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Original Research Article

Post-operative assesment of single subconjunctival triamcinolone acetate injection vs topical corticosteroid in cataract surgery: A prospective control study

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Abstract

Background: Cataract surgery, one of the most successful surgery, depends on appropriate postoperative drug therapy. Subconjunctival injection of steroid preparation allows for better absorption and prolong availability. In comparison to topical drug therapy it has many fold advantages.
Aim & Objective: the aim of the study was to check the comparative effectiveness of subconjunctival triamcinolone acetonide and topical steroids in controlling intraocular inflammation, improving best corrected visual acuity and assessing patient comfort after cataract surgery.
Materials and Methods: This was a comparative, prospective, simple randomized study conducted on 193 patients diagnosed with cataract. They were divided equally into 2 groups and both groups underwent phacoemulsification. Patients in Group A received a 0.5 mL sub-conjunctival injection of Triamcinolone Acetate along with intracameral moxifloxacin (0.5%). In contrast, Group B patients were administered only intracameral moxifloxacin (0.5%) at the conclusion of the surgery. Follow-up appointments for the patients were scheduled on post-operative Day 1, Day 7, Day 21, 6 weeks, and 12 weeks.
Results: There was better improvement in best corrected visual acuity in group A patients (LogMAR 0-0.2) in comparison to group B (LogMAR 0.3-0.5) on post operative day 1. Intraocular pressure rise was not seen post operatively in either group. Markers of inflammation- anterior chamber cells and flare were also less developed in patients of group A than group B on post-operative day 1 and subsequent visits.
Conclusion: Post-operative sub conjunctival triamcinolone acetonide is a better alternative than prolonged use of tapering topical steroids thereby overcoming ocular surface related and patient related problems.

Keywords: Cataract surgery, E subconjunctival triamcinolone injection, Topical corticosteroid.

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1. Introduction

Cataract surgery is a widely performed and successful procedure for restoring vision, particularly in developing countries where cataracts are a leading cause of blindness. Over time cataract surgery has evolved significantly from ancient methods like couching to modern techniques like phacoemulsification offering high success rates.[1] Post-surgery, medications like corticosteroids, antibiotics, and NSAIDs are commonly used to prevent inflammation and infection.[2] However, challenges such as poor drug penetration, patient non-compliance, and improper application of eye drops exist, especially in high-volume settings. Post-surgery, preventing inflammation and infection is crucial, and medications such as corticosteroids, antibiotics, and NSAIDs are commonly prescribed.[3] However, traditional topical drug delivery methods, like eye drops, face challenges such as poor corneal penetration, patient non-compliance, and the risk of contamination, especially in high-volume settings with limited healthcare personnel.

Subconjunctival drug delivery is an innovative method being explored to overcome these limitations. This involves administering medication beneath the conjunctiva, which allows for better absorption and prolonged drug release. By bypassing the corneal barrier, subconjunctival injections can deliver higher drug concentrations directly to the eye, improving efficacy in controlling inflammation and reducing complications after cataract surgery. Subconjunctival triamcinolone acetonide, a corticosteroid, has shown promise

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in managing post-operative inflammation more effectively than traditional topical steroids, such as prednisolone acetate.[4] This method also reduces the need for frequent eye drop administration, improving patient compliance, especially among elderly or those in settings with limited healthcare resources.[5]

In comparison to topical eye drops, subconjunctival injections offer a targeted and controlled drug delivery system that minimizes side effects while ensuring more consistent drug levels within the eye.[6] This approach is a step forward in optimizing post-operative care for cataract surgery patients.

2. Materials and Methods

The study involved 193 patients in total. Patients with either a single eye or both eyes affected by cataracts, who visited the eye outpatient department at F.H. Medical College, were assessed for participation. Those who needed cataract surgery and satisfied the inclusion criteria were selected for the study.

The patients were then randomized by simple random sampling, and allocated into two equal groups.

