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Analysis of Intraocular Pressure Variation with Use of Steroid Eye Drops as Post-operative Medication in Cataract Patients

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ABSTRACT

Background and aim: Steroid drops are necessarily used after cataract surgery to control the ocular inflammation, but they can increase the intraocular pressure. Using two different steroid eye drops as post-operative medication after cataract surgery to compare the intraocular pressure variation and control of ocular inflammation.

Material and methods: A comparative hospital-based study was conducted on 180 patients who underwent cataract surgery with Intraocular lens implantation. Two groups 1 and 2 were made based on the exposure to either Dexamethasone 0.1% e/d or Prednisolone acetate 1% e/d, respectively. Both drops were prescribed six times daily for the first week and gradually tapered off in 6 weeks. The anti-inflammatory effect and mean IOP rise from baseline in groups 1 and 2 were analyzed and compared. Statistical analysis was done using SPSS 24.0.

Results: Intraocular Pressure increase was noted more in group 1 (25.56%) versus group 2 (17.78%), with a statistically significant difference ($p<0.05$) after one week. after the fourth and sixth weeks, the intraocular pressure rise (IOP) was observed in 15.56% and 8.89% versus 10% and 4.44% of the subjects in Group 1 and group 2, respectively. Both the drugs effectively controlled ocular inflammation, and there was no significant difference in their anti-inflammatory effects.

Conclusions: Our study concludes that dexamethasone is equally efficacious to Prednisolone in managing post-cataract ocular inflammation with marginally raised IOP in the first week in steroid responders. IOP returns to baseline with a reduction of the drop's frequency.

1. Introduction

A cataract is the development of any opacity in the lens or its capsule, which initially prevents clear vision and eventually progresses to blindness if left untreated. It is the leading cause of blindness worldwide. 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.[1] immediate visual rehabilitation is possible following cataract surgery after an intraocular lens (IOL) is implanted. Manual small incision cataract surgery and phacoemulsification are the commonly used techniques of cataract surgery nowadays. Topical steroids are routinely used after cataract surgery to reduce inflammation and improve visual outcomes.[2] François was the first to publish a report on intraocular pressure (IOP) rise after long-term therapy with topical cortisone in 1954.[3] Steroids inhibit the release of leukotrienes and prostaglandins post-operatively, thereby reducing intraocular inflammation, most often measured by observing anterior chamber cells and flare. Although steroids help reduce inflammation and speed up recovery, they also have significant side effects, whether topically or systemically.[4] One of the common side effects of topical steroids includes increased IOP.[5] About 5% of the general population is a high steroid responder, 35% are moderate, and 60% are non-responders.[6] Factors that increase the risk of corticosteroid-induced increased IOP are glaucoma,[7] advanced age,[8] diabetes mellitus,[9] and high myopia.[10] Topical administration causes a more significant increase in IOP as compared to systematically administered steroids. Steroid-induced glaucoma may lead to irreversible blindness if continued for a longer duration.[11] Despite the known risks, steroids are used regularly because the benefits outweigh the losses. Factors that play a role in the elevation of IOP are the type of steroid, frequency of installation, and steroid responsiveness of the individual.[12] The present study was conducted to analyze the intraocular pressure variation and control of ocular inflammation using two different steroid eye drops as post-operative medication after cataract surgery.

2. Material and methods

Ethical approval

The Ethical Committee approved the study of our college (Ref. No. MMC/IEC/2020/72). All the participants took informed and written consent.

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Non-compliant patients or those using topical/inhaled/systemic steroids were excluded from the study.

