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Original Article

Ophthalmology Section

Evaluation of Intraocular Pressure Changes with Topical Dexamethasone 0.1%, Prednisolone 1% and Difluprednate 0.05% Postcataract Surgery- A Randomised Clinical Trial

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ABSTRACT

Introduction: Topical corticosteroids are most commonly used for the control of postoperative inflammation after cataract surgery. Topical steroids may cause increase in Intraocular Pressure (IOP) which, if left untreated may lead to progressive optic nerve damage and glaucomatous field defects.

Aim: To compare the ocular hypertensive response of three commonly used corticosteroids in an effort to generate evidence for managing postcataract surgery inflammation more effectively.

Materials and Methods: This randomised clinical trial was carried out for a period of one year from November 2018 to October 2019, among 150 patients undergoing cataract surgery. Patients were divided into three groups. Group A-50 patients received topical dexamethasone 0.1%, Group B-50 patients received topical prednisolone 1% and Group C-50 patients received topical difluprednate 0.05% four times a day for six weeks after cataract surgery. Postoperative IOP was recorded preoperatively, on first postoperative day and at the end of first week, third week and sixth week with non contact tonometer and statistical significance was assessed with the help of repeated measures mixed model Analysis of Variance (ANOVA).

Results: The mean age of the patients was 64.4±9.39 years, 48% were males and 52% patients were females. Mean IOP in the three drug groups was not statistically significant at 1st week, 3rd week and at 6th week after cataract surgery. Two patients belonging to difluprednate group at the end of 1st week and one patient at the end of 3rd week after cataract surgery developed significant rise in IOP (>31 mmHg).

Conclusion: It can be concluded that all three steroids were equally safe and did not cause any statistically significant rise in IOP over six-week postoperative period. However, higher values were noted in difluprednate group at the end of first and third week after cataract surgery.

Keywords: Ocular hypertension, Phacoemulsification, Steroids, Tonometry

INTRODUCTION

Cataract surgery is the most common ophthalmological surgical procedure performed on geriatric age group. Surgical trauma to the eye initiates an inflammatory reaction, which results in recruitment of neutrophils and macrophages to the site of trauma and release of arachidonic acid, which inturn causes production of prostaglandins [1].

Postoperative surgical inflammation after cataract surgery may be associated with complications like corneal oedema, increase in IOP, posterior synechiae formation, posterior capsular opacification and cystoid macular oedema [2]. Topical corticosteroids are most commonly used for the control of postoperative inflammation after cataract surgery [3]. Corticosteroids mediate their anti-inflammatory actions by acting on glucocorticoid receptors. At the histological level, corticosteroids inhibit capillary dilation, cellular infiltration, proliferation of fibroblasts, collagen deposition, and eventual scar formation. Corticosteroids stabilise intracellular and extracellular membranes and increase the synthesis of lipocortins. Lipocortins, inturn inhibit phospholipase A2, an enzyme which converts phospholipids to arachidonic acid, thereby, preventing the release of its metabolites, including prostaglandins [4].

Topical steroids can produce side-effects, like increase in IOP, cataract formation (in phakic eyes) and lowered resistance to infection [5-7]. Increase in IOP, if left untreated may lead to progressive optic nerve damage and glaucomatous field defects, leading to corticosteroid induced glaucoma. Corticosteroids increase IOP by several mechanisms [8]. Corticosteroids alter trabecular meshwork cell morphology by causing increase in nuclear size and Deoxyribonucleic Acid (DNA) content. FKBP51, FK506-binding immunophyllin, mediates nuclear transport of human glucocorticoid Receptor, Glucocorticoid receptor beta (GRbeta), causing increased glucocorticoid responsiveness. Corticosteroids stabilise the lysosomal membrane, which leads to accumulation of polymerised glycosaminoglycans, which become hydrated, increasing the resistance to aqueous outflow. Corticosteroids inhibit the phagocytic activity of trabecular meshwork endothelial cells, allowing for the debris to accumulate in meshwork and act as a barrier to outflow of aqueous humour. Myocillin gene, initially referred to as trabecular meshwork inducible- glucocorticoid response or Trabecular Meshwork Inducible Glucocorticoid Response (TIGR) gene product, a 55kDa protein, is induced after exposure to corticosteroids. This gene causes decreased aqueous humour outflow and increase in IOP [8].