2.1. Inclusion criteria

1. Age: 45-75 years.
2. All patients with cataractous lens according to lens opacities grading system III (LOCS III).

2.2. Exclusion criteria

1. Prior history of intra-ocular complications such as uveitis or evident Intra-ocular inflammation on examination, patients suffering from glaucoma, high myopes (Axial Length >25mm), those with history of corneal diseases or having corneal diseases.
2. Patients who underwent previous ocular surgeries
3. Patients who developed intra-operative complications
4. Patients with any history of comorbidities.

Institution ethics committee approval was obtained before commencement of the study and informed consent taken from each participant.

The duration of study was 24 months (i.e. 2 years); from December 2020 to December 2022. The study period included the follow-up time period.

All patients included in the study were evaluated with detailed history and baseline examination that included visual acuity, applanation tonometry, anterior segment examination by slit lamp and dilated fundus examination done by Indirect ophthalmoscope and 90D lens. In the next step all the patients underwent Randomisation. Patients were randomised by simple random sampling. Randomisation was done 1:1 into two groups A & B.

Thereafter, the patients were taken up for Intervention / Management. Surgical technique of choice was phacoemulsification cataract surgery under local anaesthesia (Peribulbar technique) and implantation of a monofocal single-piece hydrophobic posterior chamber intraocular lens (PCIOL) performed by a single surgeon.

2.3. Study medication

A vial of triamcinolone acetonide injection (KENACORT, Abbott Pharmaceuticals) with a concentration of 40 mg/mL in 1mL was utilized. A 1-mL syringe equipped with a 26-gauge needle was used to extract 0.5 mL (20 mg), which was then administered subconjunctivally in the lower quadrant for patients in Group A at the conclusion of the surgery. Consequently, at the end of the procedure, Group A patients (Study Group) received 1- 0.5 mL of Subconjunctival Triamcinolone Acetate and 2- Intracameral Moxifloxacin (0.5%), whereas Group B patients (Control Group) were given only Intracameral Moxifloxacin (0.5%) at the surgery's end.

After surgery, both groups were administered topical Moxifloxacin (0.5%) four times daily for a duration of two weeks. Additionally, Group B was given tapering doses of Topical Prednisolone Acetate (1%) following a schedule of 6-4-3-2-1 times per day, each for a week. Patients were instructed to refrain from using any systemic anti-inflammatory medications during the study period. All individuals who had cataract surgery were evaluated post-operatively by a different surgeon. Follow-up visits were scheduled for Day 1 (visit 1), Day 7 (visit 3), Day 21 (visit 4), 6 weeks (visit 5), and 12 weeks (visit 6). At each follow-up, the post-operative assessment included: 1) Best Corrected Visual Acuity (BCVA) after surgery, 2) Intraocular Pressure (IOP) measured with a Goldmann Applanation Tonometer, 3) Anterior chamber cells/flare examined using a Slit-Lamp and graded according to the standardisation of uveitis nomenclature working group criteria (SUN), 4) Macular edema assessed through Optical coherence tomography (OCT) Macular Scan, and 5) any other adverse events, if present.

Statistical analysis was done using Epi Info version 7. The values were represented in Number [n] and Percentage [%]. The sample sizes were calculated with the possibility of at least 10% difference between the 2 groups. Therefore, in order to obtain an alpha error of 5% and confidence interval of 95%, results calculated using openepi.com (recognized by CDC). The Pearson chi-square test is employed to assess the differences in Demographics, Best Corrected Visual Acuity, Intra-ocular Pressure, and AC Flare/cells between the two groups. A p-value below 0.05 was deemed statistically significant for all variables, with a 95% confidence interval.

3. Results

3.1. This study initially enrolled 200 patients with each treatment group comprising of 100 patients.

But a total of seven patients were lost to follow-up, including both the groups. Hence, finally Group A had 95 patients and Group B had 98 patients.

