# Travoprosta 0,004% efficacy in intraocular pressure in patients with glaucoma

Eficácia do travoprosta 0,004% na redução da pressão intraocular em pacientes com glaucoma

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### **ABSTRACT**

Objective: to evaluate how much decreases intraocular pressure (IOP) with TRAVAMED® (travoprost 0,004%) (Germed, Brazil) in patients with primary open angle glaucoma (POAG) and ocular hypertension (OH) and possible side effects. Methods: controlled and randomized study, it was evaluated 70 eyes of 38 patients with age of 18 years old or more diagnosed with POAG and OH. All the patients had TRAVAMED® as first drop for treatment used once daily (at night) and 30 days later they had IOP measured by Goldmann tonometry, with the same examiner in the same tonometer at the same times. Results: the mean decrease in IOP was 7,46 mmHg after 30 days using the drops. 15.71% (11) of eyes had conjunctival redness, 8.57% (6) had pain, 8.57% (6) had burning, 2.86% (2) had blurring vision and 1.56% (1) of the eyes there wasn't a significant reduction in IOP. Conclusion: TRAVAMED® was efficient when evaluating IOP decrease. The most correlated side effects were conjunctival redness (15.71%), pain (8.57%) and burning (8.57%), but studies with

**Keywords:** Glaucoma; Ocular hypertension/drug therapy; Travoprost/adverse effects

#### **R**ESUMO

Objetivo: avaliar a eficácia do colírio TRAVAMED® (travoprosta 0,004%) (Ofta, Brasil) na redução da pressão intraocular (PIO), em pacientes com glaucoma primário de ângulo aberto (GPAA) ou hipertensão ocular (HO), bem como avaliar os efeitos colaterais decorrentes do uso da droga. Métodos: estudo randomizado, controlado, com 70 olhos de 38 pacientes acima de 18 anos de idade, com diagnóstico de GPAA ou HO. Todos os pacientes receberam o colírio TRAVAMED® como primeira droga a ser introduzida no tratamento, tendo sido utilizada uma gota uma vez ao dia (à noite), e 30 dias após foram submetidos à tonometria de aplanação (Goldmann) para mensuração da PIO, com o mesmo examinador, no mesmo tonômetro e nos mesmos horários. Resultados: A média de redução da PIO após 30 dias de uso do TRAVAMED® foi de 7,46 mmHg. Em relação aos efeitos colaterais, 15,71% (11) dos olhos apresentaram hiperemia conjuntival, 8,57% (6) apresentaram dor, 8,57% (6) apresentaram ardência, 2,86% (2) apresentaram embaçamento visual e em 1,56% (1) dos olhos não houve queda significativa da PIO. Conclusão: A medicação TRAVAMED® foi eficiente na redução da PIO após 30 dias de uso contínuo, na dose de 1x/dia. Acerca dos efeitos colaterais, os mais observados foram hiperemia ocular (15,71%), dor (8,57%) e ardência (8,57%), porém estudos com maior tempo de seguimento se fazem necessários.

Descritores: Glaucoma; Hipertensão ocular/tratamento farmacológico; Travoprosta/efeitos adversos

The authors declare no conflicts of interests.

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### **I**NTRODUCTION

OAG is a progressive, chronic optic neuropathy characterized by typical alterations of the optic disc (OD) and the retinal nerve fiber layer (RNFL), with characteristic repercussions in the visual field (VF). Most often, it is followed by IOP measurements greater than the levels considered statistically normal. Individuals with pressure levels above 21 mmHg but without the characteristic signs of optic neuropathy are considered HO.<sup>(1)</sup> Among the hypotensive ocular medications currently available to treat POAG, prostaglandin analogs are the most potent ones, among them travoprost (0.004%), latanoposta (0.005%), and bimatoprost (0.03%).<sup>(2)</sup>

Travoprost is a selective agonist of the prostanoid receptor FP that undergoes hydrolysis by the esterases in the cornea so that the free acid is activated. Like all classes of prostaglandin analogues, its main activity is to increase the aqueous humor flow, both by trabecular and uveo-scleral pathways. The mechanisms by which this activity is achieved are not yet fully understood, but experimental studies have shown relaxation of the ciliary muscle and increased activity of extracellular matrix metalloproteinases and collagenases. (3.4)

Comparative studies have shown an equivalent or greater efficacy of travoprostol (0.004%) compared to latanoprost and timolol for IOP reduction. (5-7) And in cases of failure to control pressure with latanoprost, travoprosta showed clinically and statistically significant reduction of IOP, and may therefore be an option in these cases. (8)

Regarding adverse effects, the most related to the use of travoprost as well as to the other analogues of prostaglandins are conjunctival hyperemia, ocular irritation, pruritus, ocular pain, burning, iriana discoloration, papebral dermal hyperpigmentation of eyelids, and eyelash alterations.<sup>(3,4)</sup>

In this context, the present study aimed to evaluate the efficacy of TRAVAMED® (travoprost 0.004%) (Germed, Brazil) to reduce the IOP of patients with POAG or HO, and to evaluate the side effects of drug use..

