Section: Ophthalmology

Original Research Article

COMPARATIVE STUDY OF PERCENTAGE OF RAISED INTRAOCULAR PRESSURE BETWEEN POST-CATARACT SURGERY PATIENTS ON DEXAMETHASONE AND PREDNISOLONE AT A TERTIARY CARE CENTRE

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Abstract

Background: The World Health Organization (WHO) estimates that nearly 18 million people are bilaterally blind from cataracts worldwide, representing almost half of all global cases of blindness. This is to study, know and compare percentage of raised Intraocular Pressure in patients on Dexamethasone and Prednisolone following Cataract surgery at tertiary care centre. **Materials and Methods:** The present study was conducted among all the cases undergoing Cataract surgery in age group 35-75 both age and sex matched and follow up of uncomplicated Cataract Surgeries were enrolled at Department of Ophthalmology in a Medical college and tertiary care centre. **Result:** The mean IOP overall in Group A was 14.28 ± 2.48 and Group B was 14.68 ± 2.81 mm of Hg with no significant difference. The mean IOP operated by SICS in Group A and Group B was 14.35 ± 2.56 and 14.72 ± 2.72 mm of Hg respectively with no statistical significance (P>0.05). The mean IOP operated by Phacoemulsification in Group A and Group B was 14.23 ± 2.42 and 14.64 ± 2.51 respectively with no statistical significance. (P>0.05) The comparison of mean IOP at different intervals showed that on POD 5 mean IOP in Group A (21.11 ± 2.93) was less compared to Group B (22.29 ± 2.49) with no statistically significant difference. (p>0.05) At POD 12, 19, 26 and 42 Group A had slightly less IOP compared to Group B with no statistically significant difference (p>0.05). **Conclusion:** Dexamethasone is equally efficacious to Prednisolone in managing post-cataract surgery ocular inflammation. Prednisolone provides superior analgesia and early clearance of AC reaction, which may further aid in early visual rehabilitation and recovery.

INTRODUCTION

Steroids along with antibiotics are most commonly instilled in post-cataract surgery patients now a day. Corticosteroids are 21-C compounds secreted by adrenal cortex. They have potent anti-allergic, anti-fibrotic, anti-inflammatory action. Corticosteroids reduce inflammation by reduction of leucocytic and plasma exudation, maintenance of cellular membrane integrity with inhibition of tissue swelling, inhibition of lysosome release from Granulocytes, increased stabilization of intracellular lysosomal membrane and suppression of circulating lymphocytes.[1]

Steroids are well-known to induce ocular hypertension when administered with topical, periocular, and even general systemic or inhalational routes Some people are well- known to experience a high degree of IOP elevation with low doses or short durations of treatment with topical corticosteroids.[2] Around one third of individuals experience moderate increase in IOP following topical steroid use. But 5-6% of normal population will develop an increase in IOP after 4 weeks of topical steroid therapy.[3,4] Thus 5% of the overall general population is taken into consideration to be “high steroid responder”, i.e., may develop steroid induced rise in IOP when steroids are administered. Topical corticosteroids are usually used following cataract surgery to decrease the inflammation and improve the visual outcomes. Steroids inhibit the production of leukotrienes & prostaglandins post-surgery, thereby reducing ocular inflammation. Though steroids facilitate in decreasing inflammation by speeding up recovery

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and improving visual outcomes, they are well-known to have important side effects, whether topically or systemically administered.[5]

A steroid responder is someone who experiences an increase in intraocular pressure (IOP) after taking steroid medication. This phenomenon is known as "steroid response" and is recognized by most ophthalmologists. In literature, a steroid responder is defined as someone who has an IOP above 21–24 mmHg, or an increase of more than 5–10 mmHg from baseline. The normal population can be divided into three groups based on their steroid response:[6]