3.2. Demographics

The average age of patients in Group A was 55.26 years with a standard deviation of 7.76, while in Group B, it was 58.01 years with a standard deviation of 11.36. There was no statistically significant difference in the age distribution between Group A and Group B, as indicated by a p-value greater than 0.05. In Group A, 54 patients (56.84%) were male and 41 (43.16%) were female. In contrast, Group B had 36 male patients (37.14%) and 62 female patients (62.86%).

There was no difference in the type and method of surgery used and energy used.

3.3. Baseline evaluation

The following tables (**Table 1** and **Table 2**) show the Preoperative unaided visual acuity and intraocular pressure in both Group A and Group B.

Table 1: Pre-op visual acuity (LogMAR value) (Unaided) among Group A (Study Group) and Group B (Control Group)

VA (LogMAR value)	Group A (N=95)		Group B (N=98)	
	No.	%	No.	%
1.0	84	88.42	86	87.75
0.6-0.8	6	6.32	14	14.28
0.3-0.5	5	5.26	0	0.00
0-0.2	0	0.00	0	0.00
Total	95	100.00	98	100.00

Table 2: Pre-op IOP (in mmHg) among Group A (Study Group) and Group B (Control Group).

IOP (mmHg)	RE				LE			
	Group A(N=95)		Group B (N=98)		Group A(N=95)		Group B (N=98)	
	No.	%	No.	%	No.	%	No.	%
<10	5	5.26	5	5.10	11	11.58	5	5.10
10-15	78	82.11	84	85.71	75	78.95	84	85.71
16-21	12	12.63	9	9.18	9	9.47	9	9.18
>21	0	0.00	0	0.00	0	0.00	0	0.00
Chi-square value	0.604				2.713			
p-value	0.739				0.257			

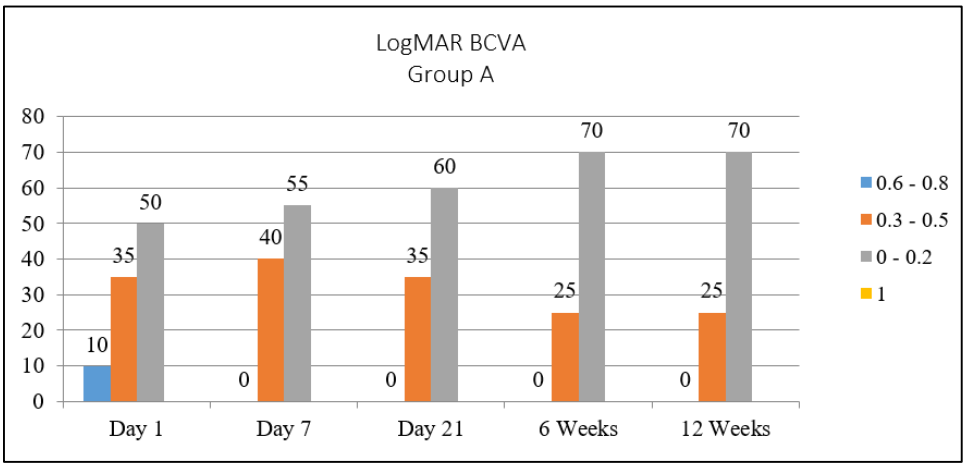

Figure 1: Comparison of LogMAR BCVA values of Group A patients achieved on various Post-operative follow-up visits

It shows that the results obtained at Post-operative 6 weeks and 12 weeks were similar.

