

## Original Research Article

# Study of Effect of Topical 0.05% Difluprednate on Intra Ocular Pressure in Patients Operated By Small Incision Cataract Surgery

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**Abstract:** Our study was carried out over 5 months from April 2014 to August 2014. Patients of uncomplicated cataract operated at tertiary care centre, Nanded by same surgeon with Manual small incision cataract surgery (SICS) with posterior chamber intra ocular lens (PCIOL) were studied. Objective is to find out co-relation between High IOP and topical 0.05% Difluprednate use on post-operative patients. Study Design was hospital based, prospective, observational Cohort study. Patients were started on topical antibiotic plus 0.05% difluprednate combination on first post-operative day and advised q.i.d. dosing. Then patients were followed for 6 weeks their IOP was measured by Goldmann Applanation Tonometer. Total of 56 eyes of either sex were included in the study. Our study showed that there is low risk of IOP rise in postoperative cataract patients i.e. 3.57% (2 out of 56 eyes) if schedule is followed. So our study concludes that strict following of dosing is necessary to get good outcome with difluprednate.

**Keywords:** Manual small incision cataract surgery (SICS) posterior chamber intra ocular lens (PCIOL), Goldmann Applanation, Tonometer, Intra ocular pressure (IOP), corticosteroid, and inflammation.

## INTRODUCTION

Corticosteroids are effective drugs to reduce ocular inflammation [1]. They are evolved as the one of the most important drugs in ophthalmology. Required in day to day practice of all ophthalmologists. Indicated in post-operative period of cataract surgery in topical form to control ocular inflammation[2]. But they are known to cause various ocular & systemic side effects. Hence known as 'Two Edged Sword'[1]. Difluprednate is the new corticosteroid approved for topical use recently(2008).Potency is 6 times than prednisolone[3].

Objective of our study is to find out co-relation between High IOP and topical 0.05% Difluprednate on post-operative SICS with PCIOL patients followed for 6 weeks.

Similar study was conducted by Melissa M. Cable about Intraocular Pressure Spikes in Difluprednate Ophthalmic Emulsion 0.05% for Postoperative Cataract Inflammation[4]. Eric D Donnenfeld also carried out study on topical difluprednate on prevention of post-surgical inflammation[5]. Stephen Smith et al evaluated Difluprednate ophthalmic emulsion 0.05% (Durezol®) administered two times daily for managing ocular inflammation and pain following cataract surgery[6].

## MATERIAL AND METHODS

Study Design was hospital based, Prospective, Observational Cohort study Carried out in Dept. Of

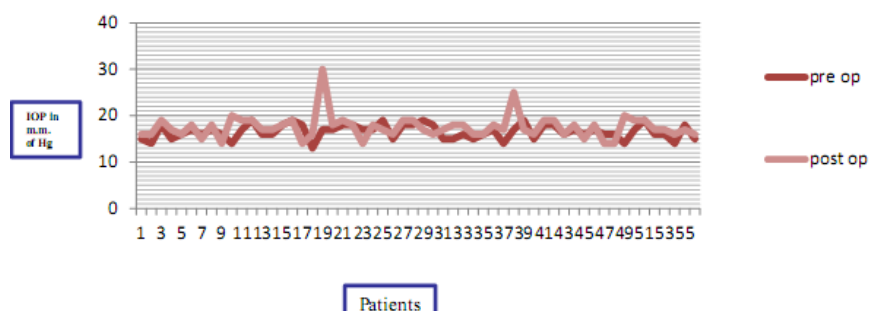
Ophthalmology of tertiary care center. Study was institutional ethical committee approved.

Present study was conducted over a period of 5 months from April 2014 to August 2014. Total of 56 eyes of either sex of uncomplicated cataract operated at tertiary care centre operated by same surgeon by SICS With PCIOL were studied. Above patients were started on topical antibiotic plus 0.05% difluprednate combination on first post-operative day and advised q.i.d. dosing. Forty day dosing schedule followed was as follows, for first 10 days q.i.d. dosing, next 10 days t.i.d., after that b.i.d for 10 days, and for last 10 days o.d. dosage. Patients were followed for 6 weeks and their IOP was measured by Goldmann Applanation Tonometer. First follow up was on third day and then weekly till six weeks.

