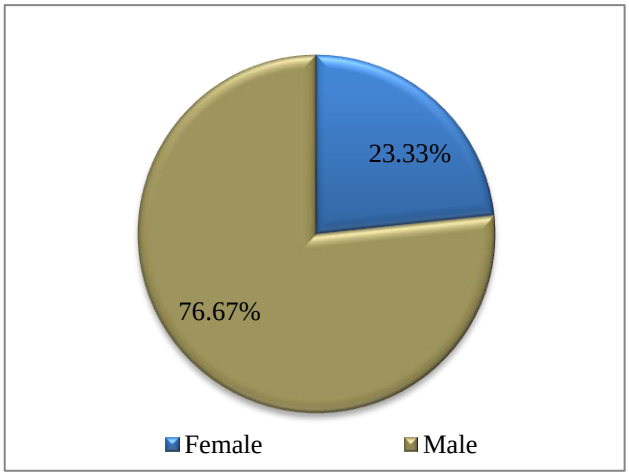

Figure 2: Gender wise distribution (n=30).

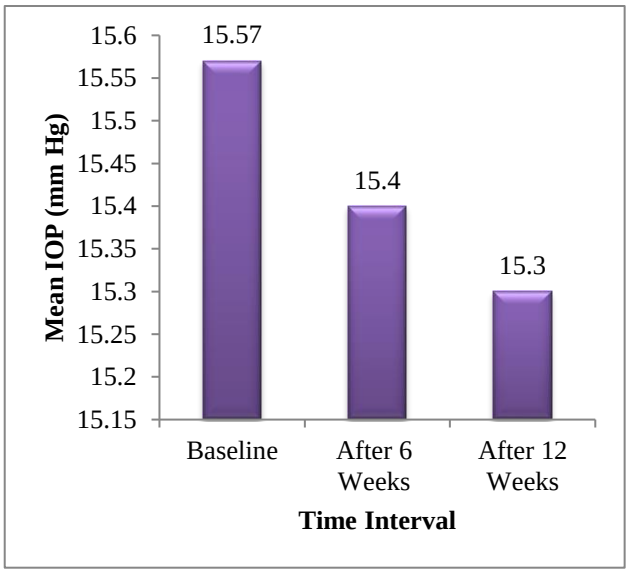

Figure 3: Comparison of intraocular pressure (IOP) at baseline (BKC-preserved latanoprost) versus intraocular pressure (IOP) at 6 and 12 weeks (BKC-free latanoprost) in POAG patients.

Thus, IOP decreased from 15.57±0.85mmHg at baseline to 15.40±0.89mmHg at 6 weeks to 15.30±0.70mmHg at 12 weeks (Figure 3). P value was found to be 0.209 and 0.115 at 6 and 12 weeks respectively. Hence, no statistically significant change in IOP was observed.

DISCUSSION

Reduction of IOP is the core element of treatment of glaucoma. Good IOP control is necessary for adequate and efficient management and long term prognosis. The purpose of present study was to compare the extent of IOP reduction with BKC-preserved latanoprost versus

BKC-free latanoprost in patients of primary open angle glaucoma (POAG).

The present study found no statistically significant change in baseline IOP with BKC-preserved therapy as compared to IOP after 12 weeks of BKC-free therapy. IOP changed from 15.57±0.85 at baseline to 15.40±0.89 at 6 weeks to 15.30±0.70 at 12 weeks. p value was not found to be statistically significant at both the time points. Wang et al in 2013 did a meta-analysis of five studies and did not find any difference in IOP control between BKC-preserved and BKC-free therapies.[16] Goldberg et al in 2015 conducted a study to evaluate the influence of BKC-free treatment on IOP and found non-significant results as compared to pre-treatment IOP values.[17] Similar kind of results were observed by Miyashiro, Hamacher and Walimbe.[18-20]

In contrast, in a study conducted by Hommer et al in 2011 a significant decrease was observed in IOP with preservative-free tafluprost as compared to preserved medication after a period of 12 weeks.[21]

The study is entangled with its own limitations owing to its open-label design, lesser number of subjects and a shorter period of follow-up.

CONCLUSION

It has thus been observed that BKC-free therapies achieve adequate IOP control and are equally effective as BKC-preserved therapies in the management of glaucoma. Since BKC has been playing a havoc in quality of life of glaucoma patients, it is wise to replace BKC-preserved medications with BKC-free anti-glaucoma therapies which will not only be effective in lowering IOP but also prevent the occurrence of OSD. The pharmaceutical sector has already introduced BKC-free therapies into the market; though other alternatives for BKC are also being sought for.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Kaur A, Palta S, Chhabra H, Singh G, Gupta A. Effect of benzalkonium chloride-preserved latanoprost and benzalkonium chloride-free latanoprost on intraocular pressure in patients of primary open angle glaucoma. Int J Res Med Sci 2018;6:2495-8.