Dexamethasone, prednisolone, and flourometholone are early generation corticosteroids and rimexolone, difluprednate, and loteprednol etabonate are relatively newer corticosteroids used for control of postoperative inflammation. Dexamethasone is available as phosphate derivative in the form of a 0.1% ophthalmic suspension or solution. Prednisolone is a synthetic analog of hydrocortisone. It is formulated as an acetate and a phosphate [9]. Difluprednate is a prednisolone acetate derivative that is augmented by two fluorinations at carbons 6 and 9, a butyrate group at carbon 17 and an acetic acid group at carbon 21 [9].

Keeping in view the IOP raising potential of various steroids which are routinely used for the management of postcataract surgery inflammation, this study was conceptualised to compare the ocular

hypertensive response to three commonly used corticosteroids in an effort to generate evidence for managing postcataract surgery inflammation more effectively.

MATERIALS AND METHODS

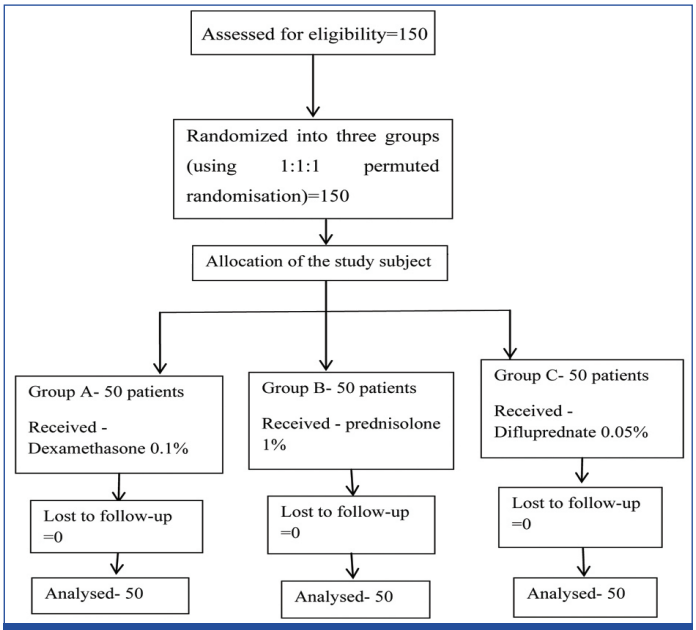
The present randomised clinical trial was conducted for a period of one year from November 2018 to October 2019 after obtaining ethical clearance from Institutional Ethics Committee vide letter number IEC/GMC/2019/800 in the Ophthalmology Department of Government Medical College, Jammu and Kashmir, India.

This study included 150 patients undergoing cataract surgery with Posterior Chamber Intraocular Lens Implantation (PCIOL). A written informed consent was taken from all the study participants after explaining the purpose of the study.

Inclusion criteria: Patients above 40 years of age, diagnosed to have senile cataract and having cortical cataract and nuclear sclerosis grade 1, 2, 3 cataract on Lens Opacities Classification System III (LOCS III) [10] were included in the study.

Exclusion criteria: Patients below 40 years of age and who had glaucoma, patients with complicated cataracts (traumatic cataracts, radiation induced cataracts, ubluxated lens) and who had grade 4 and 5 nuclear sclerosis on Lens Opacities Classification System III (LOCS III) were excluded. Patients with pseudoexfoliation syndrome and lens related glaucoma were excluded. Who had pigment dispersion syndrome, diabetes mellitus, myopia (>5D) and patients already on corticosteroid treatment were excluded. Patients with fundus pathologies having influence on IOP like central retinal artery occlusion, central retinal vein occlusion, branch retinal artery occlusion, branch retinal vein occlusion, retinal detachment and who were developing intraoperative complications during cataract surgery were also excluded.

