

Comparative efficacy of topical corticosteroids in the post-operative management of cataract surgery

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Abstract

Cataract is the leading cause of blindness worldwide and cataract extraction is the treatment of choice leading to the improvement in the quality of life¹, cognitive functions² and productivity as reported by multiple published studies. **Purpose:** To study and compare the efficacy and safety of topical Prednisolone acetate 1%, Dexamethasone sodium phosphate 0.1% and Betamethasone sodium phosphate 0.1% Measurement of post operative Intra-ocular Pressure (IOP) in study population. **Materials And Methods:** 120 patients who underwent uneventful Small Incision Cataract Surgery (SICS) with Posterior Chamber Intra-ocular Lens (PC-IOL) implantation were randomly assigned to either of the three study groups. The anti-inflammatory efficacy of the three drugs under study was compared by closely examining the operated eye for inflammatory response and visual acuity on post-operative day one, day three, day ten, day 17 and day 30. **Results:** The final visual outcome was correlated with all the results which showed that topical 1% Prednisolone acetate is clinically more effective than topical 0.1% Dexamethasone sodium and 0.1% Betamethasone sodium to control the post-op inflammation in uneventful SICS. **Conclusion:** Topical 1% Prednisolone acetate is clinically more effective than topical 0.1% Dexamethasone sodium and 0.1% Betamethasone sodium to control the post-operative inflammation in uneventful SICS.

Key Word: topical corticosteroids.

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INTRODUCTION

Cataract is a major cause of blindness and severe visual impairment leading to bilateral blindness in an estimated 20 million people worldwide in 2004³. Over half of all persons over the age of 65 develop age related cataracts with visual disability⁴. Globally the number of cataract cases is expected to increase as populations age and the life span increases.⁵ There is no medical treatment for

cataracts.^{4,5} Surgical removal of cataract remains the only treatment option for patients with failing vision⁵. Small incision cataract surgery using phacoemulsification has largely replaced extra capsular cataract extraction because of faster healing, smaller wounds and fewer resultant complications, with improved patient's outcomes.

Despite surgical advances, post-cataract surgery inflammation is still a common cause of patient discomfort, delayed recovery and reduced visual outcome. Ocular inflammation after cataract surgery is generally managed by topical anti-inflammatory drugs such as corticosteroids or non-steroidal anti-inflammatory drugs (NSAIDs). Corticosteroids act to reduce inflammation at multiple points in the inflammatory cascade, including both the cyclo-oxygenase pathway and the lipo-oxygenase pathway through inhibition of phospholipase A2, producing a reduction in both prostaglandins and leukotrienes¹¹.

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MATERIALS AND METHODS

A comparative, prospective study was conducted at Ophthalmology OPD of SVS Medical College and Hospitals, Mahabubnagar, Telangana over a period of one year from January 2017 to January 2018. Ninety patients with senile cataract who underwent uneventful Small Incision Cataract Surgery (SICS) with, in the bag Posterior Chamber Intra-ocular Lens (PCIOL) implantation were included in this study after obtaining informed consent.

The inclusion criteria were as follows:

- Age above 50 years
- Senile cataract [LOCS (Lens Opacity Classification System) grade 2-3]
- Uncomplicated SICS with, in the bag implantation of PCIOL.

The exclusion criteria were as follows:

- Mature senile cataracts
- Complicated cataracts
- Lens induced glaucomas
- Previous ocular surgery
- Previous ocular disease
- Allergy to any drugs
- Bleeding disorders or on anticoagulant therapy
- Systemic diseases such as hypertension, diabetes mellitus, ischemic heart disease, bronchial asthma, connective tissue disorders, immunological disorders
- Poor compliance.

Preoperatively all patients underwent visual acuity testing using Snellen's visual acuity chart, measurement of intraocular pressure (IOP) using Goldmann's applanation tonometry and detailed slit lamp examination. Preoperative preparation of eye was identical in all patients. Anaesthesia used was peribulbar block of 2% lignocaine mixed with 1:1000 dilution of epinephrine and hyaluronidase. All patients were operated by a single surgeon using similar instruments and techniques, in the same operating theatre. Patients were randomly assigned to the three study groups; **Group A**, who received topical 1% Prednisolone acetate. **Group B** received topical 0.1%

Dexamethasone sodium. **Group C** received topical 0.1% Betamethasone sodium. A total of 120 patients studied were divided into three groups of 40 patients each. Group A treated with Prednisolone acetate 1%, Group B with Dexamethasone sodium phosphate 0.1% and Group C with Betamethasone sodium phosphate 0.1%. 40 patients were randomly assigned to each group post-operatively. Post operative treatment comprised of eight times a day instillation of corticosteroid eyedrops for one week. Later patients were instructed to decrease the frequency of corticosteroids to six times a day for one week then gradually taper weekly four/three/two/one times respectively and discontinued after six weeks post-operatively. All patients received additional drops of Moxifloxacin four times daily and Cyclopentolate two times daily from first post op day until day 15. Follow up visits were scheduled for Day 1st, Day 3rd, Day 10th, Day 17th, and Day 30th.