- High responders: 5% of the population, who experience a marked elevation of IOP by more than 15 mmHg
- Moderate responders: 30% of the population, who experience a moderate elevation of IOP by 6–15 mmHg
- Non-responders: 65% of the population, who experience an elevation of up to 5 mmHg, which is considered irrelevant

The efficacy of topical corticosteroids as ocular anti-inflammatory drugs following cataract surgery is well-documented. They also help to prevent a range of complications associated with post-operative ocular inflammation, as well as corneal oedema & cystoid macular oedema.[7]

Considering the inclination of steroids to provoke an increase in intraocular pressure (IOP), vigilant monitoring of IOP changes is imperative for early identification and prompt intervention. Presently, there exists limited comparative data on the diverse effects of different topical steroids on IOP and the occurrence of clinically significant IOP elevations.

Therefore, the present study was done to compare percentage of raised intraocular pressure in patients on Dexamethasone and Prednisolone following cataract surgery.

MATERIALS AND METHODS

The present hospital based longitudinal analytical study was conducted among all the cases undergoing Cataract surgery in age group 35-75 both age and sex matched and follow up of uncomplicated Cataract Surgeries were enrolled at Department of Ophthalmology in a Medical college and tertiary care centre. Duration of study period was August 2022 to August 2024. The study was approved by the Ethical Committee of the institute.

Sample Size:

A sample size of 950 patients attending OPD with cataract undergoing uncomplicated cataract surgery were enrolled for the study.

Sample Size Estimation;

Sample size was calculated with the following assumptions. Based on the pilot study, the incidence of cataract surgery was taken as 10%.[8] Sample size was estimated at 5% level of significance with an allowable error of 5%, using the following formula:

$$n = \frac{Z(1-\frac{\alpha}{2})2pq}{L^2}$$

So,

$$n = \frac{1.96*1.96\ (0.10)(0.90)}{(0.02)^2} = 864.36$$

Considering a loss to follow-up of 10%, N=864 +86=950

Hence, a minimum sample size of approximately 950 cases during study period was selected and included in present study.

Inclusion Criteria:

- Patients of age group 35-75 years undergoing routine uncomplicated cataract surgery who either received Prednisolone(1%w/v) or Dexamethasone (0.05%w/v) for a period of 6 weeks post-operatively with cells <2+ in Anterior chamber on slit lamp examination.

Exclusion Criteria:

- Complicated cataract
- Patients who had not given consent
- Pediatric cataract
- Traumatic cataract
- History of previous Ocular surgery
- Cataract surgery with intra-operative complication
- Post-operative intense inflammation or infection
- Patient on systemic steroid for systemic illness
- Patient receiving intravitreal or subtenon steroid
- Patient on pre-operative steroid treatment (topical/systemic)
- Patient on systemic steroid treatment post-operatively
- Any other condition requiring prolonged steroid use (>6wks)
- Known patient of glaucoma already on antiglaucoma medication
- Pigment dispersion syndrome
- Pseudoexfoliation syndrome
- Connective tissue disorder and type I Diabetes Mellitus.

Methodology of Study:

- Detailed history was taken as Demographic details, Past medical or surgical history, previous ocular history.
- Examination done including general physical examination.
- Patients were screened pre-operatively and baseline Intraocular Pressure was established by taking average of 3 Intraocular Pressure readings by Perkins Tonometer.
- In post-operative period patients were divided into two groups:
- Group-A: Patients prescribed Prednisolone(1%w/v) (patients without any complication Anterior Chamber- cells <+2)
- Group-B: Patients prescribed Dexamethasone (0.05%w/v) (patients without any complication Anterior Chamber- cells <+2)
- Patients will be matched for age, sex, clinical profile and baseline Intraocular Pressure reading.

Pre-operative ocular assessment as:

1. Corrected and Uncorrected Visual Acuity

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2. Anterior Segment Evaluation
3. Fundus Examination
4. Slit Lamp Examination for screening of validity according to inclusion criteria
5. Follow Up of patients taken on post-operative day 05 and then weekly as on post-operative day 12, post-operative day 19, Post-operative day 26 and lastly on post-operative day 42 when Topical steroids were discontinued.