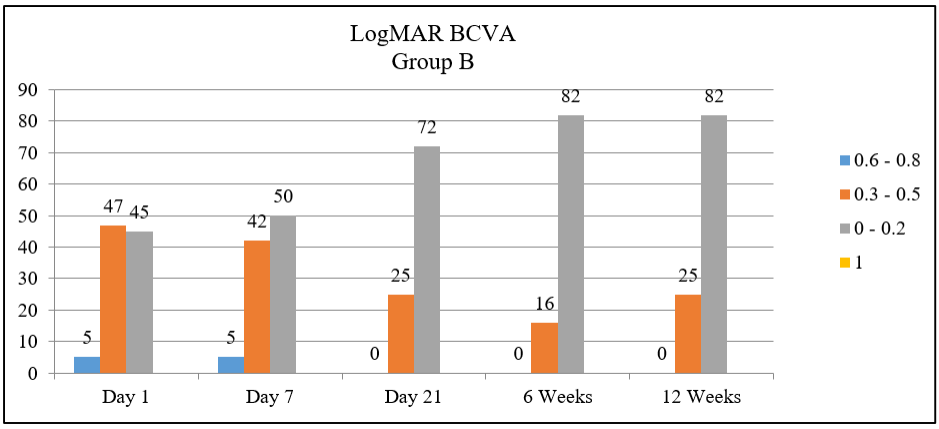

Figure 2: Comparison of LogMAR BCVA values of Group B patients achieved on various Post-operative follow-up visits

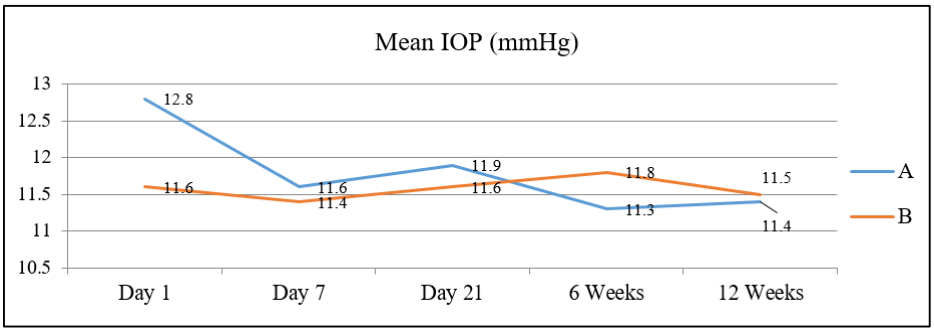

Figure 3: Comparison between Mean IOP (in mmHg) obtained at various follow-up visits among Group A (Study Group) and Group B (Control Group)

3.4. Best-corrected visual acuity (BCVA) on post-operative visits

Visual acuity improved in both the groups. According to **Figure 1 and Figure 2**, postoperative vision on Day 1 was better in Group A than Group B with maximum patients in Group A having BCVA between 0-0.2, which was reported as 53% of total number of patients in Group A. On the first day after surgery, the majority of patients in Group B, accounting for 49% of the group, had a BCVA ranging from 0.3 to 0.5. There was no statistically significant difference between Groups A and B on this day (p-value >0.05). By the seventh day, BCVA showed a gradual improvement. In Group A, 58% of patients had BCVA LogMAR values between 0 and 0.2, compared to 51% in Group B. By the 21st day, Group B's visual acuity surpassed that of Group A, with 74% of Group B patients achieving BCVA LogMAR values between 0 and 0.2, compared to 63% in Group A. However, no statistically significant difference was found between the two groups (p-value >0.05). The most significant improvement in BCVA was observed at six weeks, with 74% of Group A and 84% of Group B patients having BCVA LogMAR values between 0 and 0.2. Visual acuity remained consistent at 12 weeks, and no statistical significance was noted in visual acuity between the groups at any of the visits.

3.5. At post-operative 6 weeks

A total of 82 patients had BCVA LogMAR value 0-0.2
A total of 16 patients had BCVA LogMAR value 0.3-0.5
The results obtained at post-operative 12 weeks were similar.

3.6. Postoperative IOP

Figure 3 presents the average IOP and standard deviation recorded for Group A and Group B during different post-operative visits. The variations in mean IOP values between the two groups at each visit were not statistically significant (p-value >0.05). No patients in either Group A or Group B experienced an IOP greater than 21 mm Hg at any visit. Additionally, there was no need to remove the SCTA depot due to elevated IOP.