Sample size calculation: A sample size of 150 was calculated using effect size of 0.6 and these patients were divided into three groups (A, B and C) of 50 patients each using 1:1:1 block permuted randomisation using online software sealed envelope [Table/Fig-1].



[Table/Fig-1]: CONSORT flowchart.

Detailed history regarding ocular and systemic diseases were noted from each patient. IOP was recorded with SHIN NIPPON Non Contact Tonometer (NCT)-200 by single investigator at the same time of the day, in the morning.

All patients underwent cataract surgery with PCIOL implantation. All the surgeries were performed by a single surgeon. All the patients were included only once in the study. IOP was recorded on first day after cataract surgery before installation of any drug by a single investigator at same time of the day by NCT. Group A patients received topical dexamethasone 0.1%, Group B patients received topical prednisolone 1% and Group C patients received topical difluprednate 0.05%. Each drug was given four times a day for six weeks after cataract surgery. IOP was recorded by NCT, preoperatively, postoperatively- on first postoperative day and then at the end of 1st week, 3rd week and 6th week. Any patient, who developed rise in IOP >21 mmHg after two readings taken 24 hours apart was started on anti-glaucoma medications and the medications continued till IOP was <20 mmHg on two readings taken 24 hours apart after stopping the drugs. Patients who developed rise in IOP in response to topical steroids continued follow-up for six weeks.

STATISTICAL ANALYSIS

All the data were entered into Microsoft Excel and analysed with the help of IBM Statistical Package for the Social Sciences (SPSS) version 22.0. Mean IOP (±SD) was estimated for all the three groups and statistical significance assessed with the help of repeated measures mixed model Analysis of Variance (ANOVA). Post-hoc comparisons were adjusted by the Bonferroni method. A p-value <0.05 was considered as statistically significant. All p-values used were two-tailed.

RESULTS

The mean age in this study was 64.4±9.39 years. Majority of the patients belonged to the age group of 61-70 years. As seen in [Table/Fig-2], out of 150 patients, 52% were females and 48% patients were males. The right eye was operated in majority of patients i.e., 52.7% and left eye in 47.3%.

Variables		Group A N (%)	Group B N (%)	Group C N (%)	Total N (%)
Total (n)		50	50	50	150 (100%)
Age in years (Mean±SD)		63.5±8.4	66.3±9.76	63.4±9.84	64.4±9.39
Gender	Males	24 (48%)	28 (56%)	20 (40%)	72 (48%)
	Females	26 (52%)	22 (44%)	30 (60%)	78 (52%)
Laterality	Right eye	30 (60%)	26 (52%)	23 (46%)	79 (52.7%)
	Left eye	20 (40%)	24 (48%)	27 (54%)	71 (47.3%)

[Table/Fig-2]: Demographic data of patients in different study groups.

Mean IOP readings with three drugs over a six-week postoperative period is shown in [Table/Fig-3]. Mean IOP was higher in difluprednate group at 1st, 3rd and 6th postoperative week which was not statistically significant.

IOP (mmHg)	Group A (Mean±SD)	Group B (Mean±SD)	Group C (Mean±SD)	Total (Mean±SD)	p-value
Preoperative	15.71±2.65	15.96±2.71	16.11±2.56	15.93±2.63	0.752
Postoperative at 1st day	17.49±5.29	17.31±6.61	17.24±5.65	17.35±5.87	0.977
Postoperative at 1st week	15.74±3.61	14.96±3.38	16.58±5.36	15.76±4.23	0.158
Postoperative at 3rd week	15.79±2.77	15.42±2.66	16.64±4.10	15.95±3.26	0.163
Postoperative at 6th week	16.03±3.12	15.59±3.19	16.96±3.00	16.19±3.14	0.08

[Table/Fig-3]: Comparative effects of drugs on IOP (mmHg) over a six week follow-up period after cataract surgery, Intraocular Pressure (IOP).
Test used: Mixed methods analysis of variance (ANOVA)

Bonferroni post-hoc tests comparing different time intervals revealed a significant difference in the mean IOP between that measured preoperatively and at first day of surgery (p=0.03) and also between first postoperative day and first week after cataract surgery (p=0.026) in all the three groups. However, the mean IOP in three different groups was not statistically significant at 1st week, 3rd week and at 6th week after cataract surgery [Table/Fig-4].