This prospective, observational, comparative, hospital-based study was conducted on 180 patients attending the Ophthalmology Department of college between November 2019 to May 2021 who underwent phacoemulsification or SICS with IOL implantation. Patients with corneal opacity, inflammatory eye disease, glaucoma, retinal diseases, intraoperative complications, ocular trauma, taking medication for any eye diseases, high myopic or systemic illness (e.g., tuberculosis, uncontrolled diabetes, autoimmune disorders) were excluded from the study. Postoperative patients were divided into two groups by a simple random sampling method. Topical 0.1% Dexamethasone e/d was prescribed in Group 1, and 1% Prednisolone acetate e/d was given in Group 2 six times per day in the first postoperative week and was tapered off gradually for 6 weeks. Details of every patient were recorded preoperatively, and ocular findings regarding visual acuity, IOP, AC cells, and flare were recorded post-operatively on day one after the first, fourth, and sixth-week duration. Grading of anterior chamber cells/flare was done using the SUN (Standardization of Uveitis Nomenclature) grading system with the help of a slit lamp. The IOP rise from baseline was analyzed, and patients were classified as either steroid responders if IOP increased >6 mm Hg from baseline or non-responder <6mm Hg. Any symptom or sign of active ocular inflammation was graded and documented according to the below-mentioned criteria.

1. Ocular Pain Score:
Grade 1: Trace – the slight sensation of pain or discomfort.
Grade 2: Mild - mild, tolerable aching of the eye.
Grade 3: Moderate - moderate and prolonged aching sufficient to require the use of analgesics.
Grade 4: Moderately severe - prolonged intense aching requiring the use of analgesics.
Grade 5: Severe - prolonged sharp ocular or periocular pain.

2. Grading of Anterior Chamber Cells:
0= <1, + 0.5= 1-5, + 1= 6-15, + 2= 16-25, + 3= 26-50, +4= > 50.
3. Grading of Aqueous Flare:
Nil 0.
Just detectable +1.
Moderate (Iris and lens details clear) +2.
It is marked (Iris and lens details hazy) +3.
Intense (Fibrin exudates) +4.12.

The collected data were analyzed statistically using SPSS software version 24. The difference between the two groups was determined using the student t-test and chi-square test, considering the statistical significance at $p<0.05$.

3. Results

There was male predominance in the study. M: F ratio was 1.5:1 and 1.32:1 in groups 1 and 2, respectively. The mean age in groups 1 and 2 was 61.07±5.73 and 62.82±4.98, respectively. The distance vision assessment was done using Snellen's chart, which was later converted to log MAR values for comparative purposes. In comparing both groups, there were no differences in mean visual acuity in the patients under the study at various time intervals. The mean pre-operative baseline IOP of group 1 subjects was 16.61 mm Hg, which increased to 26.89 mmHg after one week of Dexamethasone e/d usage following cataract surgery. In group 2, after Prednisolone e/d usage mean IOP value was 23.15 mm Hg from pre-operative 16.23 mm Hg. The increase was noted more in the Dexamethasone group than the Prednisolone group, with a statistically significant difference ($p<0.05$). Three patients from group 1 and one from group 2 had IOP values of more than 30 mm Hg, and topical anti-glaucoma (Brinzolamide and Timolol combination) drops were prescribed for one week, and their IOP reverted into the normal range. After an initial spike in IOP was found at the end of the first week, it subsequently decreased in further follow-ups when the frequency of e/d was decreased in both the groups with no significant difference (Table 1).

Table 1. Vision and intraocular pressure among the study groups.

Vision	Group 1 (Dexamethasone)		Group 2 (Prednisolone)		P-value
	Mean	SD	Mean	SD	
Pre-operative vision	0.629	0.17	0.662	0.14	0.34
1st Week post-operative	0.301	0.08	0.28	0.11	0.23
4th Week post-operative	0.146	0.14	0.093	0.17	0.16
6th Week post-operative	0.011	0.07	0.052	0.04	0.10
IOP (in mmHg)					
Pre-operative	16.61	2.85	16.23	1.84	0.43
1st Week post-operative	26.89	4.19	23.15	5.14	0.037*
4th Week post-operative	17.22	1.91	16.69	2.17	0.38
6th Week post-operative	16.94	2.48	16.29	2.04	0.13

*: statistically significant

It was observed that group 1 had 25.56% steroid responders compared to 17.78% in group 2 in the first week. After the fourth and sixth weeks, the same was revealed in 15.56% and 10% versus 8.89% and 4.44% of the subjects in Group 1 and 2, respectively (Fig 1).