Grading of postoperative inflammation was done based on the following observations:

1. conjunctival erythema and ciliary flush [IER (International Eye Research) grading of bulbar redness]
2. anterior chamber cells and flare (Based on Hogan's slit lamp grading system of cells/flare per field under 1*1 slit beam at 16x magnification)

OBSERVATIONS AND RESULTS

Groups were comparable in age, sex and type of cataract. Majority of patients in this study were in the age group of 50-60 years accounting for 72% and 60-70 years accounting for 28%. Total Males (63%) were more than Females (37%). Male: Female ratio is 2:1.

Analysis of post operative inflammation: Resolution of post operative inflammation from Grade 1,2,3 to grade 0 was as follows:

Table 1-Conjunctival erythema and ciliary flush: (Based on Institute for Eye Research-IER slit lamp biomicroscopic qualitative grading of bulbar redness)

Grade 1 scores of inflammation resolution to Grade 0						
DAY	Group A (Prednisolone acetate 1%)		Group B (Dexamethasone sodium phosphate 0.1%)		Group C (Betamethasone sodium phosphate 0.1%)	
	No. of patients	% of resolution	Total no. of patients	% of resolution	Total no. of patients	% of resolution
1	4	-	6	-	6	-
3	2	50%	+	Nil	+	Nil
10	2	50%	6	100%	6	100%
17	-	-	-	-	-	-
30	-	-	-	-	-	-

Grade-2 scores of inflammation resolution to Grade-0						
1 st day	30	-	32	-	28	-
3 rd day	30	Nil	32	Nil	28	Nil
10 th day	25	83.33%	25	78.12%	21	75%
17 th day	15	50%	17	53.12%	7	25%
30 th day	-	-	-	-	-	-

Grade-3 scores of inflammation resolution to Grade-0						
1 st day	6	-	2	-	6	-
3 rd day	+	Nil	+	Nil	+	Nil
10 th day	4	66.6%	1	50%	2	33.33%
17 th day	2	33.33%	1	50%	4	66.66%
30 th day	-	-	-	-	-	-

Table 2: Anterior chamber cell count

(Based on Hogan's slit lamp grading of anterior chamber cell count per field in a 1*1 slit beam under 16x magnification)

DAY	Grade-1 scores of inflammation resolution to Grade-0		Grade-1 scores of inflammation resolution to Grade-0		Grade-1 scores of inflammation resolution to Grade-0	
	Group A(Prednisolone acetate 1%)		Group B(Dexamethasone sodium phosphate 0.1%)		Group C (Betamethasone sodium phosphate 0.1%)	
	Total no. of patients	% of resolution	Total no of patients	% of resolution	Total no of patients	% of resolution
1 st day	4	-	5	-	5	-
3 rd day	3	75%	3	60%	3	60%
10 th day	1	25%	2	40%	2	40%
17 th day	-	-	-	-	-	-
30 th day	-	-	-	-	-	-

Grade-2 scores of inflammation resolution to Grade-0						
1 st day	32	-	33	-	30	-
3 rd day	7	21.87%	4	12.12%	3	10%
10 th day	21	65.62%	23	69.69%	15	50%
17 th day	3	9.37%	5	15.15%	12	40%
30 th day	-	-	-	-	-	-

Grade-3 scores of inflammation resolution to Grade-0						
1 st day	4	-	2	-	5	-
3 rd day	+	Nil	+	Nil	+	Nil
10 th day	3	75%	1	50%	2	40%
17 th day	1	25%	1	50%	3	60%
30 th day	-	-	-	-	-	-

Grade 0=no cells, Grade 1=5to10 cells per field, Grade 2=10to20 cells per field, Grade 3=20to50 cells per field, Grade 4=50+ cells per field

Table 3: Anterior chamber flare count

(Based on Hogan's slit lamp grading of anterior chamber flare per field in a 1*1 slit beam under 16x magnification)

