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PROSTAGLANDIN F2-ALPHA EYE DROPS (BIMATOPROST) IN GRAVES' ORBITOPATHY: A RANDOMISED CONTROLLED DOUBLE MASKED CROSSOVER TRIAL (BIMA TRIAL).

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BACKGROUND:

Previous in vitro experiments have demonstrated that PGF2α reduced proliferation and adipogenesis in a murine cell line and human orbital fibroblasts derived from subjects with inactive Graves' orbitopathy (GO). The objective of this study was to determine if the PGF2α analogue Bimatoprost is effective at reducing proptosis in this population.

METHODS:

A randomized controlled double-masked crossover trial was conducted in a single tertiary care academic medical center. Patients with longstanding, inactive GO but persistent proptosis (> 20 mm in at least one eye) were recruited. Allowing for a 15% dropout rate, 31 patients (26 females) were randomized in order to identify a treatment effect of 2.0 mm (p=0.05, two-sided paired t-test, power 0.88). Following informed consent, participants were randomized to receive Bimatoprost or placebo for three months after which they underwent a two-month washout, before switching to the opposite treatment. The primary outcome was the change in exophthalmometry readings over the two 3-month treatment periods.

RESULTS:

The mean exophthalmometer at baseline was 23.6 (range 20.0-30.5) mm and the mean age was 55 (range 28-74) years. The median duration of GO was 7.6 (IQR 3.6-12.3) years. The majority were still suffering from diplopia (61.3%) with bilateral involvement (61.3%). Using multilevel modeling adjusted for baseline, period and carryover, Bimatoprost resulted in a -0.17 mm (reduction) exophthalmometry change (95% CI -0.67 to +0.32) p=0.490. Intraocular pressure was reduced -2.7 mmHg (95% CI -4.0 to -1.4) p=0.0070. One patient showed periorbital fat atrophy (PAP) on treatment which resolved on stopping treatment. Independent analysis of proptosis by photographic images (all subjects) and subgroup analysis on monocular disease (n=12) did not show any apparent benefit.

CONCLUSION:

In inactive GO, Bimatoprost treatment over a 3-month period does not result in an improvement in proptosis.

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