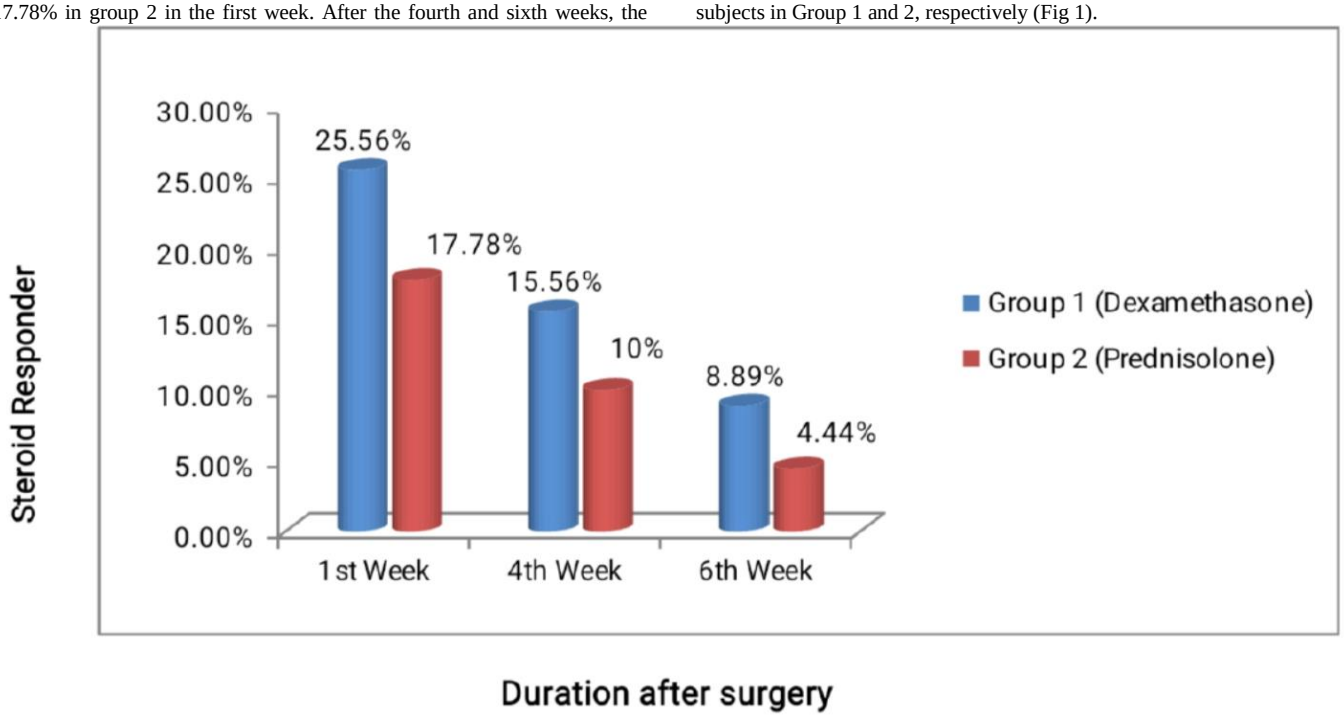

Fig. 1. Steroid responder among the study groups at different follow-ups.

More than 2/3rd of the subjects revealed mild ocular pain in both the groups on the first postoperative day and first follow-up, i.e., day 7th, but there was a statistically insignificant difference ($p>0.05$) at later follow-ups in groups 1 and 2. On analysis of the anterior chamber flare, a statistically insignificant difference was observed in patients between the two groups at various intervals (p-value: 0.22, 0.61, and 1 on day 1, first week, fourth week, and sixth week, respectively). However, at the end of the first week, AC flare was more with Dexamethasone drop users than Prednisolone users (Table 2).

Table 2. Anterior chamber (AC) flare assessment comparison among the study groups.