Grading of Intraocular Pressure rise:

1. Mild (>6 mmHg)
2. Moderate (6-15 mmHg rise from baseline)
3. Severe (>15 mmHg)

INVESTIGATIONS: BSL-R, ECG, HIV, HBsAg, Xylocaine Sensitivity Testing, Urine Routine

Each patient under study was operated with Small Incision Cataract Surgery or Phacoemulsification and was given Post-operative Steroids

Surgical Technique

SICS

Phacoemulsification

Post-Operative Assessment:

- Patient was monitored from post-operative day 5 and then followed up weekly until day 42.
- Separate record was kept for Dexamethasone and Prednisolone as well as those operated by SICS and Phacoemulsification.
- Patients were screened for degree of rise in Intraocular Pressure and change in Intraocular Pressure rise over period of 6 weeks
- At each visit preliminary examination like visual acuity, slit lamp examination, intraocular pressure was done.

Statistical Analysis: The data was filled in excel sheet and the results were described as frequency and proportion. Results are presented as mean, standard deviation and range values for continuous data, number and percentages for categorical data. Intergroup comparisons are done by unpaired t test and intra group comparisons by paired t test. p value of 0.05 or less was considered for statistically significance. The comparison was done by chi-square test with significance at $p < 0.05$.

RESULTS

The mean age in Group A was 65.23 ± 6.49 years and Group B was 64.07 ± 8.73 years. There was no significant difference in age distribution in two groups (p>0.05).

The majority of patients were males in Group A (56%) and Group B (53.05%). The male: female ration in Group A and Group was 1.27:1 and 1.13:1 respectively. There was no significant difference in gender distribution in two groups. (p>0.05).

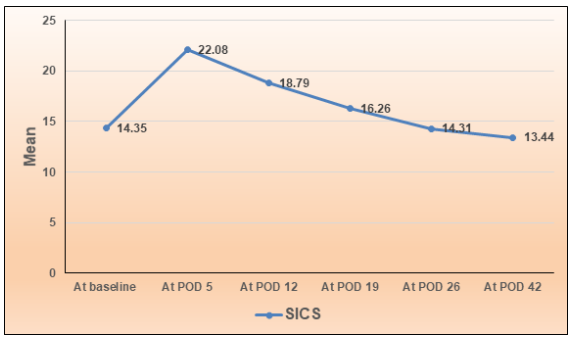

Figure 1: Mean IOP among Group A (Prednisolone) operated with SISC at different intervals

The mean IOP in Group A operated by Phacoemulsification on POD 5, POD 12, POD 19, POD 26 and POD 42 was 21.05 ± 2.18, 18.27 ± 2.29, 16.43 ± 2.43, 14.09 ± 2.78 and 13.06 ± 2.13 mm of Hg respectively with statistically significant difference. (P<0.0001) This shows maximum IOP was on day 5 post-operative and decreases thereafter till day 42.

The mean IOP in Group B on POD 5, POD 12, POD 19, POD 26 and POD 42 was 22.29 ± 2.49, 19.03 ± 2.52, 17.10 ± 2.41, 14.87 ± 2.32 and 13.79 ±2.41 mm of Hg respectively with statistically significant difference. (P<0.0001) This shows maximum IOP was on day 5 post-operative and decreases thereafter till day 42.