Time (I)	Time (J)	Mean difference (I-J)	Std. error	p-value
Preoperative IOP	IOP on 1st postoperative day	-1.419	0.478	0.035*
	IOP after 1st week	0.168	0.314	1
	IOP after 3rd week	-0.023	0.256	1
	IOP after 6th week	-0.263	0.229	1
IOP on 1st postoperative day	Preoperative IOP	1.419	0.478	0.035*
	IOP after 1st week	1.587	0.518	0.026*
	IOP after 3rd week	1.395	0.496	0.056
	IOP after 6th week	1.156	0.486	0.186
IOP after 1st week	Preoperative IOP	-0.168	0.314	1
	IOP on 1st postoperative day	-1.587	0.518	0.026*
	IOP after 3rd week	-0.191	0.307	1
	IOP after 6th week	-0.431	0.319	1
IOP after 3rd week	Preoperative IOP	0.023	0.256	1
	IOP on 1st postoperative day	-1.395	0.496	0.056
	IOP after 1st week	0.191	0.307	1
	IOP after 6th week	-0.239	0.242	1
IOP after 6th week	Preoperative IOP	0.263	0.229	1
	IOP on 1st postoperative day	-1.156	0.486	0.186
	IOP after 1st week	0.431	0.319	1
	IOP after 3rd week	0.239	0.242	1

[Table/Fig-4]: Bonferroni Post-Hoc tests comparing IOP measured at different times, Intraocular Pressure (IOP).
*p-value is considered statstically significant

The results of a mixed model repeated measures ANOVA using type of drug as between subjects' factor and time as within subjects' factor, and IOP as dependent variable showed that the IOP was significantly affected by time, F (2.4, 353)=5.65, p=0.002. However, Eta^2 effect size (η^2=0.037) indicated that only 3.7% of the variance was accounted for by time [Table/Fig-5]. As evident in [Table/Fig-6], on the first day after cataract surgery, 7 patients had IOP >31 mmHg. At the end of first week after cataract surgery, two patients developed IOP >31 mmHg. Both patients belonged to difluprednate group, whereas eight patients had IOP between 21-30 mmHg. Out of these, five patients belonged to dexamethasone group, two patients belonged to prednisolone group and one patient to difluprednate group. At the end of 3rd week, only one patient belonging to difluprednate group had IOP >31 mmHg. Four patients had IOP between 21-30 mmHg. Out of these, one patient belonged to dexamethasone group, two patients belonged to prednisolone group and one patient to difluprednate group.

At the end of 6th week, no patient had IOP >31 mmHg. Twelve patients had IOP between 21-30 mmHg. Six patients belonged to dexamethasone group, two patients belonged to prednisolone group and four patients belonged to difluprednate group [Table/Fig-6]. There were no cases of severe uveitis in postoperative six-week period requiring more frequent use of topical steroids or oral and injectable steroids.

Source		Type III Sum of squares	df	Mean square	F	p-value	Partial Eta squared
Time	Sphericity assumed	245.716	4	61.429	5.653	0.001	0.037
	Greenhouse geisser	245.716	2.403	102.250	5.653	0.002	0.037
	Huynh-Feldt	245.716	2.479	99.117	5.653	0.002	0.037
	Lower bound	245.716	1.000	245.716	5.653	0.019	0.037
Time-drug	Sphericity assumed	64.912	8	8.114	0.747	0.650	0.010
	Greenhouse geisser	64.912	4.806	13.506	0.747	0.584	0.010
	Huynh-Feldt	64.912	4.958	13.092	0.747	0.588	0.010
	Lower bound	64.912	2.000	32.456	0.747	0.476	0.010
Error (time)	Sphericity assumed	6389.204	588	10.866			
	Greenhouse geisser	6389.204	353.255	18.087			
	Huynh-Feldt	6389.204	364.422	17.532			
	Lower bound	6389.204	147.000	43.464			