Anterior chamber (AC) Flare	Group 1 (Dexamethasone)		Group 2 (Prednisolone)		P-value
	N	%	N	%	
Day 1					
Absent	11	12.22	14	15.56	0.22
Mild	51	56.67	58	64.44	
Moderate	28	31.11	18	20.00	
Severe	0	0	0	0	
1st Week					
Absent	43	47.78	49	54.44	0.61
Mild	38	42.22	36	40.00	
Moderate	9	10.00	5	5.56	
Severe	0	0	0	0	
4th and 6th Week					

Absent	0	0	0	0	1
Mild	0	0	0	0	
Moderate	0	0	0	0	
Severe	0	0	0	0	

A statistically significant difference (p=0.041) in AC cells was observed in patients between the two groups on the first postoperative day and the first week of follow-up. Patients treated with Prednisolone presented fewer cells in the AC compared to Dexamethasone on day 7th, as shown in table 3.

Table 3. Assessment of ac cells comparison among the study groups.

Anterior chamber (AC) Cells	Group 1 (Dexamethasone)		Group 2 (Prednisolone)		P-value
	N	%	N	%	
Day 1					
Absent	8	8.89	11	12.22	0.36
Grade 1	61	67.78	63	70.00	
Grade 2	16	17.78	14	15.56	
Grade 3	5	5.56	2	2.22	
1st Week					
Absent	48	53.33	62	68.89	0.041*
Grade 1	42	46.67	28	31.11	
Grade 2	0	0	0	0	
Grade 3	0	0	0	0	
4th and 6th Week					
Absent	0	0	0	0	1
Grade 1	0	0	0	0	
Grade 2	0	0	0	0	
Grade 3	0	0	0	0	

On analysis of the corneal edema over 6 weeks of follow-up, the study did not yield any significant difference between the two groups (Table 4).

Table 4. Corneal edema comparison among the study groups.

Corneal edema	Group 1 (Dexamethasone)		Group 2 (Prednisolone)		P-value
	N	%	N	%	
Day 1					
None	26	28.89	23	25.56	0.12
Mild	49	54.44	58	64.44	

Moderate	15	16.67	9	10.00	
Severe	0	0	0	0	
1st Week					
None	77	85.56	80	88.89	0.76
Mild	13	14.44	10	11.11	
Moderate	0	0	0	0	
Severe	0	0	0	0	
4th and 6th Week					
None	0	0	0	0	1
Mild	0	0	0	0	
Moderate	0	0	0	0	
Severe	0	0	0	0	

