To Study the Effect of Topical Diclofenac Sodium 0.1% as An Alternative to Topical Steroid, Dexamethasone Phosphate 0.1% for Post-Operative Control of Inflammation after Small Incision Cataract Surgery

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Abstract

Aims: To study the effect of topical Diclofenac sodium 0.1% as an alternative to topical steroid, Dexamethasone phosphate 0.1% for post-operative control of inflammation after small incision cataract surgery. *Settings and Design:* Double blinded study done in a tertiary care hospital. *Methods and Material:* 100 patients with uncomplicated senile cataract who underwent uneventful small incision cataract surgery with posterior chamber intra ocular lens implantation were selected and divided into 2 groups of 50 each. One group was given dexamethasone phosphate 1%, other group diclofenac sodium 0.1% topically. They were examined on 7, 15, 30th day for congestion, corneal edema, anterior chamber flare, cells, intraocular pressure and grading was done as per severity and total score was assessed. The results were compared between the two groups. *Statistical Analysis used:* Chi square test with p value < 0.05 as significant. *Results:* Day 7 and 15 the response was good for dexamethasone group for all the parameters. By day 30 there was no significant difference between the two groups in all the parameters. No significant difference in IOP at baseline and at 6 weeks post operatively between the two groups. *Conclusions:* The resolution of inflammation was quicker in the dexamethasone group than in the diclofenac group. But by the end of 30 days the effect on inflammation in both the groups are similar. So Diclofenac sodium 0.1% can be used as an alternative to Dexamethasone phosphate 0.1% in post operative patients following cataract surgery.

Keywords: Postoperative Inflammation; Dexamethasone Phosphate 0.1%; Diclofenac sodium 0.1%.

Introduction

In India 3.8 million become blind yearly due to cataract [1]. Mild post-operative inflammation is a normal accompaniment occurs due to surgical trauma leading to disruption of blood aqueous barrier, leakage of protein and cells into anterior chamber triggering the inflammatory cascade[2]. Anti-inflammatory therapy is to hasten the resolution and avoid complications of prolonged inflammation, like pain, photophobia, foreign body sensation, reduced visual acuity, posterior synechiae, raised intraocular pressure [3].

Topical corticosteroids are effective in suppressing

postoperative inflammation. However, they have many side effects, like impaired wound healing, elevation of intraocular pressure and increased tendency of infections, tear-film instability[4]. Recent studies suggest that topical non-steroidal antiinflammatory drugs (NSAIDs) are as effective as corticosteroids in re-establishing the blood aqueous barrier following cataract surgery.

This study aims at studying the effect of topical Diclofenac sodium 0.1% as an alternative to topical

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steroid, Dexamethasone Phosphate 0.1% for postoperative control of inflammation after cataract surgery.

Key Message

Topical Diclofenac is an alternative for topical Dexamethsone after SICS.

Subjects and Methods

This study was conducted in a tertiary care hospital from 2013 to 2014.Written informed Consent was obtained from the patients. It is a randomized double blind study. Included 100 patients.

All the patients who were having an uncomplicated senile cataract who underwent uneventful SICS+PCIOL implantation were included in the study. Any operative or postoperative complication, those taking topical/oral steroids or NSAIDs, patients requiring postoperative additional medication, ocular or systemic diseases, and patients having history of ocular trauma were excluded. Preoperative assessment was done. Patients underwent SICS with PCIOL under LA. Post operatively either Diclofenac (group A) or Dexamethasone (group B) was administered to the 2 groups which included 50 patients in each group. Patients were examined postoperatively on days 7, 15, 30. Patients were examined for congestion, corneal edema and anterior chamber flare and cells, intraocular pressure. All parameters were graded (0, 1, 2, 3) according to their severity. Total score was assessed. Grade None (0) Mild (1-3) Moderate (4-7) and Severe (8 & above).

Results

Mean age of the patients was 59.98 ± 9.11 years with age range of 40 - 75 years.

