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ORIGINAL ARTICLE

COMPARISON OF EFFICACY AND SAFETY OF DEXAMETHASONE 0.1% AND DIFLUPREDNATE 0.05% IN THE MANAGEMENT OF OCULAR INFLAMMATION AFTER PHACOEMULSIFICATION

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ABSTRACT: PURPOSE: To compare the efficacy and safety of dexamethasone 0.1% and difluprednate 0.05% ophthalmic solution in the management of ocular inflammation after phacoemulsification. **DESIGN:** Prospective randomized control study. **SETTING:** Ophthalmology Department, Mahatma Gandhi Medical College & Hospital, Sitapura, Jaipur. **METHODS:** 50 patients (Age 45 to 75 year) with senile cataract were taken. After surgery 25 patients were treated with dexamethasone 0.1% and 25 patients with difluprednate 0.05%. Patients were examined and compared on postoperative day 1, 7, 14, 28 for anterior segment, intraocular pressure and side effects. **RESULTS:** Anterior chamber cell loss on day 7 was more in difluprednate group. Both drugs show equivalent efficacy in decreasing the anterior chamber flare. No clinically significant IOP elevation was noted in any patient during study. The adverse effects reported were mild discomfort and watering and foreign body sensation were slightly more in dexamethasone group than difluprednate group. No serious adverse effects were reported during the study. **CONCLUSION:** Both drugs dexamethasone 0.1% and difluprednate 0.05% shows equivalent efficacy to control postoperative inflammation with difluprednate being more rapid. **FINANCIAL DISCLOSURE:** No author has a financial interest in any material or method mentioned.
KEYWORDS: Dexamethasone, Difluprednate, Anterior chamber, IOP.

INTRODUCTION: Cataract surgery is an invasive procedure that requires incision and cutting of ocular tissue as well as considerable intraocular tissue manipulation. Surgical manipulation during phacoemulsification leads to the disruption of the blood aqueous barrier, resulting in intraocular inflammation. Postoperative inflammation can lead to complications such as pain, discomfort, photophobia, corneal edema, posterior synechiae, elevation in IOP and cystoid macular edema.[1,2] Topical corticosteroids are a very effective treatment for postoperative ocular inflammation. Corticosteroids inhibit the release of arachidonic acid from cell membrane phospholipids and prevent the formation of both leukotrienes and prostaglandins, thus disrupting the inflammatory cascade.[3] Corticosteroids have been used to treat ocular inflammation however, they carry a risk of side effects, particularily an increase in IOP. If left untreated, could lead to glaucoma.[4] The postoperative inflammation can be assessed by monitoring anterior chamber signs such as, cell grade, flare grade with slit lamp examination.

Difluprednate ophthalmic emulsion 0.05%, a strong topical steroid, was approved by US Food and Drug Administration (FDA) in June 2008, for treatment of ocular inflammation and pain associated with ocular surgery[5,6] along with less frequency of dosage (4 times) for better patient compliance.

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Dexamethasone is a synthetic analog of naturally occurring glucocorticoids. It has good glucocorticoid potency and receptor binding capacity.

Corticosteroids are continued till the anterior chamber reaction has resolved and blood aqueous barrier has been re-established.[7]

AIMS AND OBJECTIVES: To compare efficacy and safety of dexamethasone 0.1% and difluprednate 0.05% in the management of ocular inflammation after phacoemulsification.

MATERIALS AND METHODS: This is a prospective randomized control study in which 50 patients (Between 45 to 75 years) with senile cataract attending our eye OPD of Mahatma Gandhi Medical College & Hospital, Jaipur were taken. A detailed history, complete physical examination and routine investigations were done. All patients having uneventful phacoemulsification with PCIOL surgery under local anaesthesia were divided into two group i.e. (A=25 and B= 25) randomly. Treatment was started 24 hours after surgery. Group A patients were treated with dexamethasone 0.1% eye drop 6 times per day for 2 weeks followed by tapering dose. Group B patients were treated with difluprednate 0.05% eye drops 4 times per day for 2 weeks followed by tapering dose. Patients with Intraoperative complications, Pre-existing ocular disease, History of glaucoma and steroid-related intraocular pressure (IOP) rise in the study eye and with uncontrolled systemic disease were excluded from the study. Patients were examined on postoperative day 1, 7, 14 & 28 for - Intraocular pressure, Anterior chamber cells and flare with slit lamp examination (graded according to the standardization of uveitis nomenclature), Best corrected visual acuity (BCVA) on day 28 and adverse effects like corneal oedema, keratic precipitates, foreign body sensation, congestion, discomfort and watering etc.

