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Indian Journal of Clinical and Experimental Ophthalmology

Journal homepage: www.ijceo.org

Original Research Article

Impact of prednisolone, dexamethasone, and fluorometholone eye drops on intraocular pressure in patients post-cataract surgery: A randomized controlled study

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ARTICLE INFO

Article history:
Received 28-11-2023
Accepted 13-12-2023
Available online 29-12-2023

Keywords:
Cataract surgery
IOP
Corticosteroids
Glaucoma
Intraocular pressure

ABSTRACT

Background: After cataract surgery, topical corticosteroids are prescribed for inflammation reduction, but prolonged use may lead to side effects like steroid-induced glaucoma. These steroids can elevate intraocular pressure (IOP), and if elevated IOP isn't promptly addressed, it may advance to glaucoma. Vigilant monitoring of IOP changes is crucial for early detection and intervention, forming the basis for this study. The objective of this study was to evaluate and compare the impact of post-cataract surgery administration of eye drops containing prednisolone, dexamethasone, and fluramethalone on Intra-Ocular pressure (IOP) in patients.

Materials and Methods: Seventy-five patients were randomly allocated to three groups, each comprising thirty individuals. Participants were administered prednisolone, dexamethasone, and fluramethalone eye drops, respectively, with a tapered dosage over a 42-day period. The study involved documenting intraocular pressure (IOP) measurements both before and after the surgery. Subsequently, patients were monitored for a duration of three months.

Results: Among the 75 patients, approximately 5.77% (n = 4) exhibited an increase in intraocular pressure (IOP) of ≥10 mmHg from their baseline. A moderate elevation in IOP (≥5 mmHg) was observed in about 13.44% (n = 13) of the patients. Notably, a clinically significant rise in IOP, defined as an increase of ≥10 mmHg and an overall IOP of ≥20 mmHg, occurred in 4.98% (n = 4) of the patients, all of whom were in the fluramethalone group. The mean post-operative IOP differed significantly among the three treatment groups.

Conclusion: Flurometholone possesses a heightened propensity to induce an early and substantial increase in intraocular pressure (IOP), necessitating careful and vigilant usage with continuous monitoring.

1. Introduction

Cataract surgery has risen to prominence as a leading ocular surgical procedure globally, with an estimated 30 million surgeries conducted each year.[1] Despite the standardized nature of the surgical technique, there is significant variability in the postoperative regimens prescribed by different physicians. A worldwide survey conducted by Rossi et al. reveals that a substantial majority of surgeons recommend postoperative anti-inflammatory treatment.

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https://doi.org/10.18231/j.ijceo.2023.098

However, the specific anti-inflammatory protocols differ widely, encompassing the use of topical non-steroidal anti-inflammatory drugs (NSAIDs), topical steroids, or a combination of both. Despite some studies advocating the superiority of one drug group over the other, topical steroids continue to be a prevalent choice for postoperative treatment following cataract surgery.[2]

Topical steroidal eye drops vary in potency and their ability to penetrate the anterior chamber (AC), with higher potency offering swifter control of ocular inflammation but also posing a greater risk of side effects, particularly elevated intraocular pressure (IOP).[3–6] While rapid inflammation control is desirable for its positive impact on postoperative visual acuity and the incidence of macular edema,[7] prioritizing patient safety is crucial. Therefore, the selection of postoperative topical steroidal treatment should be informed by robust data that comprehensively assesses both the risks and benefits associated with different drugs.

Corticosteroids have proven efficacy in mitigating inflammation subsequent to cataract surgery. In the management of ocular conditions, the preference leans toward the topical application of corticosteroids rather than systemic delivery. This preference is influenced by the attainment of higher drug concentrations within the eye and the minimal occurrence of systemic adverse events. These corticosteroids play a preventive role in post-ocular inflammation, corneal edema, and cystoid macular edema. Nevertheless, it is imperative to recognize that prolonged corticosteroid use is correlated with adverse effects, with steroid-induced glaucoma being a notable complication.[8]

Steroid usage has the potential to elevate intraocular pressure (IOP) in susceptible individuals. Roughly one-third of individuals are estimated to undergo a moderate increase in IOP when utilizing topical steroids. Furthermore, approximately 5–6% of the general population may experience a noteworthy elevation in IOP after 28–42 days of topical steroid therapy, classifying them as high responders to steroids.[9]

Concerning topical steroids, the likelihood of increasing intraocular pressure (IOP) generally correlates with their anti-inflammatory potency. Widely used potent steroids such as betamethasone, dexamethasone, and prednisolone are recognized for their increased potential to induce a significant rise in IOP.[3]

Research outcomes suggest that failure to address elevated intraocular pressure (IOP) may lead to the progression of optic nerve damage and the emergence of visual field defects characteristic of glaucoma. This advancement could eventually culminate in the onset of steroid-induced glaucoma.[4]

Although steroids are recognized for their established anti-inflammatory properties, they concurrently carry a notable potential for raising intraocular pressure (IOP). When choosing a particular steroid for a patient, it is essential to evaluate the probability of clinically significant increases in IOP (≥10 mmHg).[5]

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, our study sought to assess and compare the impact of three commonly used topical steroids—Prednisolone, dexamethasone, and fluramethalone eye drops—on IOP and identify potential adverse effects. Consequently, the present investigation was undertaken to evaluate and compare the effects of prednisolone, dexamethasone, and fluramethalone eye drops on IOP in patients post-cataract surgery.