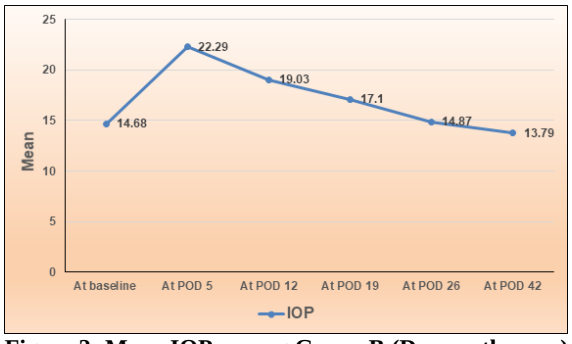

Figure 2: Mean IOP among Group B (Dexamethasone) at different intervals:

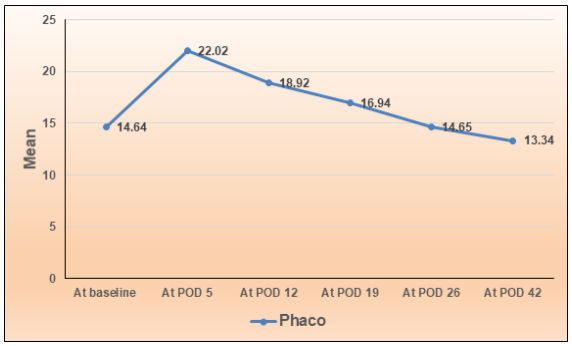

Figure 3: Mean IOP among Group B (Dexamethasone) operated with Phacoemulsification at different intervals:

Table 1: Type of surgery distribution among both groups:

Type of surgery	Group A (Prednisolone)	Group B (Dexamethasone)	Total
SICS	343 (72.21%)	321 (67.57%)	664 (69.89%)
Phacoemulsification	132 (27.79%)	154 (32.43%)	286 (30.11%)

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Total	475 (100%)	475 (100%)	950 (100%)
P value	X2=1.28; DF=3 P=0.12 (NS)		

The majority of patients operated by SICS in Group A (72.21%) and Group B (67.57%). Phacoemulsification was done in 27.79% and 32.43% in Group A and Group B respectively. There was no significant difference in type of surgery distribution in two groups. (p>0.05).

Table 2: Baseline IOP among both groups:

IOP	Group A (Prednisolone)	Group B (Dexamethasone)	P value
SICS	14.35 ± 2.56	14.72 ± 2.72	0.83
Phacoemulsification	14.23 ± 2.42	14.64 ± 2.51	0.79
Overall	14.28 ± 2.48	14.68 ± 2.81	0.77

The mean IOP overall in Group A was 14.28 ± 2.48 and Group B was 14.68 ± 2.81 mm of Hg. There was no significant difference in IOP in two groups. (p>0.05)

The mean IOP operated by SICS in Group A and Group B was 14.35 ± 2.56 and 14.72 ± 2.72 mm of Hg respectively with no statistical significance. (P>0.05)

The mean IOP operated by Phacoemulsification in Group A and Group B was 14.23 ± 2.42 and 14.64 ± 2.51 respectively with no statistical significance. (P>0.05).

Table 3: Mean IOP among Group A (Prednisolone) at different intervals:

IOP	Mean	P value
At baseline	**14.28 ± 2.48**	**<0.0001 (S)**
At POD 5	**21.11 ± 2.93**	
At POD 12	**18.31 ± 2.32**	
At POD 19	**16.52 ± 2.18**	
At POD 26	14.22 ± 2.55	
At POD 42	13.21 ± 2.03	

The mean IOP in Group A on POD 5, POD 12, POD 19, POD 26 and POD 42 was 21.11 ± 2.93, 18.31 ± 2.32, 16.52 ± 2.18, 14.22 ± 2.55 and 13.21 ± 2.03 mm of Hg respectively with statistically significant difference. (P<0.0001). This shows maximum IOP was on day 5 post-operative and decreases thereafter till day 42. The mean IOP in Group A operated by SISC on POD 5, POD 12, POD 19, POD 26 and POD 42 was 22.08 ± 2.81, 18.79 ± 2.48, 16.26 ± 2.43, 14.31 ± 2.76 and 13.44 ±2.01 mm of Hg respectively with statistically significant difference. (P<0.0001) This shows maximum IOP was on day 5 post-operative and decreases thereafter till day 42.