RESULTS:

Anterior chamber flare – is shown in **Table 1.** By day 14 all patients had anterior chamber flare of grade 0. The P value was > 0.05 which is not significant.

DM GROUP	**DAY 1**	**DAY 7**	**DAY 14**	**DAY 28**
GRADE 0	32% (8)	84% (21)	100% (25)	100% (25)
GRADE 1	44% (11)	16% (4)	0%	0%
GRADE 2	24% (6)	0%	0%	0%
GRADE 3	0%	0%	0%	0%
DF GROUP				
GRADE 0	32% (8)	88% (22)	100% (25)	100% (25)
GRADE 1	48% (12)	12% (3)	0%	0%
GRADE 2	20% (5)	0%	0%	0%
GRADE 3	0%	0%	0%	0%
P VALUE	0.937	0.684	1.00	1.00

Table 1: Grades of Aqueous flare during follow up (On SLE)

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Anterior chamber cells – is shown in **Table 2.** By day 14 all patients had anterior chamber cells of grade 0. **Thus P value on day 7 was <0.05 which is significant.** But by day 14 all patients had anterior chamber cells of grade 0.

DM GROUP	DAY 1	DAY 7	DAY 14	DAY 28
GRADE 0	0% (0)	40% (10)	100% (25)	100% (25)
GRADE 1	24% (6)	60% (15)	0%	0%
GRADE 2	44% (11)	0%	0%	0%
GRADE 3	32% (8)	0%	0%	0%
GRADE 4	0%	0%	0%	0%
DF GROUP				
GRADE 0	0% (0)	68% (17)	100% (25)	100% (25)
GRADE 1	20% (5)	32% (8)	0%	0%
GRADE 2	28% (7)	0%	0%	0%
GRADE 3	48% (12)	0%	0%	0%
GRADE 4	4% (1)	0%	0%	0%
P VALUE	0.753	0.047	1.00	1.00

Table 2: Grades of AC cells during follow up (On SLE)

The **mean IOP** was calculated for preoperative IOP and postoperative IOP at day 1, 7, 14, & 28 (**Table 3)**. No clinically significant IOP elevation was noted in measured IOP of any patient during study.

	DEXAMETHSONE	DIFLUPREDNATE
PREOPERATIVE IOP MEAN±SD	15.27±2.18	15.44±2.41
POSTOPERATIVE IOP MEAN±SD	16.17±1.60	16.43±1.33
T TEST VALUE	1.66	1.78
P VALUE	0.10	0.08

Table 3: Mean±standard deviation IOP of both groups

The **BCVA** on day 28 was 6/6 in both groups.

The **adverse effects** reported were mild discomfort, foreign body sensation and watering seen in 8 patient (32%) in DM and in 7 patients (28%) in DF group.

DISCUSSION: Cataract surgery has become one of the safest, most successful and most frequently performed Surgeries.[8] Advances in techniques and equipment have led to a dramatic increase in the popularity of phacoemulsification with increased safety and accuracy.

The role of steroids in postoperative period is undisputable. In 1950 **Gordon** and **Mclean** introduced steroids in ocular therapy and in 1951 ocular formulations arrived. In 1959 dexamethasone 0.1% eye drops were introduced to treat ocular inflammation.[9] After 1973, difluprednate is first steroid to be approved by FDA in 2008.

Diestelhorst M et al.[10] (1992) studied effect of dexamethasone 0.1% and prednisolone acetate 1.0% eye drops on the blood-aqueous barrier after cataract surgery. They were unable to demonstrate

difference in the efficacy in protecting the blood-aqueous barrier after cataract extraction and posterior chamber lens implantation between two drugs. They concluded even with greater potency and more affinity to glucocorticoid receptors dexamethasone had efficacy equivalent to prednisolone.