DAY	Grade-1 scores of inflammation resolution to Grade-0		Grade-1 scores of inflammation resolution to Grade-0		Grade-1 scores of inflammation resolution to Grade-0	
	Group A (Prednisolone acetate 1%)		Group 2 (Dexamethasone sodium phosphate 0.1%)		Group 3 (Betamethasone sodium phosphate 0.1%)	
	Total no. of patients	% of resolution	Total no. of patients	% of resolution	Total no. of patients	% of resolution
1 st day	3	-	4	-	3	-
3 rd day	3	100%	4	100%	3	100%
10 th day	-	-	-	-	-	-
17 th day	-	-	-	-	-	-
30 th day	-	-	-	-	-	-

Grade-2 scores of inflammation resolution to Grade-0

1 st day	34	-	30	-	31	-
3 rd day	15	44.11%	6	20%	6	19.35%
10 th day	15	44.11%	21	70%	22	70.96%
17 th day	3	8.8%	3	10%	3	9.67%
30 th day	-	-	-	-	-	-

Grade-3 scores of inflammation resolution to Grade-0

1 st day	3	-	6	-	6	-
3 rd day	+	Nil	+	Nil	+	Nil
10 th day	2	66.66%	3	50%	2	33.33%
17 th day	1	33.33%	3	50%	4	66.66%
30 th day	-	-	-	-	-	-

Grade 0=complete absence, Grade 1=faint flare(barely detectable),Grade 2=moderate flare(iris and lens details clear),Grade 3=marked flare(iris and lens details hazy),Grade 4=intense flare(fixed, coagulated aqueous humor with considerable fibrin) All these observations and results show that topical 1% Prednisolone acetate is clinically and statistically more effective in early post-operative period than 0.1% Dexamethasone sodium and Betamethasone sodium to control the inflammation in uneventful cataract surgeries.

Intra-ocular pressure at the end of 6 weeks: (measured using slit lamp mounted Goldmann's applanation tonometer)

I.O.P (mm of Hg)	Prednisolone acetate 1%		Dexamethasone sodium 0.1%		Betamethasone sodium 0.1%	
	Number	Percent	Number	Percent	Number	Percent
14mmHg	16	40%	6	15%	5	12.5%
16mmHg	20	50%	18	45%	14	35%
18mmHg	4	10%	10	25%	14	35%
20mmHg	-	-	6	15%	7	17.5%
22mmHg	-	-	-	-	-	-

In the present study for baseline IOP, rise in IOP is marginally high with Dexamethasone sodium (0.1%) and Betamethasone sodium (0.1%) when compared to Prednisolone acetate (1%). There is no clinically significant raise in IOP(>10mm of Hg) in all these groups post-operatively as period of instillation of steroid drops is short (45days) and dose was tapered over six weeks.

DISCUSSION

Acquired cataract is the leading cause of blindness worldwide⁶. Surgical treatment is the treatment of choice for those diagnosed with visually significant cataract. All though there are no standardized post-operative regimens for uncomplicated cataract surgery, the common or prevailing therapeutic regimen is a three drug combination of an anti-microbial, a topical steroid and a topical NSAID. Despite surgical advances, post cataract surgical inflammation is still a common cause of patient discomfort, delayed recovery and reduced visual outcome^{7,8}. Post cataract surgery inflammation presents as protein flare and inflammatory cells in the anterior chamber, hyperemia, miosis, corneal edema due to leukocyte migration, fibroblast proliferation and scar formation along with other local responses to the released pro-inflammatory cytokines^{9,10}. Ocular inflammation after cataract surgery is generally managed by topical anti-inflammatory drugs such as corticosteroids and/or non-steroidal anti-inflammatory drugs. Compared with Non-steroidal anti-inflammatory drugs(NSAIDs), corticosteroids have a wider range of activity in relieving inflammation. In this study the percentage of Male was

nearly 63% as compared to Female 37% in this study, the variation could be because of small group of patients taken up for study. Approximately Male to Female ratio is 2:1.

Grade-1 scores of inflammation showed resolution to **Grade-0** as follows:

In **Group A** treated with **Prednisolone acetate 1%** eyedrops

- Conjunctival erythema and ciliary flush in 50% of patients by day 3 and rest 50% by day 10
- Anterior chamber cells in 75% of patients by day 3 and 25% by day 10
- Anterior chamber flare in 100% of patients by day 3

In **Group B** treated with **Dexamethasone sodium phosphate 0.1%** eyedrops

- Conjunctival erythema and ciliary flush in 100% of patients by day 10.
- Anterior chamber cells in 60% of patients by day 3 and 40% of patients by day 10.
- Anterior chamber flare in 100% of patients by day 3

In **Group C** treated with **Betamethasone sodium phosphate 0.1%** eye drops.

