Vol 5|Issue5| 2015 |275-278.

ISSN 2249 - 7641
Print ISSN 2249 - 765X

International Journal of Pharmacology Research

www.ijprjournal.org

A 3-MONTH SAFETY AND EFFICACY STUDY OF TRAVOPROST 0.004% OPHTHALMIC SOLUTION COMPARED WITH TIMOLOL IN PEDIATRIC PATIENTS WITH GLAUCOMA OR OCULAR HYPERTENSION

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ABSTRACT

There are two types of childhood glaucoma. The 9th World Consensus Report divides the world into two categories: primary and secondary. The Glaucoma Association is a non-profit organisation dedicated to the treatment of glau Congenital structural glaucoma may cause primary childhood glaucoma. Primary congenital glaucoma (PCG) and adolescent glaucoma are examples of abnormalities. Open-angle glaucoma is a form of glaucoma in which the pupil dilates Secondary childhood glaucoma develops as a result of a separate illness trauma or processes (i.e, surgical removal of the native lens in eyes with congenital cataracts). Despite the fact that surgery is the preferred treatment for childhood glaucoma, pharmacologic control is popular. The aim of this study was to assess travoprost's IOP-lowering effects in paediatric patients and show that it was noninferior to timolol. Travoprost (n = 3) had a higher rate of discontinuations (n = 1) than timolol (n = 1). Patients in the travoprost community discontinued early due to insufficient IOP power. At weeks 2 and 6, one patient (aged 3 months) showed a clinically significant decrease in IOP. However, the investigator found that the patient's IOP regulation was ineffective, presumably due to his age. The investigator also dropped another patient who had a decrease in IOP at weeks 2 and 6. These two patients had an IOP of more than 31 mm Hg at the outset. In one patient, travoprost caused a short-term decrease in IOP, which was accompanied by a rise after week 6. The remaining three patients did not respond to travoprost treatment; two of these patients were on multiple IOP-lowering drugs prior to the screening visit, so travoprost alone may not have been enough to control IOP. There were no patients in the travoprost population who had to stop taking it because of side effects.

Keywords: Travoprost, Timolol, Intra ocular pressure (IOP), drug related side effects, pediatrics.

INTRODUCTION

Glaucoma in children is a potentially blinding disease marked by structural changes in the optic disc and high intraocular pressure (IOP) [1]. There are two types of childhood glaucoma [2]. The 9th World Consensus Report divides the world into two categories: primary and secondary[3]. The Glaucoma Association is a non-profit organisation dedicated to the treatment of glau Congenital structural glaucoma may cause primary childhood glaucoma [4]. Primary congenital glaucoma (PCG) and adolescent glaucoma are examples of abnormalities [5]. Open-angle glaucoma is a form of glaucoma in which the pupil dilates Secondary childhood glaucoma develops as a result of a separate illness trauma or processes (i.e, surgical removal of the native lens in eyes with congenital cataracts) [6]. Despite the fact that surgery is the preferred treatment

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for childhood glaucoma, pharmacologic control is popular [7]. The first-line therapy -blockers, carbonic anhydrase inhibitors, and other IOP-lowering drugs are currently used in adults [8, 9]. CAIs, PGAs, cholinergic agonists, and 2-agonists are all examples of prostaglandin analogues. Just a few Data on the use of popular IOP-lowering agents in paediatric patients is available. Reduced body mass and surface area, reduced renal clearance, and reduced blood flow as compared to Makes paediatric patients more vulnerable to systemic adverse effects as compared to adults any unfavourable circumstances. In infants and small children, incidents such as central nervous system depression caused by 2-agonists may be fatal [10]. Travoprost 0.004 percent and latanoprost 0.005 percent were recently introduced.In Europe, they've been licenced for paediatric usten, eleven Timolol is often used as the first line of pharmacologic therapy in children with glaucoma. Topical application of -blockers, on the other hand, may cause asthma, bradycardia, heart block, and heart failure. In diabetic children, failure and the masking of hypoglycemia are common [11]. Latanoprost therapy, a safe IOP-lowering treatment for adults, has been shown to result in higher systemic blood pressure. In younger children, exposure to the biologically active metabolic substance latanoprost acid. It has been shown to be effective in lowering IOP and has been approved for use in adults since 2001 with ocular hypertension or primary open-angle glaucoma Travoprost was approved in Europe. In 2014, it was approved for use in children. Travoprost was shown to be effective in children in a small retrospective sample. It worked well and was well tolerated. 54 percent of eyes in children with glaucoma responded to treatment. After one month of therapy, the IOP had decreased by 15%. The most common form of lash growth was eyelash growth.This is a normal side effect [12]. Travoprost was used as an alternative to chemotherapy in a sample of paediatric patients. Compared to other glaucoma drugs, 60% of patients responded to travoprost, with a 10% reduction in eye pressure. IOP stands for International Organization of Plants. Conjunctival hyperemia was the most common side effect.