Table 1: Superficial conjunctival congestion

Total score	Day 7		Day 15		Day 30	
Grades	Group A	Group B	Group A	Group B	Group A	Group B
None	29(58%)	4(8%)	49(98%)	33(67%)	50(100%)	50(100%)
Mild	21(42%)	45(90%)	1(2%)	17(32.6%)	0(0%)	0(0%)
Moderate	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Severe	0(0%)	1(2%)	0(0%)	0(0%)	0(0%)	0(0%)

p value for day 7 is 0.00001 statistically significant

p value for day 15 is not statistically significant

Table 2: Ciliary congestion

Total score	Day 7		Day 15		Day 30	
Grades	Group A	Group B	Group A	Group B	Group A	Group B
None	49(48%)	28(56%)	50(100%)	47(95.9%)	50(100%)	50(100%)
Mild	1(2%)	22(44%)	0(0%)	3(4%)	0(0%)	0(0%)
Moderate	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Severe	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)

For day 7 p value is statistically significant

For day 15 p value is 0.14. not significant

Table 3: Corneal edema

Total score	Da	Day 7		Day 15		Day 30	
Grades	Group A	Group B	Group A	Group B	Group A	Group B	
None	46(92%)	44(88%)	47(94%)	48(96%)	50(100%)	50(100%)	
Mild	4(8%)	6(12%)	3(6%)	2(4%)	0(0%)	0(0%)	
Moderate	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	
Severe	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	

p value for day 7 is 0.5 not statistically significant p value for day 15 is 0.64 not statistically significant

Table 4: Anterior chamber flare

Total score	Day 7		Day 15		Day 30	
Grades	Group A	Group B	Group A	Group B	Group A	Group B
Absent	45(90%)	11(22%)	49(98%)	41(83.6%)	50(100%)	50(100%)
Mild	3(6%)	36(72%)	1(2%)	8(14.2%)	0(0%)	0(0%)
Moderate	2(4%)	3(6%)	0(0%)	1(2%)	0(0%)	0(0%)
Severe	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)

P value for day 7 is <0.0001 statistically significant

p value for day 15 is 0.007 statistically significant

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Total score	Day 7		Day 15		Day 30	
Grades	Group A	Group B	Group A	Group B	Group A	Group B
Absent	25(50%)	0(0%)	43(86%)	22(45%)	50(100%)	50(100%)
Mild	24(48%)	30(60%)	7(14%)	27(53%)	0(0%)	0(0%)
Moderate	1(2%)	20(40%)	0(0%)	1(2%)	0(0%)	0(0%)
Severe	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)

 Table 5: Total score of postoperative inflammatory response

p value for day 7 and day 15 are > 0.05 so statistically not significant

Table 6: Intraocular pressure at end of 6 weeks

IOP	Group A	Group B
14 mm of Hg	4(8%)	4(8.3%)
16 mm of Hg	18(36%)	27(56.2%)
18 mm of Hg	21(42%)	17(35.4%)
20 mm of Hg	7(14%)	0(0%)
Total	50(100%)	50(100%)

In This Study

Days 7 & 15: Significant difference was noted with respect to conjunctival and ciliary congestion, with faster response occurring in patients on Dexamethasone

Anterior chamber flare and cells responded much quicker, within 15 days to topical Dexamethasone 0.1%, when compared to Diclofenac 0.1%.

At the end of 30 days, according to total scoring of inflammation both drugs showed equal efficacy.

No significant difference in IOP at baseline and at 6 weeks post operatively between the two groups.

Discussion

It is a routine practice to use steroids after cataract surgery. Steroids interfere with the inflammatory response in a variety of ways, but the steroid treatment can have many side effects such as increased IOP, delayed wound healing and increased chance of post operative ocular infection[5].

Diclofenac indirectly modulates also the lipoxygenase pathway in the arachidonic acid cascade. The potential advantages of using NSAIDs after cataract surgery are the lack of IOP rise and decreased impairment of wound healing. Thus NSAIDs can be used after cataract surgery to control inflammation as shown in study[6].

In a study conducted by Muhammed Wasim and Humayun the anterior chamber cell count was not comparable postoperatively between the two groups on the first day and first week where dexamethasone showed a better anti inflammatory response than the diclofenac group. The anterior chamber cell distribution did not vary significantly between the two groups at 3 weeks or 5 weeks postoperatively [7] comparable to our study.

In a study between diclofenac sodium and dexamethasone, Reddy *et al.* found that the treatment effects for any of the variables including aqueous cells, flare, ciliary congestion, descemets' folds and intraocular pressure did not show statistical difference three weeks postoperatively[8].

Conclusion

The resolution of inflammation was quicker in the dexamethasone group than in the diclofenac group. But by the end of 30 days the effect on inflammation in both the groups are similar. So Diclofenac sodium 0.1% can be used as an alternative to Dexamethasone phosphate 0.1% in post operative patients following cataract surgery.

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