3.7. Post-operative anterior chamber flare (according to SUN grading)

23% patients in group A developed AC flare as compared to 29% patients in group B in the 1st visit (Day 1). The incidence of AC flare reduced to 4% and 9% of total patients in Groups A and B respectively by Day 7. (**Figure 4**) The difference in AC flare in both groups were not found to be statistically significant (*p-value >0.05*) on both visits. AC flare resolved completely in both groups by post-operative Day 21 and was not present in any of the following visits.

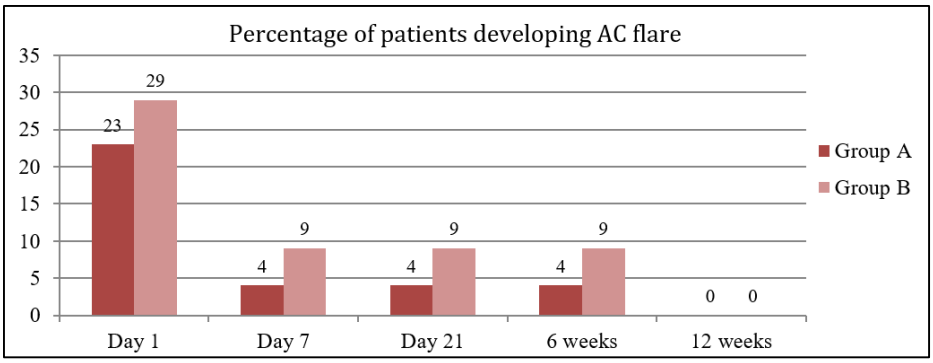

Figure 4: Anterior chamber reaction (AC Flare/Cells) observed on various post-operative visits

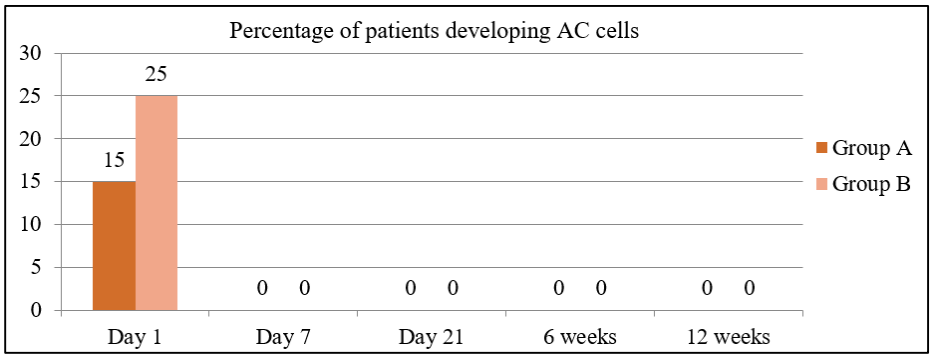

Figure 5: Post-operative anterior chamber cells (according to SUN grading)

3.6. Post-operative anterior chamber cells (according to SUN grading)

15% patients in group A developed AC cells as compared to 25% patients in group B (**Figure 5**). The difference in AC cells in both groups was not found to be statistically significant *(p-value >0.05*) on post-operative Day 1. There was complete resolution of AC cells in both groups A and B by Post-operative fay 7 and remained same in the following visits.

3.8. Other observations

1. The average size of the SCTA depot at the time of injection was 6.5 mm. During follow-up, the mean sizes were recorded as 4.5 mm at the first visit, 2.5 mm at the second visit, and 1 mm at the third visit. Minimal SCH was observed in 8 patients during the first visit, which had completely resolved by the third visit. No other local adverse effects such as chemosis, congestion, necrosis, or ulceration were observed in any of the follow-up visits.
2. Among both the groups receiving treatment, there was no evidence of postoperative macular oedema on slit-lamp examination which was then confirmed by Optical Coherence Tomography (OCT).
3. There weren't any other abnormal clinically significant ophthalmic findings.