Table 4: Mean IOP among Group B (Dexamethasone) operated with SISC at different intervals:

IOP	SICS	P value
At baseline	14.72 ± 2.72	<0.0001 (S)
At POD 5	22.79 ± 3.02	
At POD 12	19.31 ± 2.77	
At POD 19	17.54 ± 2.52	
At POD 26	15.04 ± 2.56	
At POD 42	14.12 ± 2.31	

The mean IOP in Group B operated by SISC on POD 5, POD 12, POD 19, POD 26 and POD 42 was 22.79 ± 3.02, 19.31 ± 2.77, 17.54 ± 2.52, 15.04 ± 2.56 and 14.12 ± 2.31 mm of Hg respectively with statistically significant difference. (P<0.0001) This shows maximum IOP was on day 5 post-operative and decreases thereafter till day 42.

The mean IOP in Group B operated by Phacoemulsification on POD 5, POD 12, POD 19, POD 26 and POD 42 was 22.02 ± 2.21, 18.92 ± 2.43, 16.94 ± 2.63, 14.65 ± 2.81 and 13.34 ± 2.21 mm of Hg respectively with statistically significant difference. (P<0.0001) This shows maximum IOP was on day 5 post-operative and decreases thereafter till day 42.

Table 5: Comparison of mean IOP among two groups at different intervals:

IOP	Group A (Prednisolone)	Group B (Dexamethasone)	P value
At baseline	14.28 ± 2.48	14.68 ± 2.81	0.16 (NS)
At POD 5	21.11 ± 2.93	22.29 ± 2.49	0.32 (NS)
At POD 12	18.31 ± 2.32	19.03 ± 2.52	0.21 (NS)
At POD 19	16.52 ± 2.18	17.10 ± 2.41	0.24 (NS)
At POD 26	14.22 ± 2.55	14.87 ± 2.32	0.21 (NS)
At POD 42	13.21 ± 2.03	13.79 ± 2.41	0.33 (NS)

The comparison of mean IOP at different intervals showed that on POD 5 mean IOP in Group A (21.11

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± 2.93) was less compared to Group B (22.29 ± 2.49) with no statistically significant difference. (p>0.05)

Similarly, on POD 12, 19, 26 and 42 Group A had slightly less IOP compared to Group B with no statistically significant difference. (p>0.05).

Table 6: Comparison of mean IOP by SICS among two groups at different intervals:

IOP	Group A (Prednisolone)	Group B (Dexamethasone)	P value
At baseline	14.35 ± 2.56	14.72 ± 2.72	0.22 (NS)
At POD 5	22.08 ± 2.81	22.79 ± 3.02	0.18 (NS)
At POD 12	18.79 ± 2.48	19.31 ± 2.77	0.34 (NS)
At POD 19	16.26 ± 2.43	17.54 ± 2.52	0.28 (NS)
At POD 26	14.31 ± 2.76	15.04 ± 2.56	0.18 (NS)
At POD 42	13.44 ± 2.01	14.12 ± 2.31	0.17 (NS)

The comparison of mean IOP operated by SICS at different intervals showed that on POD 5 mean IOP in Group A (22.08 ± 2.81) was less compared to Group B (22.79 ± 3.02) with no statistically significant difference. (p>0.05). Similarly, on POD 12, 19, 26 and 42 Group A had slightly less IOP compared to Group B with no statistically significant difference. (p>0.05).

