EFFICACY AND SAFETY OF AN INNOVATIVE FORMULATION OF BENZALKONIUM CHLORIDE-FREE LATANOPROST FOR THE TREATMENT OF OPEN-ANGLE GLAUCOMA

Virginia Zanutigh 1, Celina Logioco 1, María Silvia Passerini 1, María de Lourdes Rodríguez 1, Myriam Núñez 2, María José Castro 2
1Ophthalmology, Centro de Ojos Quilmes, 2Statistics, Universidad de Buenos Aires, Buenos Aires, Argentina

PURPOSE

Benzalkonium chloride (BAK) is usually employed in formulations of prostaglandin analogues due to its dual action of preservative and adjuvant in the formulation. However, this preservative has known toxic effects on the ocular surface, causing ocular dryness and discomfort on long-term use. The aim of this study is to evaluate the efficacy and tolerability of the new BAK-free latanoprost 0.005% ophthalmic emulsion (LEBAK-free) in comparison to the traditional BAK-containing ophthalmic solution of latanoprost 0.005% (LSBAK) for the treatment of open-angle glaucoma.

METHODS

A prospective, open-label, single-arm, 12-week study was carried on. Patients with primary open-angle glaucoma who were taking LSBAK for ≥ 6 months (baseline), switched to LEBAK-free. As primary efficacy variable intraocular pressure (IOP)-lowering efficacy of the new formulation was evaluated after 4, 8 and 12 weeks of treatment with LEBAK-free (n=30 eyes). The primary safety variable was the adverse effects reported by patients at each time point as well as tolerability of LEBAK-free.

RESULTS

LEBAK-free was non-inferior in lowering IOP than LSBAK. The mean IOP decreased from baseline (15.47 ± 5.04 mmHg) to 14.20 ± 4.66, 14.13 ± 3.86 and 13.67 ± 4.18 mmHg, p=0.005, after 4, 8 and 12 weeks of treatment with LEBAK-free respectively (fig. 1). In addition, the most frequent ocular adverse event, conjunctival hyperemia, was reported in 2 (13.4%) patients at the end of the study versus 11 (73.3%) patients at baseline (p=0.008) (fig. 2). Burning sensation, was reported in 1 (6.7%) patient at the end of the study versus 10 (66.7%) patients at baseline (p=0.009) (fig. 3). 80% of patients qualified BAK-free emulsion as better tolerated than LSBAK, while 20% reported similar tolerability to LSBAK (p<<0.05) (fig. 4). No serious treatment-related adverse effects were reported.