4. Discussion

Cataract surgery in modern times comes with high expectations by patients. Advanced cataract surgery techniques, equipment, and pharmacologic agents have raised the bars for both surgeons and patients. The use of topical steroids as postoperative medication to control inflammation has been the standard practice in most ocular surgeries, as uncontrolled ocular inflammation can affect not only visual recovery but also the surgical outcome. Topical antimicrobial and anti-inflammatory therapy have various limitations and hence impose burden on patient and physician and can further compromise the outcomes. With recent growing interest towards alternative postoperative 'dropless' ophthalmic drug delivery methods, our study is set out to explore a simple subconjunctival approach with common and widely available ophthalmic topical corticosteroids.[7]

Corticosteroids are commonly administered following cataract surgery due to their ability to decrease the production of various inflammatory mediators. Triamcinolone acetonide (TA) is a corticosteroid of moderate potency that offers a relatively extended duration of effect. Subconjunctival TA depot provides a treatment method in immediate post-operative period as it provides an anti-inflammatory coverage in first 24 hours after cataract surgery as apposed to topical formulations of corticosteroids, which can be instilled only after 24 hours, once the eye bandage is removed.

Moreover, Subconjunctival TA serves the purpose of pro-longed anti-inflammatory therapeutic effect, which can

last upto 40 days and can help in reducing the complications related to patient non-adherence with eye drop administration.

Other attributes include- safety, efficacy and ease of removal if necessary. With increasing incidence of cataracts in recent times, there are multiple patient-related issues such as non-compliance, patient in convenience and increasing cost. Several eye health issues, including adverse effects on the cornea, disruption of the tear film, and irritation from topical treatments, can be addressed with a single subconjunctival corticosteroid injection. Triamcinolone acetonide has gained popularity in ophthalmology due to its safety and effectiveness, as it minimizes the likelihood of post-surgery inflammation and reduces the risk of post-operative endophthalmitis.[8,9] Triamcinolone is utilized in treating various eye conditions, such as cystoid macular edema, age-related macular degeneration (ARMD), and persistent uveitis. It is also administered as a sub tenon injection to manage inflammation following surgery.

In our research, 53% of patients in Group A and 46% in Group B exhibited a BCVA ranging from 0 to 0.2 on the first day after surgery. At the initial visit, there was no statistically significant difference in post-operative BCVA between the two groups (p-value = 0.14). By the seventh day post-operation, BCVA showed a gradual improvement. In Group A, 53% of patients had a BCVA between 0 and 0.2, compared to 51% in Group B. Again, no statistically significant difference was found between the BCVA values of Group A and Group B at the second post-operative visit (p-value = 0.295). During subsequent follow-up visits, no statistically significant differences in BCVA values were observed between the two groups (p-value > 0.05).Hence, both groups prove to be equally efficacious in terms of Post-operative BCVA.

Study conducted by Lindholm *et al* showed comparison between topical Dexamethasone eye drops and Triamcinolone Acetonide groups, where Corrected distance visual acuity (CDVA; LogMAR) improvement was observed at 7 days (*p-value*= 0.827), at 28 days (*p-value*= 0.796), and at 90 days (*p-value* = 0.634).[10]

The difference in mean IOP values obtained between Group A and Group B on post-operative Day 1 was not found to be statistically significant(*p-value* = 0.119). Similar results were obtained on further follow-up visits. No statistically significant difference was obtained on any further post-operative visit. Hence, both groups prove to be equally safe and efficacious in terms of Post-operative IOP.