2. Materials and Methods

An open-label observational study was prospectively conducted from November 2020 to October 2022, involving patients who underwent cataract surgery at the Department of Ophthalmology, Chamarajanagar Institute of Medical Science in Chamarajanagar, Karnataka. The relevant information was extracted from the records of post-operative cataract patients who utilized topical steroids during the specified study duration. The initiation of the study was preceded by obtaining necessary permissions from higher authorities and obtaining clearance from the Institutional Ethics Committee.

2.1. Sample size

Approximately 98 cataract patients scheduled for cataract surgery underwent screening, from which 75 patients meeting the inclusion/exclusion criteria were selected for the study during the specified period. The sampling method employed was simple randomization. The study utilized Goldmann's applanation tonometer, administered by ophthalmologists, for the measurement of intraocular pressure (IOP).

2.2. Selection criteria

This inclusion criteria comprise individuals aged 18 years and above, including both males and females, who have been scheduled to undergo cataract surgery in our tertiary hospital. In contrast, the exclusion criteria entail individuals with established cases of glaucoma, a documented history of ocular hypertension, a background of ocular trauma or vitreous hemorrhage, instances of ischemic proliferative diabetic retinopathy, and individuals with a record of prolonged steroid use through alternative administration routes. These criteria are designed to delineate a specific cohort for the study, ensuring that

participants are representative of the targeted population undergoing cataract surgery while excluding those with conditions or histories that could confound the research objectives.

1. Group 1: Patients treatred with 1% prednisolone eye drops over a period of day 42.
2. Group 2: Patients treated with 0.1% dexamethasone eye drops for a duration day 4.
3. Group 3: Patients treated with 0.1% fluramethalone eye drops for the duration of day 42.

The application of topical steroids adhered to a prescribed 6-week regimen as recommended by ophthalmologists. On the first day after the surgery, the drops were administered hourly for a 24-hour period, followed by a systematic tapering plan. During the initial week, the frequency was decreased to six times a day, progressively reducing to five times a day in the second week, four times a day in the third week, three times a day in the fourth week, two times a day in the fifth week, once a day by day 42.

Key information, including Identification (I.P.) Number, date of admission, age, gender, and intraocular pressure (IOP) measurements (solely conducted by ophthalmologists), was systematically documented in a pre-designed form.

The initial intraocular pressure (IOP) before cataract surgery and its measurements at day 21 and day 42 post-surgery were recorded. Additionally, any other observed adverse effects were documented.

2.3. Statistical analysis

The data analysis was conducted utilizing GraphPad Prism software version 10, and calculations were performed to determine frequencies and percentages. To compare intraocular pressure (IOP) measurements across the three groups, analysis of variances (ANOVA) was employed. Graphical representations were employed as visual aids to depict the data.

3. Results

In this conducted study, we enrolled a prospective cohort of 75 cataract patients undergoing cataract surgery and were prescribed steroids by topical administration in the Department of Ophthalmology at tertiary care hospital, Chamarajanagar. The participants were randomly assigned to three groups, each comprising 25 individuals. Comprehensive data collection encompassed demographic profiles, intraocular pressure (IOP) measurements, and details of post-operative treatments. The follow-up period extended to 45 day, during which we meticulously tracked the patients progress. Table 1 visually represents the mean values of pre-operative and postoperative IOP measurements. Notably, while there was no significant disparity in mean postoperative IOP among the three groups, a notable difference was discerned in baseline.

Examining the findings presented in Table 2, it was observed that three patients in Group III exhibited a clinically significant IOP increase, reaching ≥10 mmHg from baseline, along with an overall IOP of ≥20mmHg. Further exploration in Table 2 revealed that, out of the 75 patients, three displayed an IOP increase of ≥5 mmHg from baseline, with one patient demonstrating an elevation of ≥10 mmHg at postoperative day 21. Additionally,Table 3 outlined that eight patients exhibited a moderate increase in IOP (≥5 mmHg), and three patients experienced a more pronounced elevation of ≥10 mmHg.

Table 1 depicted, we examined the mean increase in IOP from baseline at postoperative day 42. Although Group III exhibited a greater mean rise in IOP compared to the other two groups, these differences did not reach statistical significance. These intricate findings contribute to our understanding of the enhanced effects of topical steroids on post-cataract surgery patients, emphasizing the need for meticulous monitoring and individualized treatment approaches.

4. Discussion

The study assessed the impact of prednisolone, dexamethasone, and flurametahlone eye drops on intraocular pressure (IOP) for early detection and prevention of steroid-induced glaucoma. Despite being commonly used for post-operative inflammation, these ophthalmic steroids displayed varying effects on IOP.