#### **METHODS**

A randomized, controlled study carried out by the Department of Glaucoma of Centro de Oftalmologia Tadeu Cvintal, São Paulo, Brazil. The sample comprised 70 eyes of 38 patients. Participants included were adult patients of either POAG or HO. All received TRAVAMED® eye drops as the first drug to be introduced in the treatment. The medication was instilled once a night in all patients, and after 30 days, they were submitted to aplanation tonometry (Goldmann) to measure the IOP by a single examiner in the same device and at the same times. In addition, participants were asked about the perception of side effects noted after the onset of eye drops. The following patients were excluded from the study: in use of topical or systemic corticosteroids, use of artificial tears, with infectious or noninfectious active conjunctivitis, keratitis, scleritis or uveitis, history of intraocular surgery prior to the introduction of medication or during the course of the study, history of inflammatory ocular diseases, progressive retinal diseases such as retinal degeneration or age-related macular disease, retinal detachment, and history of hypersensitivity to travoprostol (0.004%). The efficacy of eye drops was evaluated after 30 days of continuous use.

### RESULTS

Statistically significant IOP variation was observed before and 30 days after continuous use of eye drops (p <0.001), as observed in table 1.

Table 2 shows the reasons for discontinuation of treatment, whether related to eye drops intolerance or not.

The average eduction observed was 7.46 mmHg, ranging from zero to a reduction of 19 mmHg.

Table 1 IOP during follow-up

IOP (mmHg) (n = 64)		Evaluation 30 days after	Variation (Post - Pre)
Average	21.14	13.68	-7.46
Median	21	13	-8
Minimum / Maximum	15 / 39	9 / 20	0 / -19
Pre x Post			p < 0.001

Table 2
Reasons to discontinue treatment

Variables	(n = 70)	
Descontinuation – n (%)		
No	64 (91.43)	
Yes: intolerance to eye drops		
(major pain and hyperemia)	06 (8.57)	

According to table 3, the side effects demonstrated in the eye sample were as follows: 15.71% (11) of eyes had conjunctival hyperemia, 8.57% (6) presented pain, 8.57% (6) presented ardence, 2.86% (2) presented visual blurring, and 1.56% (1) of eyes had no significant decrease in IOP.

Table 3
Side effects in the eye sample

Efeitos colaterais – n (%)	(n = 70)
Hyperemia	
No	59 (84.29)
Yes	11 (15.71)
Pain	
No	64 (91.43)
Yes	06 (8.57)
Eyelash Growth	
No	70 (100.0)
Yes	00 (0.00)
Burning	
No	64 (91.43)
Yes	06 (8.57)
Visual blurring	
No	68 (97.14)
Yes	02 (2.86)

#### Discussion

Currently, the only factor with which we can work to avoid the progression of the POAG is in the reduction of IOP. Therefore, maintaining it at levels considered safe for the patient

is crucial. Studies show that the reduction of IOP in patients with HO reduces the risk of developing glaucoma,  $^{(9,10)}$  as well as the progression of VF loss in patients with established glaucoma.  $^{(11,12)}$ 

In the present study, an average reduction of 7.46 mmHg was observed with the use of travoprost (0.004%) 1x/day, corroborating data found in the literature. (13-17) In their study, Orengo Nania et al. found IOP reductions ranging from 5.7 to 7.2 mmHg. (18) In study carried out in the Egyptian population, Macky found an average reduction of 7.84 mmHg. (19) Gandolfi, however, found variations between 7.6 and 9.2 mmHg. (20) In a meta-analysis published in 2009, there was an average IOP reduction of 7.13 mmHg after three months of continuous use of travoprost (0.004%). (21)

Among the patients studied, 15.71% complained of conjunctival hyperemia, an incidence higher than that found by Brooks et al. (2.2%), but lower than that of Chichton (49%) and Feldman (50%). (22-24) 8,57% of the patients discontinued treatment due to intolerance to the eye drops, a higher value than that found by Brooks (5,0%) and Kumar (4,3%). (22.25) 8.57% had ocular pain or burning after instilling the eye drops, values higher than those found by Cheng (4.4 and 4.6%, respectively). (21) No pigmentary alterations or growth of eyelashes were observed, and this can be explained by the fact that the patients were followed for only one month, a time shorter than that found in the literature for observation of the effect. (26.27)

# **C**ONCLUSION

The present study led us to conclud that TRAVAMED® was efficient in reducing IOP after 30 days of continuous use at a dose of 1x/day. Regarding side effects, the most commonly observed were ocular hyperaemia, pain and burning. However, studies with a longer follow-up period are necessary.

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