FIG. 1

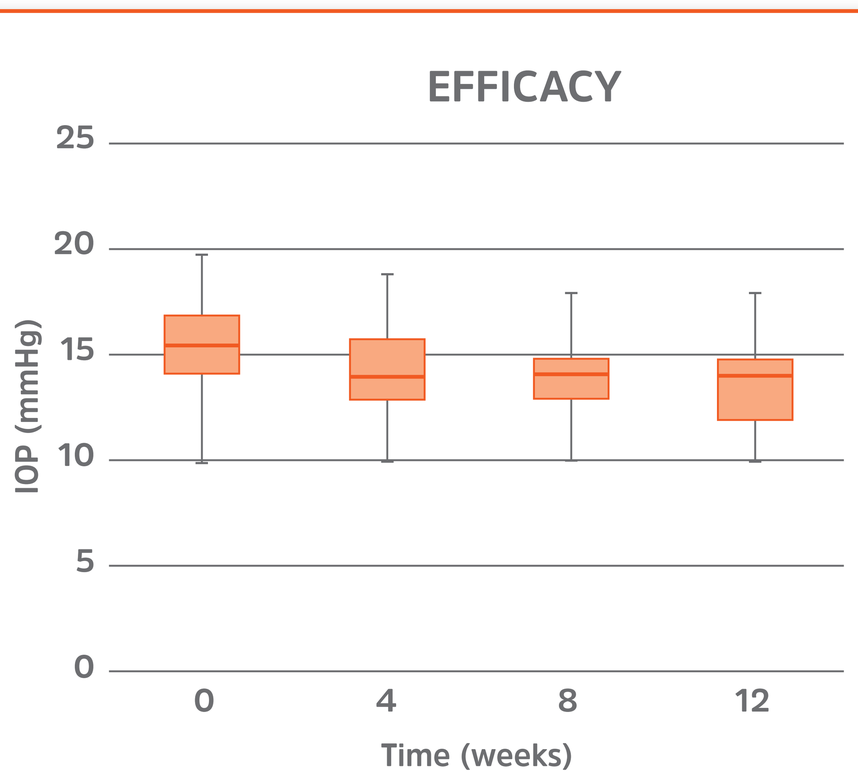


FIG. 2

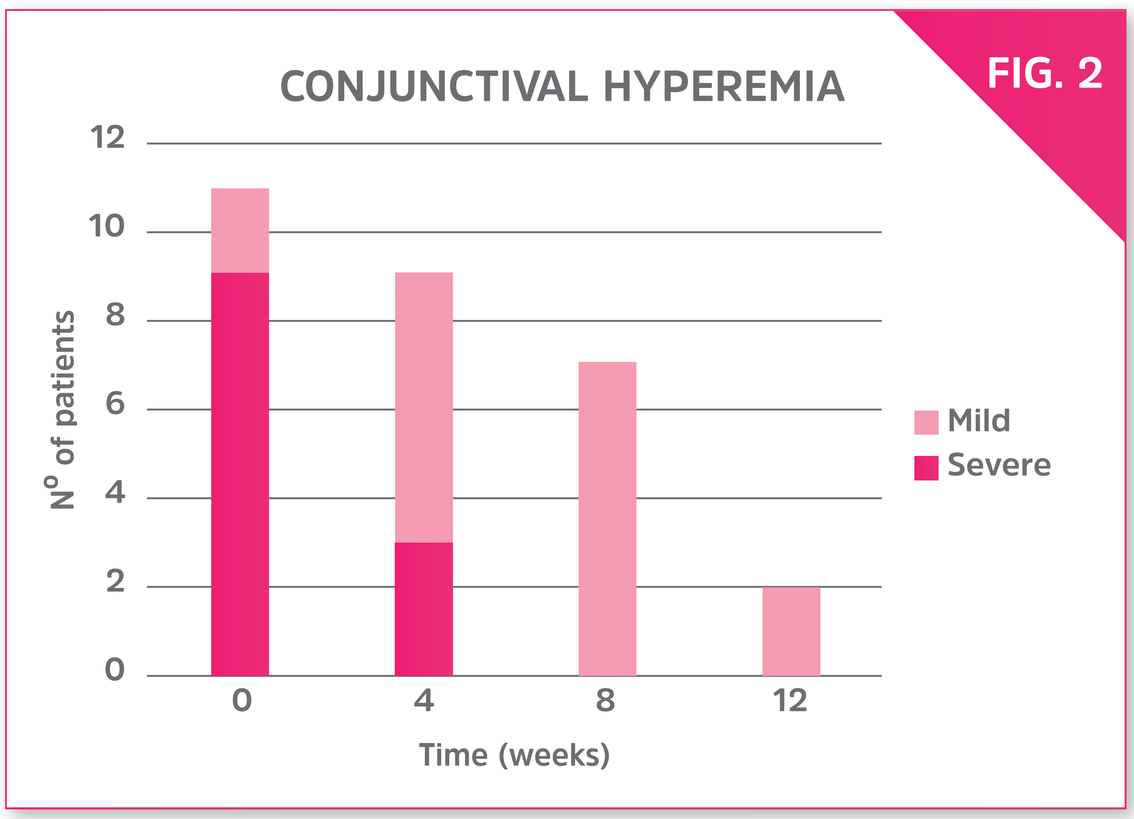


FIG. 3

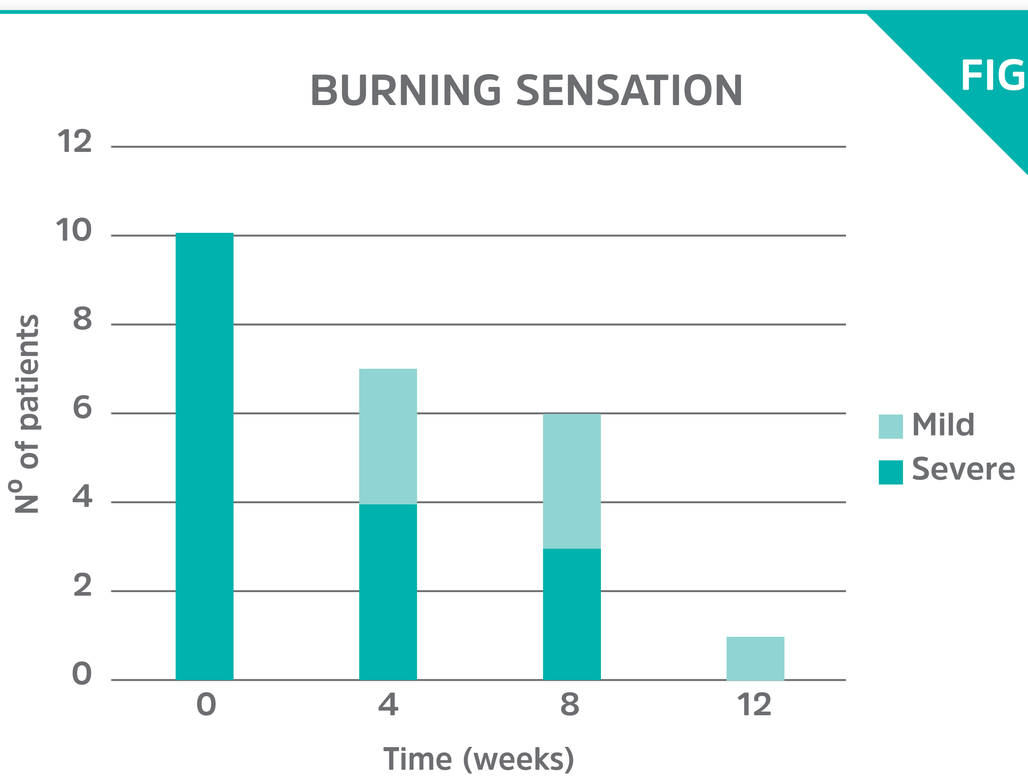
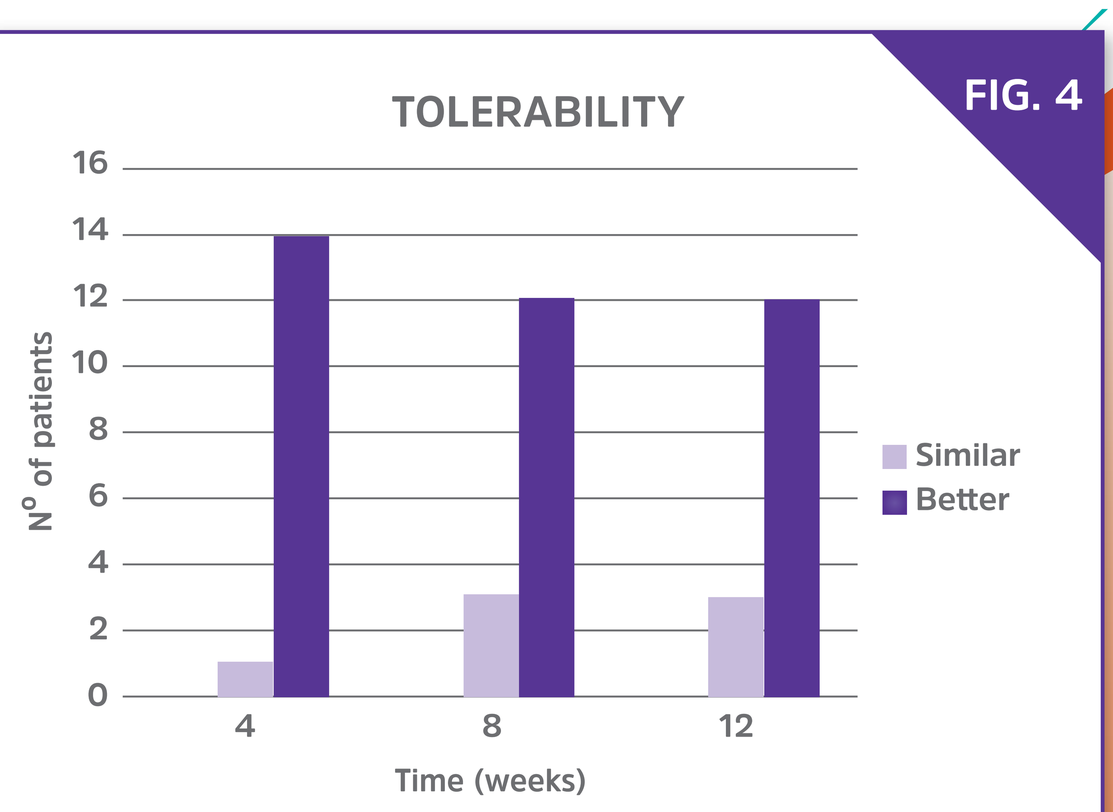


FIG. 4



CONCLUSIONS

The new formulation of BAK-free latanoprost in emulsion guarantees the same efficacy in reducing IOP as the traditional solution, with an improved local tolerability and fewer undesirable effects on the ocular surface such as conjunctival hyperemia and burning sensation.