AIMS AND OBJECTIVE:

The aim of this study was to assess travoprost's IOP-lowering effects in paediatric patients and show that it was noninferior to timolol.

MATERIAL AND METHODS:

This was a multicenter, randomised, double-masked, parallel-group phase 3 analysis that lasted three months. This research was carried out in accordance with good clinical practise and ethical standards derived from the Declaration of Helsinki, and it was accepted by the ethical review boards of each institution. This research was carried out at 38 locations in 15 countries between September 2012 and March 2014. Patients' parents or guardians gave written informed consent, and patients gave their consent to participate when necessary. Patients had to be between the ages of 2 months and 18 years old, have a history of paediatric glaucoma or ocular hypertension, and have an IOP of less than 20 mm Hg in at least one eye during the eligibility visit.

RESULTS AND DISCUSSION:

Thirty of the 123 patients (mean age: 8.6 years) were given travoprost and thirty were given timolol. At 3 months, both patients had a substantial reduction in IOP in the study eye: the mean IOP drop from baseline for travoprost was 5.4 mm Hg; 5.3 mm Hg for timolol. At month three, the difference between travoprost and timolol was 0.1 mm Hg (95 percent CI, 1.5 to 1.4 mm Hg). Ocular hyperemia and eyelash development were the most common treatment-related adverse events in the travoprost population. There were no significant side effects reported.

Table 1: Summary of treatment-emergent adverse events

Adverse event category, n (%)	Travoprost (n = 30)	Timolol (n = 30)
Deaths	0	0
Nonfatal serious AE	0	1(3.33%)
Discontinued due to an AE	0	0
Patients with ≥1 treatment-emergent AE	5 (16.6%)	2(6.6%)
Ocular hyperemia	1 (3.3%)	0
Headache	1(3.3%)	1(3.3%)
Growth of eyelashes	1(3.3%)	0
Conjunctival hyperemia	2(6.6%)	1 (3.3%)
Patients with ≥1 treatment-related AE	3(10%)	3(10%)
Ocular hyperemia	1(3.3%)	0
Growth of eyelashes	1(3.3%)	0
Eye pruritus	1(3.3%)	0
Photophobia	0	0
Eye pain	0	0
Lacrimation increased	0	0

Erythema of eyelid	0	0
Keratitis	0	0
Conjunctival hyperemia	0	0
Dry eye	0	0
Eye irritation	0	1(3.3%)
Foreign body sensation	0	0
Dizziness	0	1(3.3%)
Visual field defect	0	1(3.3%)

The mean length of exposure (with standard deviation) for the 123 patients (aged 2 months to 17 years) was 84.0 14.2 days for patients receiving travoprost and 88.3 6.6 days for patients receiving timolol. Two patients in the timolol community had significant side effects that were not linked to the study drug (pneumonia and bacterial keratitis in one patient, and viral infection in the other; Table 2). There were no serious side effects recorded in the travoprost community. There were no patients who dropped out of the study due to an adverse event. Dizziness was identified as a systemic treatment–related AE in one patient receiving timolol; no such incidents were reported in patients receiving travoprost. Ocular hyperemia (17%) and eyelash development (17%) were the most common treatment-related adverse effects in the travoprost population (7 percent). Ocular hyperemia was identified in 1% of the timolol population, but there were no reports of eyelash formation. Other side effects of travoprost included ocular pain, photophobia, scratching, dry eye, and corneal surface irritation, which are all common with topical ocular medications.

Travoprost (n = 3) had a higher rate of discontinuations (n = 1) than timolol (n = 1). Patients in the travoprost community discontinued early due to insufficient IOP power. At weeks 2 and 6, one patient (aged 3 months) showed a clinically significant decrease in IOP.

However, the investigator found that the patient's IOP regulation was ineffective, presumably due to his age. The investigator also dropped another patient who had a decrease in IOP at weeks 2 and 6. These two patients had an IOP of more than 31 mm Hg at the outset. In one patient, travoprost caused a short-term decrease in IOP, which was accompanied by a rise after week 6. The remaining three patients did not respond to travoprost treatment; two of these patients were on multiple IOP-lowering drugs prior to the screening visit, so travoprost alone may not have been enough to control IOP. There were no patients in the travoprost population who had to stop taking it because of side effects.

LIMITATIONS OF STUDY AND CONCLUSION:

The lack of an extended wash-out period for prior IOP-lowering medications, the limited treatment time (3 months), and the small number of patients under the age of 3 were all potential shortcomings of the current research (16 patients). Future research may need to look at the long-term consequences of chronic travoprost therapy, such as prostaglandin-associated periorbitopathy in adults, as well as the effectiveness and protection of travoprost in infants and young children.

Travoprost was found to be noninferior to timolol in lowering IOP in children with glaucoma or ocular hypertension in this study. Travoprost was well tolerated, and no systemic adverse effects were identified as a result of the procedure.

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