

Diclofenac Verses Dexamethasone in Un-complicated Cataract Surgeries.

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ABSTRACT

Background: Uncomplicated cataract procedures have become very easy to perform with minimal complications. Treatment of inflammation post-surgery was usually by corticosteroids. Of late, Diclofenac sodium, a non-steroid anti-inflammatory agent is being widely tested to be used instead of corticosteroids as steroids are known for their side effects. **Methods:** 179 patients of both genders, undergoing elective unilateral ECCE with IOL implantation were included into this study. The patients were divided into 2 groups. Group 1 consisted of 89 patients who were given diclofenac sodium and Group 2 of 90, who were treated with dexamethasone post operatively. All patients were subjected to visometric, eye biomicroscopic, ophthalmoscopic and tonometric examination before surgery and on 1st, 3rd, 7th and 14th days post-surgery. **Results:** By 7th day, the visual acuity was 75% in group 1 and 69% in Group 2. Inflammation was seen in less than 8% of the cases in both the groups showing that both the drugs are equally efficient. **Conclusion:** As diclofenac is as good as dexamethasone, if not better, diclofenac can be used in lieu of the latter for the treatment of inflammation in uncomplicated cataract surgeries.

Keywords: Cataract surgery, Diclofenac, Dexamethasone.

INTRODUCTION

The operative procedures of cataract surgery have developed in the recent times. As a result the operation itself has become easier and less traumatic to the eye. There is less inflammation of the eye post operatively and less breakdown of blood aqueous barrier (BAB).^[1-3] This is probably due to development of refined surgical techniques as well as more biocompatible intraocular lenses (IOL).^[4] Although the inflammation is usually self limiting, anti-inflammatory drugs are given to prevent complications of the inflammation such as cystoid macular edema that could interfere with visual rehabilitation.^[5]

Diclofenac Sodium Ophthalmic Solution 0.1% is a sterile, topical, non-steroidal, anti-inflammatory product for ophthalmic use. Diclofenac Sodium is designated chemically as 2-[(2,6-dichlorophenyl)amino] benzene-acetic acid, monosodium salt, with an empirical formula of C₁₄H₁₀Cl₂NO₂Na.^[6] The mode of action responsible for its inflammatory action is thought to be the inhibition of prostaglandin synthesis by inhibition of cyclooxygenase (COX). It is also involved in bacteriostatic activity by inhibiting DNA synthesis.^[7] Dexamethasone is a type of steroid medication with many uses, one of it being used as an anti-inflammatory especially after cataract surgery. They

may be used as topical drops.^[8]

Topical corticosteroids are commonly used as routine anti-inflammatory agents post operatively for several weeks. However, this is not without side effects. Elevation of intraocular pressure, inhibition of wound healing and facilitations of infections are common side effects.^[9] Therefore, diclofenac which is a non-steroidal anti-inflammatory drug (NSAIDs) has been used as an alternative in reducing the breakdown of BAB.^[10]

In this study, we have tried to compare the efficacy of diclofenac as an anti-inflammatory against dexamethasone in cataract surgery patients.

MATERIALS AND METHODS

This study was conducted by the Department of Pharmacology, MNR Medical College, Sangareddy and Mallareddy Institute of Medical Sciences, Hyderabad. 179 patients of both genders, undergoing elective unilateral ECCE with IOL implantation were included into this double blind study after obtaining clearance from the institutional ethical committee and from patients through informed consent. The patients were divided into 2 groups. Group 1 consisted of 89 patients who were given diclofenac sodium and Group 2 of 90, who were treated with dexamethasone post operatively.

All patients who had glaucoma, acute or chronic conjunctivitis, uveitis, dry eye syndrome, pseudo-exfoliation diabetic retinopathy, insulin-dependent diabetes, or any other ocular pathology that could affect response to the treatment or evaluation were excluded from the study. Patients who had

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intraoperative complications and those who received systemic or topical anti-inflammatory within 2 weeks before surgery were also excluded from the study.

Patients were randomly assigned to Group 1 or Group 2. Group 1 received diclofenac sodium 0.1% eye drops 1-2 drops 4 times a day, and Group 2 were given dexamethasone phosphate eye drops, 1-2 drops 4 times a day. Both were to be taken for one month after surgery.

All patients were subjected to visometric, eye biomicroscopic, ophthalmoscopic and tonometric examination before surgery and on 1st, 3rd, 7th and 14th days post-surgery. During these examinations, pain syndrome relief by the drug, time of disappearance of inflammation, frequency of

complications if any were observed. Final evaluation was done after 1 month.