Weijtens *et al* suggested that periocular injections of corticosteroids induce a higher concentration of the steroidal agent than topical administration.[11]

According to the research by Lindholm et al., the postoperative changes in intraocular pressure (IOP) were similar across the study groups during all follow-up appointments. There were no notable increases in IOP; none of the eyes that underwent surgery exhibited an IOP exceeding 25 mmHg or an increase from the baseline of more than 10 mmHg.[10]

Study conducted by Kalina *et al* showed that pharmacologically active triamcinolojabsne was identified upto 13 months following injection (Range- 3-13 months). The mean amount in excised sample was 5.4mg , around 20% of the original sample. Glaucoma was diagnosed after a mean of 3 months post-injection. Mean IOP was 37mmHg before excision of depot as compared to 16 mmHg after removal.[12]

Anterior chamber flare/cells, an indicator of ocular inflammation, were assessed using the Standardization of Uveitis Nomenclature (SUN) working group guidelines with a slit-lamp for clinical data reporting.[13] Levels peak on the first day after surgery, then decrease rapidly within the first week, with no significant difference in cells/flare between Group A and Group B (p-value > 0.05). By the seventh day post-surgery, there was complete resolution of cells/flare. Shah and Spalton reported a similar pattern, with cells/flare reducing to nearly none by 12 weeks.[14]

Study conductedby Merkoudis *et al* showed groups that received subconjunctival methylprednisolone injection and topical dexamethasone eye drops had no difference in mean values of anterior chamber cells and flare.[15]

Size of SCTA depot at injection time was around 5-6 mm and given in inferotemporal quadrant. The depot had completely disappeared in over 95% patients by visit 3, with the rest having a depot of less than 1 mm. But the location and size of the depot were cosmetically unacceptable to the patients initially, due to whitish appearance and mild heaviness complained by patients. However, patients were eventually satisfied with these injections being given in lower fornix.

In our study group (Group A), minimal Subconjunctival hemorrhage was noted in a total of 12 patients at visit 1, that was completely resolved by post-operative Day 7 (visit 3). Minimal Subconjunctival haemorrhage was also noted on post-operative Day 1 in a total of 9 patients in control group (Group B), that resolved completely by Post-operative Day 7 (visit 3). Apart from Subconjunctival haemorrhage, no other local adverse effects like chemosis, necrosis/ulceration were noted at any follow up visits.

Macular oedema, a common complication of cataract surgery, is best detected using OCT, particularly the centerpoint thickness parameter.[16] Macular oedema is defined as a relative increased diffuse thickening, with or without cystoid abnormalities and visual loss. No patient in either group developed postoperative macular oedema at any follow-up visit.

Advantage of this study included large sample size with a proper follow-up assessment.

5. Conclusion

In our study, both the groups (Study Group A and Control Group B) prove to be equally safe and efficacious in terms of post-operative BCVA, IOP and AC Reaction and neither any untowered complications nor any major adverse effects have been observed in either group.

Hence, we can conclude, a single subconjunctival injection of triamcinolone acetonide as a useful alternative to prolonged administration of tapering topical corticosteroids eye drops, to prevent post-operative inflammation. A single depot injection also overcomes various patient-related and ocular surface related problems. Therefore, this new physician-administered approach to infection and inflammation control is not only safe and effective, but also absolve the patient of self-dosing responsibility, and may increase patient satisfaction and improve overall patient experience

6. Limitations

1. AC flare/cells – Post-operative analysis was done using slit-lamp examination. Post-operative laser flare photometery, that provides a more objective measurement, could have added value to the study.
2. Patients falling in exclusion criteria could not be assessed. Hence, safety and efficacy in a few typical scenarios could not be explored.
3. Seven patients that dropped out of the study during follow-up could not be assessed further.
4. Documenting patient perspectives on therapeutic modalities and evaluating subjective satisfaction or comfort could add value to this study. We believe a single subconjunctival injection of triamcinolone acetonide post-routine phacoemulsification surgery can replace prolonged tapering of topical steroids to prevent intraocular inflammation and macular oedema. Though both the options prove to be equally safe and efficacious.

7. Source of Funding

None.

8. Conflict of Interest

None.

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