- Conjunctiva erythema and ciliary flush in 100% of patients by day 10
- Anterior chamber cells in 60% of patients by day 3 and 40% of patients by day 10
- Anterior chamber flare in 100% patients by day 3

Grade-2 scores of post-operative inflammation showed resolution to **Grade-0** as follows.

In **Group A** treated with **Prednisolone acetate 1%** eye drops

- Conjunctival erythema and ciliary flush in 83.3% of patients by day 10 and 50% by day 17
- Anterior chamber cells in 21.87% of patients by day 3, 65.62% by day 10 and 9.37% by day 17
- Anterior chamber flare in 44.11% patients by day 3, 44.11% by day 10 and 8.8% by day 17

In **Group B** treated with **Dexamethasone Sodium phosphate 0.1%** eye drops.

- Conjunctival erythema and ciliary flush in 78.12% of patients by day 10 and 53.12% by day 17
- Anterior chamber cells in 12.12% patients by day 3, 69.69% by day 10 and 15.15% by day 17
- Anterior chamber flare in 20% of patients by day 3, 70% by day 10 and 10% by day 17

In **Group C** treated with **Betamethasone sodium phosphate 0.1%** eye drops

- Conjunctival erythema and ciliary flush in 75% of patients by day 10 and 25% by day 17
- Anterior chamber cells in 10% of patients by day 3, 50% by day 10 and 40% by day 17
- Anterior chamber flare in 19.35% of patients by day 3, 70.96% by day 10 and 9.67% by day 17

Grade-3 scores of inflammation showed resolution to **Grade-0** as follows

In **Group A** treated with **Prednisolone acetate 1%** eye drops

- Conjunctival erythema and ciliary flush in 66.66% of patients by day 10 and 33.33% by day 17
- Anterior chamber cells in 75% of patients by day 10 and 25% by day 17
- Anterior chamber flare in 66.66% of patients by day 10 and 33.33% by day 17

In **Group B** treated with **Dexamethasone sodium phosphate 0.1%** eye drops

- Conjunctival erythema and ciliary flush in 50% of patients by day 10 and 50% by day 17
- Anterior chamber cells in 50% of patients by day 10 and 50% by day 17

- Anterior chamber flare in 50% of patients by day 10 and 50% by day 17

In **Group C** treated with **Betamethasone sodium phosphate 0.1%** eye drops

- Conjunctival erythema and ciliary flush in 33.33% by day 10 and 66.66% by day 17
- Anterior chamber cells in 40% of patients by day 10 and 60% by day 17
- Anterior chamber flare in 33.33% of patients by day 10 and 66.66% by day 17.

There was 100% reduction in signs and symptoms of inflammation by the end of 2-3 weeks post-operatively in all the groups. Restoration of visual acuity was similar in all groups. Subjective and objective tolerance was good in all three groups. There was no case of clinical cystoid macular edema. No adverse effects were noted. Four patients had posterior capsular opacity. There was no rebound of signs and symptoms of inflammation after cessation of topical corticosteroid therapy. Prolonged use of topical steroids can produce elevated I.O.P in general population and especially in corticosteroid responders. In this study there was no significant elevation of I.O.P was seen (>10mm of Hg) most likely because of short duration of usage (45 days) and decrease in dose regimen from one drop 8 times daily till day 7, gradually tapered weekly followed by discontinuation after six weeks.

CONCLUSION

The major block in quick visual rehabilitation of patients after cataract surgery is post operative inflammation¹. Post operative inflammation has been accepted as a natural consequence of cataract surgery irrespective of surgical technique, type of surgery and instrumentation used¹. To limit post operative inflammation corticosteroids are used in routine prophylactically¹. All the three topical steroid preparations used in the treatment of postoperative inflammation are useful. As per the observation and analysis Prednisolone acetate 1% is more efficacious followed by Dexamethasone sodium 0.1% and Betamethasone sodium 0.1% eyedrops in descending order of efficacy. The more potency of Prednisolone acetate 1% suspension is because of its chemical structure being marketed as an acetate derivative which has biphasic insolubility with greater bioavailability in cornea and anterior chamber as compared to phosphate derivatives. Similar study was done at Saraswathi Institute of Medical Sciences (SIMS) Hapur (West Uttarpradesh)¹² stating Prednisolone acetate is clinically and statistically more effective than Dexamethasone sodium in early post-operative period to control the inflammation in uneventful small incision cataract surgery with posterior chamber intraocular lens implantation.

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