4. Discussion

Following cataract surgery, patients were prescribed steroid eye drops to control the postoperative pain and inflammation. We conducted this study to observe the effect of topical corticosteroid on IOP rise and its ocular anti-inflammatory effect in postoperative cataract patients. In the present study, the male-to-female ratio was 1.5:1 and 1.32:1 in groups 1 and 2, respectively. Babu et al.[13] revealed similar male predominance in their study. However, in their study, Kumar et al.[14] reported more females than males. This difference might be due to the difference in sample size and study area. The mean age in groups 1 and 2 was comparable (61.07±5.73 and 62.82±4.98 years, respectively). Similar age was revealed by Babu et al.,[13] Kumar M et al.,[14] and Prasad D et al.,[15] in their study. The mean pre-operative IOP among the study subjects was 16.61 mm Hg, which increased to a mean IOP of 26.89 mm Hg after 1 week of Dexamethasone e/d usage following cataract surgery group 1 and 16.23 to 23.15 mm Hg in group 2. The increase was noted more in group 1 as compared to group 2, with a statistically significant difference ($p<0.05$) among them. IOP rise was found in 25.56% of subjects in Group 1 and 17.78% of the subjects in group 2. Three patients from group 1 and one from group 2 had IOP values of more than 30 mm Hg, and topical anti-glaucoma (Brinzolamide and Timolol combination) drops were prescribed twice a day for one week to control IOP. The anti-glaucoma drops were stopped after one week, and the steroid drops frequency was also reduced in these four patients. These patients were called after every seven days till the end of the month from surgery. On second and third follow-up, i.e., at the end of the fourth and sixth week, the IOP rise from baseline was revealed in 15.56%, 8.89%, and 10%, 4.44% of the subjects in Group 1 and group 2, respectively. Increased IOP immediately after cataract surgery can also sometimes be attributed to retained viscoelastic substances and cortical matter. However, we performed a thorough AC wash and cortical matter removal in every case to rule out the confounding factors. In a study by Kumar M et al.,[14] the prevalence of steroid-responders was 3.6%. They concluded that there was no difference in the mean IOP rise with either Prednisolone acetate 1% e/d or Dexamethasone 0.1% e/d. The highest mean IOP (20.26 mm Hg) was noted on the fifth postoperative day due to inflammation and a gradual decrease in IOP in the subsequent weeks of follow-up by the end of the sixth week. They revealed similar results with Prednisolone acetate and Dexamethasone e/d of the same concentrations as our study. Armaly et al.,[16] categorized steroid responders based on the IOP rise with topical steroids in patients 3 times daily for 4 weeks. IOP <6 mm Hg rise as low steroid responders (66%), 6-15 mm Hg rise as intermediate steroid responders (29%), and >15 mm Hg rise as high steroid responders (5%). Most of our patients fell into the intermediate grade of steroid responsiveness after the first follow-up and returned to normal gradually. According to studies by Becker et al.,[17] patients were categorized into different groups of responsiveness to steroid drops. It was done by prescribing topical steroids QID for 6 weeks and taking final IOP as the parameter. He concluded <20 (58%), 20-30 (36%) and >31 (6%) mm Hg IOP as low, intermediate and high steroid responders respectively. Mohan H et al.,[18] mentioned that the mean value of IOP in patients at the end of the first week using Dexamethasone e/d was 14.63 and with Prednisolone e/d was 14.31, and the difference was statistically insignificant, but at the end of the sixth week mean value of IOP in patients using Dexamethasone was 14.29 and Prednisolone was 13.11 with a p-value of <0.005. However, the Dexamethasone group had a higher IOP than the Prednisolone group at the end of the sixth week. In a study by Prasad D et al.,[15] with Dexamethasone, the mean pre-operative IOP was 17.05 mm Hg, which post-operatively increased by 2.27 mm Hg ($p<0.001$, statistically significant) at 6 weeks. A study conducted by Matthew K et al.,[19] stated that a statistically significant difference was observed between IOP rise in Dexamethasone drops versus Prednisolone drops. According to him, Dexamethasone was relatively safer than Prednisolone drops as far as steroid-induced IOP rise was concerned, which contradicts the outcome of our study after a one-week follow-up. More than 2/3 rd of the subjects revealed mild pain in both our study groups. On analysis of the ocular pain following

cataract surgery on day 1, first week, fourth and sixth week in both the groups, there was a statistically insignificant difference (p>0.05). Babu M et al.,[13] also revealed similar results regarding postoperative ocular pain in their study. On analysis of the AC flare, a minimum difference was observed in patients between the two groups at various intervals. However, mild to moderate AC flare was found more in the 1st group as compared to the second. In their study, Babu M et al.,[13] reported similar results supporting our findings. On analysis of the AC cells, a statistically significant difference was observed in patients between the two groups after the first follow-up. Patients treated with Prednisolone showed a lesser degree of cells in the AC when compared with Dexamethasone on day seventh. Similarly, in their study, Babu M et al.,[13] observed that Prednisolone-treated patients showed fewer AC cells than the Dexamethasone e/d user group. In their study, Malik A et al.,[20] showed that Prednisolone 1% was more effective in controlling postoperative intraocular inflammation in reducing anterior chamber cells and flare. On analysis of the corneal edema over 6 weeks of follow-up, the study did not yield any significant difference in the two groups, and Babu M et al.,[13] reported the same findings in their study.

Limitations

The patient's compliance regarding installing the drops cannot be assured, and we had to rely upon them.

5. Conclusion

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. Our study confirms that Dexamethasone e/d is equally efficacious to Prednisolone e/d 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.

Conflict of Interest

The authors declared that there is no conflict of interest.

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