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Efficacy and safety of Polyquad-preserved Travoprost in Ocular Hypertensives and Open Angle Glaucoma patients: an open label, observational, 6-month, switch study

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Abstract

Purpose

To evaluate the clinical benefit of eliminating BAK from prostaglandin analog therapy examining the safety and efficacy of polyquad -preserved travoprost ophthalmic solution compared to previous use of latanoprost monotherapy.

Methods

This was an observational study. Consecutive adults with open-angle glaucoma or ocular hypertension treated with latanoprost monotherapy who were going to change brand therapy to the generic one, were switched to travoprost BAK-free ophthalmic solution. All patients were submitted to an ophthalmic examination, IOP measurement and ocular surface status (BUT and corneal staining) evaluation. Patients' discomfort was evaluated with the Ocular Surface Disease Index (OSDI). All examinations were performed at baseline and 6 months later. Descriptive statistics were produced for demographic and clinical characteristics of cases. Median and interquartile range are presented for non-normally distribuited variables. For group comparison, parametric and non-parametric tests were used for quantitative variables and Pearson's $\chi 2$ test for categorical variables. All analysis refer to right eye, left eye's data are similar.

Results

44 patients were enrolled and treated with polyquad-preserved travoprost once a day. TF-BUT changed from 8 [IQR 6-10] sec at baseline to 10 [IQR 8-12] sec at 6 month ($p<0.0001$). No eye developed corneal staining that statistically improved after switching monotherapy: punctatae keratitis was absent in 13 (29.5%) patients at baseline and in 31 (70.4%) after 6 months. OSDI was (median [IQR]) 16 [10-30] at baseline and 9 [2-20] at 6 months ($p=.18$). The median [IQR] baseline IOP was 18 [15.5-21] mmHg and 16 [14-17] mmHg ($p<.0001$) after 6 months. At baseline, 18 (40.9%) patients had an IOP value < 18 mmHg, 11 (25%) < 16 mmHg, 2 (4.3%) < 14 mmHg and 1 (2.3%) < 12 mmHg, 6 months later the proportions were as follows 36 (81.8%) ($p<.0001$), 21 (47.7%) ($p=.0129$), 8 (18.2%) ($p=.0313$) and 6 (13.6%) ($p=.065$), respectively.

Conclusions

No patient switched from BAK-preserved latanoprost to polyquad-preserved travoprost developed ocular surface disease after 6 months. Ocular surface status statistically improved when examined by BUT and corneal staining. Many patients reached a lower IOP. Polyquad-preserved travoprost is therefore an effective drug that is safe for the ocular surface status.

Keywords: 568 intraocular pressure • 620 ocular irritancy/toxicity testing • 503 drug toxicity/drug effects