In our study, mainly females aged 51 to 68, all three steroids increased IOP, but postoperative IOP among groups did not differ significantly. Approximately 5.77% showed ≥10 mmHg IOP increase, with flurametahlone having the highest incidence. Mild adverse effects were reported, and clinically significant IOP elevation (≥10 mmHg, overall ≥20 mmHg) occurred in 4.98%, all from the flurametahlone group, suggesting caution due to early onset within 42 days

Our findings aligned with Ostrov et al.,[10] showing no significant IOP differences among steroid groups. Although Group III had increase the IOP (8.6 ± 12 mmHg), differences were statistically significant.

Sheppard et al.[11] reported small IOP changes between flurametahlone and prednisolone, with clinically significant elevation in flurametahlone, consistent with our study. Stewart et al. criteria (≥10 mmHg) were met by 3.77%, and 15.77% had a moderate rise (≥5 mmHg).

Prednisolone exhibited a lower risk of IOP elevation than dexamethasone and flurametahlone, supporting other studies. Korenfeld et al.[12] study on flurametahlone revealed a 3% IOP increase, consistent with our results. Smith et al. study supported our findings, with 3.7% in the flurametahlone group having ≥10 mmHg IOP increase.[1]

Table 1: Intraocular pressure (IOP) measurements before and after surgery in all three groups (mmHg)

Variables	Group I		Group II		Group III		P- Value
	Range	Mean±S.EM	Range	Mean±S.E.M	Range	Mean±S.E.M	
			Pre-operative				
Baseline	9-24	13.04±2.223	11-19	12.21±1.96	7-24	15.26±1.92	0.012
			Post-operative				
Day 21	6-21	11.44±2.76	7-24	14.82±2.98	4-30	12.82±0.91	0.189
Day 42	11-22	12.72±0.92	8-19	11.81±0.81	8-42	14.41±8.21	0.381

Table 2: Percentage of patients experiencing an intraocular pressure (IOP) increase of ≥10 mmHg from baseline and an overall IOP ≥21 mmHg

Variables	Group I	Group II	Group III
Increase of ≥10 mmHg and overall IOP >20 mmHg	0.3	0.5	1

Table 3: Rise in intraocular pressure (IOP) from baseline across all three groups

Variables	Group I		Group II		Group III	
	Day 21	Day 42	Day 21	Day 42	Day 21	Day 42
Elevation in Intraocular Pressure (IOP) of ≥5 mmHg from Baseline	2	3	3	4	1	1
Elevation in Intraocular Pressure (IOP) by ≥10 mmHg from Baseline	0.1	0.34	0.5	1	1	1

In our prospective study, 4.76% showed clinically significant IOP elevation with fluramethalone, indicating its similar compared to other steroids. Early elevations in IOP were observed, consistent with other studies. In addition, Mild adverse effects were reported across groups, emphasizing careful steroid use. Steroids remain crucial for post-operative inflammation, with topical steroids preferred for efficacy and higher ocular tissue concentration.

Introduced in 1950, dexamethasone and later prednisolone became integral in ocular therapy. Fluramethalone, approved in 2008, is considered a gold standard, but the study highlights the risk of IOP elevation with all topical steroids, particularly fluramethalone. Judicious use and constant monitoring are emphasized, with ongoing advancements aiming to introduce safer topical steroids for ocular inflammatory conditions, minimizing adverse reactions, including IOP elevation. [11,13]

Cataract surgery is a widely performed ophthalmic intervention, and the management of postoperative inflammation is critical for optimizing patient outcomes. This randomized controlled study sought to elucidate and compare the effects of three commonly used topical corticosteroids—Prednisolone, Dexamethasone, and Fluorometholone—on intraocular pressure (IOP) in patients following cataract surgery. [14,15]

The results of our investigation revealed distinct variations in the impact of the three corticosteroids on IOP. Notably, Fluorometholone exhibited a heightened potential to induce an early and significant rise in IOP compared to Prednisolone and Dexamethasone. This observation underscores the importance of considering the specific corticosteroid's impact on IOP when making clinical decisions.

5. Strengths and Limitations

In our study, patients were monitored for a duration of 42 days. However, it is essential to conduct a long-term follow-up of the patients, considering that steroids are recognized for their potential to induce long-term adverse effects.

6. Conclusion

In this randomized controlled study assessing the impact of prednisolone, dexamethasone, and fluorometholone eye drops on intraocular pressure (IOP) in patients post-cataract surgery, the findings contribute valuable insights into the nuanced effects of these commonly used steroids. Our study aligns with previous research indicating that topical steroids can lead to increased IOP, emphasizing the need for careful consideration in postoperative management. The observed variations in the incidence and magnitude of IOP elevation among the three steroids underscore the importance of individualizing treatment regimens. Notably, fluorometholone demonstrated a relatively lower risk of clinically significant IOP elevation, suggesting a potential advantage in terms of safety profile.

7. Source of Funding

None.

8. Conflict of Interest

None.

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Cite this article: Somayaji S, Gore SR, Srinivasa K, Abhilash, Maurya RP. Impact of prednisolone, dexamethasone, and fluorometholone eye drops on intraocular pressure in patients post-cataract surgery: A randomized controlled study. *Indian J Clin Exp Ophthalmol* 2023;9(4):516-520.