Patients with Primary open angle glaucoma(POAG),high myopes, complicated cataract, pseudo-exfoliation syndrome; patients on Systemic corticosteroid treatment, posterior segment pathology, intra & postoperative complications, irregular or no follow-up were excluded from study.

## RESULTS

Total of 56 eyes of either sex were included in this study. There were 37(66.07%) males and 19(33.92%) females.



**Fig. 1: graph showing IOP in mm of Hg in each 56 eye.**

High IOP i.e. IOP greater than 21 mm of Hg were noted in total two patients (3.57%), one male and one female. Male showed 30 mm of Hg IOP and in female 26 mm of Hg pressure noted. High IOP was noted in one diabetic patient.

## DISCUSSION

Corticosteroids are potent anti-inflammatory agents. Hence are used to control post-operative ocular inflammation. Difluprednate is a potent new corticosteroid categorized in subclass - Gluco/mineralocorticoids, Progestogens and Derivatives. It is chemically a butyrate ester of 6(alpha), 9(alpha)-difluoro prednisolone acetate. On June 24, 2008, the US Food and Drug Administration (FDA) approved difluprednate for the treatment of post-operative ocular inflammation and pain.

Corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins (lipocortins). It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

Difluprednate penetrates the corneal epithelium rapidly and effectively. And have low systemic absorption. 78.5% excreted after 24 hours, and 99.5% by 7 days.

Steroid induced glaucoma i.e. increases in IOP following corticosteroid use is observed in few patients. It is more common with topical steroids than systemic steroids. IOP rise in steroid users is variable. Most of the population i.e. 60% does not show IOP fluctuations that are on topical steroids. Few i.e. 35% shows moderate rise of IOP. But remaining 5% of patients on topical steroids shows significant rise of IOP. These 5% patients are termed as high steroid responders.

Exact mechanism for increase in IOP in topical steroid users is unknown. Few theories postulated are Glycosaminoglycans theory, endothelial cell theory and Prostaglandin theory. Glycosaminoglycans are present in the trabecular meshwork. Lysosomes present in the trabecular meshwork regulate GAG metabolism.

Corticosteroids stabilize lysosomal membrane and there is inhibition of hydrolases enzyme. Consequently there is inhibition of GAG depolymerization. That results into retention of water in extra-cellular space. Causing narrowing of trabecular space. That causes decreased outflow of aqueous outflow. Endothelial cell theory explains that endothelial lining of trabecular meshwork have phagocytic activity. It helps in phagocytosis of debris in aqueous humor. Corticosteroids suppress phagocytic activity. Hence causes decrease outflow. Prostaglandin theory states that Prostaglandin E & F (PGE & PGF) are known to cause increase in aqueous outflow. Corticosteroid inhibits synthesis of PGE & PGF and hence decreases in outflow.

Clinical features of steroid induced glaucoma is characterized by asymptomatic, headache, eyeache etc. Various signs are increased IOP, optic disc changes, visual field loss, and open angles on gonioscopy. Diagnosis is clinical and based on history of steroid use, clinical feature, and stopping of steroids causes decrease of IOP. Management is discontinuation of steroids. Causes IOP to return to normal level within 10 days to 4 weeks. Topical timolol maleate is added to decrease IOP. Filtration surgery required in intractable cases.

We found two patients with increase IOP which contributes 3.75% risk of IOP rise in topical difluprednate use. One male patient had 30 mm of Hg and female patient showed 26 mm of Hg in post-operative period. Above male patient was known diabetic and showed IOP rise. Diabetics who are on topical steroids are known for IOP rise [7]. Our study is in correlation with this. Hence we excluded further enrolment of diabetics in study.

## CONCLUSION

Difluprednate is potent new steroid with day to day rise of usage by ophthalmologist. Strict following of dosing is necessary to get good outcome with difluprednate. We found difluprednate have low risk of IOP rise if schedule is followed.

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