[Table/Fig-5]: Results of Mixed Model Repeated Measures ANOVA.
df: Degree of freedom; p-value <0.05 considered significant

DISCUSSION

The mean preoperative IOP in the present study was 15.93±2.63 mmHg, with mean preoperative IOP in dexamethasone group being 15.71±2.65 mmHg, 15.96±2.71 mmHg in prednisolone group and 16.11±2.56 mmHg in difluprednate group. This correlates with the studies of Kaur R et al., with mean preoperative IOP in prednisolone group being 15.66±1.91 mmHg [11]. Reddy R and Patil A noted mean preoperative IOP of 15.66±1.96 mmHg in Difluprednate group and 15.57±1.96 mmHg in dexamethasone group [12]. Bartin M et al., noted mean IOP of 14.93±2.23 mmHg in difluprednate group and 15.38±2.23 mmHg in prednisolone group [13].

The mean postoperative IOP at first day after cataract surgery was 17.35±5.87 mmHg, with mean IOP of 17.49±5.29 mmHg in the dexamethasone group, 17.31±6.69 mmHg in the prednisolone group and 17.24±5.65 mmHg in the difluprednate group (p-value=0.977, f-value=0.023). Similar findings were noted by Kaur R et al., with mean IOP of 17.93±2.31 mmHg in the prednisolone group and Saari KM et al., with mean IOP of 16.8±6.7 mmHg in the dexamethasone phosphate group [11,14]. Rehman M et al., noted mean IOP of 15.93±0.58 mmHg in the dexamethasone group on the first postoperative day [15]. In a study by Kamal DS et al., 12% patients developed an IOP >25 mmHg on the first day after cataract surgery corroborating well with the present study [16]. There was statistically significant difference in mean preoperative IOP and mean IOP on the first day after cataract surgery with p-value of 0.035. This postoperative rise in IOP on the first day after the cataract surgery is mainly due to the postoperative inflammation and retained visco-elastic material.

IOP in mmHg	IOP at 1st postoperative day N (%)			IOP at 1st postoperative week N (%)			IOP at 3rd postoperative week N (%)			IOP at 6th postoperative week N (%)		
	A	B	C	A	B	C	A	B	C	A	B	C
<21mmHg	42 (84%)	43 (86%)	44 (88%	45 (90%)	48 (96%)	47(94%)	49 (98%)	48 (96%)	47 (94%)	44 (88%)	48 (96%)	46 (92%)
21-30 mmHg	6 (12%)	4 (8%)	4 (8%)	5 (10%)	2 (4%)	1(2%)	1 (2%)	2 (4%)	1 (2%)	6 (12%)	2 (4%)	4 (8%)
>31 mmHg	2 (4%)	3 (6%)	2 (4%)	0 (0)	0 (0)	2 (4%)	0 (0)	0 (0)	1 (2%)	0 (0)	0 (0)	0 (0)
Total	50	50	50	50	50	50	50	50	50	50	50	50

[Table/Fig-6]: IOP readings with three drugs over a 6 week period, Intraocular Pressure (IOP).
Group A- Dexamethasone, Group B- Prednisolone, Group C- Difluprednate