RESULTS

Out of the 89 patients in group 1, 42 were males and 47 were females, and out of the 90 patients in Group 2, 44 were males and 46 were females. The mean age in Group 1 was 62.4 ± 3.2 and in Group 2, it was 64.1 ± 3.7 years [Table 1]. There was a positive visual acuity among the patients in Group 1 compared to those in Group 2 [Table 1].

Table 1: Patient's details

Particulars	Group 1 (Diclofenac sodium 0.1%)	Group 2 (Dexamethasone phosphate)
Number	89	90
Males	42	44
Females	47	46
Mean Age	62.4 ± 3.2	64.1 ± 3.7

Table 2: Rate of patients at each examination time achieving a visual acuity of 20/25 or more.

Groups	Before surgery	On 1 st day	On 3 rd day	On 7 th day	On 14 th day	After 1 month
Group 1 (n= 89)	86/89 (96.6%)	52/89 (58.4%)	55/89 (61.2%)	67/89 (75.3%)	71/89 (79.8%)	79/89 (88.8%)
Group 2 (n=90)	85/90 (94.4%)	49/90 (54.4%)	51/90 (56.7%)	62/90 (68.9%)	68/90 (75.6%)	75/90 (83.3%)

On the first day inflammation was observed in 37% patients and 42% of the patients in Group 1 and Group 2 respectively. This considerably reduced by the 7th day of surgery to almost 8% in both. Except for one

patient in Group 1, no patient had any incidence of inflammation by the 14th day of surgery.

Table 3: Rate of inflammation among patients

Groups	Before surgery	On 1 st day	On 3 rd day	On 7 th day	On 14 th day	After 1 month
Group 1 (n= 89)	0/89 (0)	33/89 (37.1%)	21/89 (23.6%)	7/89 (7.9%)	1/89 (1.1%)	0/89 (0)
Group 2 (n=90)	0/90 (0)	38/90 (42.2%)	26/90 (28.9%)	7/90 (7.8%)	0/90 (0)	0/90 (0)

Change in intraocular pressure was observed in 4 patients in group 2 on the 7th day of evaluation but none in group 1. There were no other complications seen in any of the patients post-surgery.

DISCUSSION

Inflammation in tissues can be divided for clinical and therapeutically purposes into immunogenic and "traumatic" inflammation. The latter can be caused, among others, by any physical trauma such as surgery, laser intervention or ultraviolet light.^[11]

Diclofenac sodium is known to be a very potent anti-steroid, anti-inflammatory agent which does not have any side effects unlike its counterpart dexamethasone, a corticosteroid which can cause elevation in intraocular pressure or delayed wound healing. Corticosteroids are anti-inflammatory by causing inhibition of arachidonic acid. NSAIDS on the other

hand decrease inflammation by inhibiting cyclooxygenase activity and preventing the release of prostaglandins from arachidonic acid. In contrast, Diclofenac sodium indirectly modulates lipooxygenase chain in arachidonic acid cascade. Due to this dual mechanism of action, diclofenac is preferred drug as against corticosteroids.^[12]

As there have been many improvements in the surgical procedures and reduction of BAB damage, the actual need of anti-inflammatory drugs are being questioned.^[13] In the past several years few studies have been conducted which included placebo along with diclofenac and dexamethasone, which showed very few cases with inflammation.^[14,15]

Our study compared the efficacy of diclofenac against the corticosteroid, dexamethasone. The main criteria was the estimation of inflammation by the decrease in number of cells in the liquid and the reduction of the cloudiness in the anterior chamber liquid.

We have shown that there were no significant difference between rate of visual acuity by using diclofenac as well as dexamethasone. The rate of inflammation between the two groups was not statistically significant either. In a similar study by Chichua et al, similar observations were noted.^[16] Same was the case in a study by Othenin-Girard et al, where no significant difference was found in the affectivity by both the drugs.^[17]

Herbert et al found that Diclofenac given in combination with gentamicin followed by Diclofenac was a better choice of drug than its corticosteroid counterpart at suppressing flare and cells but showed a slightly higher incidence of punctate keratitis and eye discomfort.^[18] Similar was the case in an Indian study by Reddy et al, who observed that diclofenac was a better drug with lesser complications.^[19]

Despite the fact that NSAIDS drops have been shown to be equal in potency to corticosteroid drops, they are still not used routinely to control postsurgical inflammation. In fact in a study by Miyake et al, the anti-prostaglandin effect was demonstrated in patients treated with latanoprost after cataract surgery. This study showed that diclofenac drops were more potent than fluorometholone and abolished the pro-inflammatory effect of latanoprost.^[20]

CONCLUSION

Time and again, Diclofenac sodium is showing to be as effective as topical corticosteroid and can be used as an alternative in routine postoperative treatment following uncomplicated cataract surgery.

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