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Long term safety and tolerability of Tafluprost 0.0015% vs preservative-free beta-blockers in primary open-angle glaucoma patients

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Purpose: To compare Ocular Surface Disease (OSD) signs and symptoms of long term therapy (> 12 months) with Tafluprost 0,0015% vs preservative-free beta-blockers in primary open angle glaucoma (POAG) patients.

Methods: A cross-sectional study on 16 patients (32 eyes) treated with Tafluprost 0,0015%, 30 (60 eyes) with preservative-free beta-blockers and on 20 healthy age and sex matched volunteers. All subjects underwent a complete ophthalmic examination (including clinical tests: Schirmer I and break-up time), a corneal confocal microscopy evaluation with HRT II Rostock Cornea Module and were surveyed using the Ocular Surface Disease Index (OSDI) and the Glaucoma Symptoms Scale (GSS) questionnaires. Statistical analysis was performed using the program STATA[®] SE 12.1. According to data distribution, the groups were compared with ANOVA or Kruskal-Wallis test for continuous variables; post-hoc comparisons were performed with t test or Mann-Whitney test and Bonferroni's adjustment of p-values. P values < 0.05 were considered statistically significant.

Results: No significant differences were found in OSDI and GSS scores, Schirmer I test, break-up time (BUT), basal epithelial cells density, stromal reflectivity, number of sub-basal nerves, sub-basal nerve tortuosity and reflectivity and endothelial cells density between Tafluprost 0,0015% group and preservative-free beta-blockers group (p = 0.0756, 0.2741, 0.3667, 0.6284, 0.8762, 0.6527, 0.9358, 0.4816, 0.8901, 0.9695 respectively). Tafluprost 0.0015% group had significantly higher OSDI scores, basal epithelial cells density, stromal reflectivity, sub-basal nerve tortuosity (p = 0.0000, 0.0071, 0.0115, 0.0032 respectively) and lower GSS scores, number of sub-basal nerves (p = 0.0000, 0.0205) than controls while Schirmer test I, BUT, sub-basal nerve reflectivity and endothelial cells density were similar (p > 0.05). Similar results were found in the comparison between preservative-free beta-blockers group and controls: preservative-free beta-blockers group had significantly higher OSDI scores, basal epithelial cells density, stromal reflectivity and sub-basal nerve tortuosity (p = 0.000, 0.0216, 0.0137, 0.0059 respectively) and lower GSS scores, BUT and number of sub-basal nerves (p = 0.0000, 0.0062, 0.0028) than controls while Schirmer test I, sub-basal nerve reflectivity and endothelial cells were similar (p > 0.05).

Conclusions: Compared to preservative-free beta-blockers, Tafluprost 0.0015% showed similar features with regards to tear function and corneal status. No differences were found in terms of tolerability profile.