The mean IOP at the end of first week was 15.76±4.23 mmHg, with mean IOP of 15.74±3.61 mmHg in dexamethasone group, 14.96±3.38 mmHg in the prednisolone group and 16.58±5.36 mmHg in difluprednate group (p-value=0.158, f-value=1.866). El Saman IS et al., noted mean IOP of 15.8±4.5 mmHg in prednisolone group and 16.5±5.5 mmHg in the difluprednate group at the end of first week, with no significant difference in the mean IOP between the groups [17]. Kusne Y et al., noted a mean IOP of 15.6±4.3 mmHg in the prednisolone group and 16.2±4.2 mmHg in the difluprednate group [18]. Rehman M et al., noted mean IOP of 15.89±0.82 mmHg with dexamethasone [15]. Saari KM et al., recorded mean IOP of 16.5±8.1 mmHg in the dexamethasone phosphate group [14]. There was statistically significant difference between mean IOP at the end of 1st week after cataract surgery and mean IOP at the first day after cataract surgery (p-value=0.026), with mean IOP being high at the first day after cataract surgery. This decrease in mean IOP in all the three drug groups at the end of first week is due to resolution of inflammation by the topical steroids.

The mean IOP at the end of 3rd week was 15.95±3.26 mmHg, with mean IOP of 15.79±2.77 mmHg in the dexamethasone group, 15.43±2.66 mmHg in the Prednisolone group and 16.64±4.11 mmHg in the Difluprednate group (p-value=0.163, f-value=1.837). El Saman IS et al., noted mean IOP of 14.9±4.8 mmHg in the prednisolone group and 15.1±5.0 mmHg in the difluprednate group and Tijunelis MA et al., noted a mean IOP of 14.3±3.4 mmHg in the prednisolone group and 14.5±3.6 mmHg in the difluprednate group [17,19]. Reddy R and Patil A noted IOP of 16.98±1.58 mmHg in the difluprednate group at the end of 1 month similar to this study but mean IOP in dexamethasone group was 17.06±1.53 mmHg, which was different from this study [12].

The mean IOP at the end of 6th week was 16.19±3.14 mmHg, with mean IOP of 16.03±3.12 mmHg in dexamethasone group, 15.59±3.19 mmHg in prednisolone group and 16.96±3.00 mmHg in the difluprednate group (p-value=0.08, f-value=2.53). El Saman IS et al., noted a mean IOP of 14.6±3.9 mmHg in the dexamethasone group and 14.9±4.4 mmHg in the difluprednate group and Bartin M et al., noted mean IOP of 15.71±2.2 mmHg in the difluprednate group and 15.95±2.13 mmHg in the prednisolone group, Whereas, Gupta V and Gupta D noted mean IOP of 18.62±2.36 mmHg in prednisolone group at 6th week and Kaur R et al., noted mean IOP of 25.66±2. Twelve mmHg in prednisolone group at the end of one month [11,13,17,20].

During the six week course of topical corticosteroid therapy, Smith S et al., noted an IOP rise of >21 mmHg in three patients (3.7%) on difluprednate therapy [21]. Sahasrabudhe VM and Kamble NR noted an IOP >21 mmHg in two patients (3.57%) on difluprednate therapy [22]. Sowbhagya HN et al., recorded IOP >21 mmHg in five patients, out of which three patients had risen of IOP after 1st week [23]. El Saman IS et al., noted IOP >21 mmHg in five patients (2.9%) on difluprednate, out of which two had IOP >31 mmHg [17]. Sood P and Sood P had three patients (3.7%) in difluprednate group, who developed IOP >21 mmHg [24]. All these findings, are in tune with the present study, in which three patients developed IOP >31 mmHg. Reddy R and Patil A had no patients showing IOP >21 mmHg over a period of one month in both dexamethasone and difluprednate groups [12].

Limitation(s)

Follow-up period was short in order to evaluate the long-term effects of steroids on IOP as drug effects were observed for six weeks only and grading of inflammation as measured by cells and flare was not done.

CONCLUSION(S)

In the present study, all three steroids were equally safe and did not cause any statistically significant rise in IOP over six-week postoperative period. Hence, any of the three drugs can be safely used to manage postoperative inflammation in patients undergoing cataract surgery. However, caution is advised with use of Difluprednate 0.05%, as higher IOP (clinically significant) values were noted in two patients with it at the end of 1st week and in one patient at the end of 3rd week after cataract surgery.

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