C. Stephen Foster et al.[11] (2010) compared difluprednate ophthalmic emulsion 0.05% and prednisolone acetate suspension 1% to demonstrate similar efficacy in the treatment of inflammation in anterior uveitis. They concluded that difluprednate administered QID is at least as effective as prednisolone administered 8 times/day in resolving the inflammation and pain associated with endogenous anterior uveitis.

Meehan K et al.[12] (2010) studied intraocular pressure elevation from topical difluprednate use. Difluprednate 0.05% has a reported associated increase in intraocular pressure (IOP) in 3% of patients. And concluded clinicians need to be aware of the potential risk for significant and potentially rapid onset of IOP increase with this medication and manage patients accordingly. Some studies indicate that compliance with difluprednate is indicated to be better as it has QID dosage compared to 6times of dexamethasone.

Our study shows difluprednate is more effective drug in reducing AC cells in the early postoperative period (0 - 7 days). Both drugs show equivalent efficacy in decreasing the anterior chamber flare. No clinically significant IOP elevation was noted in any patient during study. Thus, in light of previous studies, with this study we can say that although initial rapidity at which inflammation is controlled (AC cell loss) in both drugs is different, however, final outcome is achieved at same time by day 14. Thus, both drugs have equivalent efficacy to control postoperative inflammation. Due to limited number of patients the IOP spikes were not seen in our study. The adverse effects seen were minimal namely mild discomfort, foreign body sensation and watering. All patients attained BCVA as 6/6 at day 28 in both groups. Thus, considering lower dosage frequency and equivalent efficacy, difluprednate is also a fair option to control postoperative inflammation after phacoemulsification.

CONCLUSION: In our study both drugs dexamethasone 0.1% and difluprednate 0.05% shows equivalent efficacy to control postoperative inflammation with difluprednate being more rapid. No serious adverse effects were seen during the study.

BIBLIOGRAPHY:

1. Apple DJ, Solomon KD, Tetz MR et al. Posterior capsule opacification. Surv Ophthalmol 1992; 37(2):73-116.
2. Miyake K, Maekubo K, Miyake Y et al. Pupillary fibrin membrane; A frequent early complication after posterior chamber lens implantation in Japan. Ophthalmology 1989; 96(8):1228–1233.
3. Schimmer BP, Parker KL et al. Goodman & Gilman's The Pharmacological Basis of Therapeutics, 10th Edition. New York: McGraw–Hill; 2001.p.1649–1677.
4. Becker B. Intraocular pressure response to topical corticosteroids. Invest Ophthalmol. 1965; 4:198-205.
5. Smith S, Lorenz D, Peace J et al. Difluprednate ophthalmic emulsion 0.05% (Durezol) administered two times daily for managing ocular inflammation and pain following cataract surgery. Clin Ophthalmol 2010; 4:983–991.

6. Jamal KN, Callanan DG. The role of difluprednate ophthalmic emulsion in clinical practice. Clin Ophthalmol 2009; 3:381-390.
7. Sanders DR, Kraff M. Steroidal and nonsteroidal anti-inflammatory agents. Effect on post-surgical inflammation and blood–aqueous humor barrier breakdown. Arch Ophthalmol 1984; 102(10):1453-1456.
8. Linebarger EJ, Haerdten DR et al. Phacoemulsification and modern cataract. Survey of ophthalmology 1999; 44(2); 123-147.
9. Gordon DM. Use of dexamethasone in eye. The Journal of the American Medical Association 1960; 172(4):311-312.
10. Diestelhorst M, Aspacher F, Konen W et al. Effect of dexamethasone 0.1% and prednisolone acetate 1.0% eye drops on the blood-aqueous barrier after cataract surgery: a controlled randomized fluorophotometric study.Graefes Arch Clin Exp Ophthalmol 1992; 230 (5):451-453.
11. C. Stephen Foster, Robert DaVanzo, Thomas E. Flynn, Kimberly McLeod, Roger Vogel, R. Steve Crockett. Durezol® (difluprednate ophthalmic emulsion 0.05%) compared with Pred Forte® 1% ophthalmic suspension in the treatment of endogenous anterior uveitis. J Ocul Pharmacol Ther 2010; 26(5):475–483.
12. Meehan K**,**Vollmer L, Sowka J.Intraocular pressure elevation from topical difluprednate use. Optometry 2010; 81(12):658-62.

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