Table 7: Comparison of mean IOP by Phacoemulsification among two groups at different intervals:

IOP	Group A (Prednisolone)	Group B (Dexamethasone)	P value
At baseline	14.23 ± 2.42	14.64 ± 2.51	0.10 (NS)
At POD 5	21.05 ± 2.18	22.02 ± 2.21	0.06 (NS)
At POD 12	18.27 ± 2.29	18.92 ± 2.43	0.12 (NS)
At POD 19	16.43 ± 2.43	16.94 ± 2.63	0.18 (NS)
At POD 26	14.09 ± 2.78	14.65 ± 2.81	0.19 (NS)
At POD 42	13.06 ± 2.13	13.34 ± 2.21	0.17 (NS)

The comparison of mean IOP operated by Phacoemulsification at different intervals showed that on POD 5 mean IOP in Group A (21.05 ± 2.18) was less compared to Group B (22.02 ± 2.21) with no statistically significant difference. (p>0.05), Similarly, on POD 12, 19, 26 and 42 Group A had slightly less IOP compared to Group B with no statistically significant difference. (p>0.05)

DISCUSSION

In the present study, mean age in Group A was 65.23 ± 6.49 years and Group B was 64.07 ± 8.73 years. There was no significant difference in age distribution in two groups. (p>0.05)

Kavitha Mohankumar et al,[9] in a study on prevalence of raised IOP in post cataract patients following topical steroid usage observed the mean age for 500 study sample size was 61.37 ± 7.22 years. This finding was similar to present study.

The male: female ration in Group A (Prednisolone) and Group B (Dexamethasone) was 1.27:1 and 1.13:1 respectively. There was no significant difference in gender distribution in two groups. (p>0.05)

Suhani Malhotra et al,[10] compared the intraocular pressure variation for Dexamethasone 0.1% and Prednisolone acetate 1% observed male predominance in the study. M: F ratio was 1.5:1 and 1.32:1 in groups dexamethasone and prednisolone respectively. This finding was similar to present study.

In the present study, the majority of patients operated by SICS in Group A (72.21%) and Group B (67.57%). Phacoemulsification was done in 27.79% and 32.43% in Group A and Group B respectively. There was no significant difference in type of surgery distribution in two groups. (p>0.05)

Mean IOP in Prednisolone Group at different intervals: In the present study, the mean IOP in Group A on POD 5, POD 12, POD 19, POD 26 and POD 42 was 21.11 ± 2.93, 18.31 ± 2.32, 16.52 ± 2.18, 14.22 ± 2.55 and 13.21 ± 2.03 mm of Hg respectively with statistically significant difference. (P<0.0001) This shows maximum IOP was on day 5 post-operative and decreases thereafter till day 42. The mean IOP in Group A operated by SISC on POD 5, POD 12, POD 19, POD 26 and POD 42 was 22.08 ± 2.81, 18.79 ± 2.48, 16.26 ± 2.43, 14.31 ± 2.76 and 13.44 ±2.01 mm of Hg respectively with statistically significant difference. (P<0.0001) This shows maximum IOP was on day 5 post-operative and decreases thereafter till day 42. The mean IOP in Group A operated by Phacoemulsification on POD 5, POD 12, POD 19, POD 26 and POD 42 was 21.05 ± 2.18, 18.27 ± 2.29, 16.43 ± 2.43, 14.09 ± 2.78 and 13.06 ± 2.13 mm of Hg respectively with statistically significant difference. (P<0.0001) This shows maximum IOP was on day 5 post-operative and decreases thereafter till day 42.

Suhani Malhotra et al,[10] compared the intraocular pressure variation observed after Prednisolone usage mean IOP value was 23.15 mm Hg from pre-operative 16.23 mm Hg.

Kavitha Mohankumar et al,[9] in a study on prevalence of raised IOP in post cataract patients following topical steroid usage observed that there was statistically significant difference (p=0.000) in mean IOP (mm Hg) between preoperative with next duration of follow up.

Mean IOP in Dexamethasone Group at different intervals: The mean IOP in Group B on POD 5, POD 12, POD 19, POD 26 and POD 42 was 22.29 ± 2.49, 19.03 ± 2.52, 17.10 ± 2.41, 14.87 ± 2.32 and 13.79 ±2.41 mm of Hg respectively with statistically significant difference. (P<0.0001) This shows

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maximum IOP was on day 5 post-operative and decreases thereafter till day 42. The mean IOP in Group B operated by SISC on POD 5, POD 12, POD 19, POD 26 and POD 42 was 22.79 ± 3.02, 19.31 ± 2.77, 17.54 ± 2.52, 15.04 ± 2.56 and 14.12 ± 2.31 mm of Hg respectively with statistically significant difference. (P<0.0001) This shows maximum IOP was on day 5 post-operative and decreases thereafter till day 42. The mean IOP in Group B operated by Phacoemulsification on POD 5, POD 12, POD 19, POD 26 and POD 42 was 22.02 ± 2.21, 18.92 ± 2.43, 16.94 ± 2.63, 14.65 ± 2.81 and 13.34 ± 2.21 mm of Hg respectively with statistically significant difference. (P<0.0001) This shows maximum IOP was on day 5 post-operative and decreases thereafter till day 42.

Suhani Malhotra et al,[10] compared the intraocular pressure variation observed the mean pre-operative baseline IOP of group dexamethasone subjects was 16.61 mm Hg, which increased to 26.89 mmHg after one week of Dexamethasone usage following cataract surgery.

Comparison of mean IOP among Two Groups at different intervals: The comparison of mean IOP at different intervals showed that on POD 5 mean IOP in Group A (21.11 ± 2.93) was less compared to Group B (22.29 ± 2.49) with no statistically significant difference. (p>0.05) Similarly, on POD 12, 19, 26 and 42 Group A had slightly less IOP compared to Group B with no statistically significant difference. (p>0.05).

The comparison of mean IOP operated by SICS at different intervals showed that on POD 5 mean IOP in Group A (22.08 ± 2.81) was less compared to Group B (22.79 ± 3.02) with no statistically significant difference. (p>0.05) Similarly, on POD 12, 19, 26 and 42 Group A had slightly less IOP compared to Group B with no statistically significant difference. (p>0.05).

Kavitha Mohankumar et al,[9] in a study on prevalence of raised IOP in post cataract patients following topical steroid usage observed there was no significant difference between mean IOP of two drugs during any particular time interval. (p> 0.05) This finding was similar to present study.

Sharmila Somayaji et al,[11] compared the impact of post-cataract surgery administration of eye drops containing prednisolone and dexamethasone on Intra-Ocular pressure (IOP) in patients observed Prednisolone exhibited a lower risk of IOP elevation than dexamethasone supporting present study.

A study conducted by Matthew K et al,[12] compared the steroid-induced IOP rise post cataract surgery in 100 patients in which patients were grouped into those receiving prednisolone and dexamethasone eye drops as a treatment for post-operative inflammation. They found a statistically significant difference between IOP rise in dexamethasone group as compared to prednisolone group on thus concluding that dexamethasone eye drops were relatively safer as far as steroid-induced post-operative IOP rise is concerned. This finding contrasted with present study.

Sadhana K. Hingorani et al,[13] in a study when dexamethasone group was compared with prednisolone group there was significant difference of IOP at different intervals. (p<0.05).

CONCLUSION

The present study concludes that topical steroids Dexamethasone and Prednisolone can be used in post cataract surgery patients and the rise in IOP noticed in the first few weeks following cataract surgery is mostly due to inflammation. In most cases, the IOP lowers spontaneously to the baseline within 2 weeks upon stopping the steroid.

Dexamethasone and Prednisolone drops were proven to have an equivalent effect on Steroid-induced IOP elevation except in the first postoperative week when Dexamethasone had a slightly higher IOP increase. The study confirms that Dexamethasone is equally efficacious to Prednisolone in managing post-cataract surgery ocular inflammation. Prednisolone provides superior analgesia and early clearance of AC reaction, which may further aid in early visual rehabilitation and recovery.

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