



Effects of Anti Inflammatory Agents Following Cataract Surgery

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ABSTRACT

Objectives: To assess and compare the analgesic and anti inflammatory efficacy of nepafenac and prednisolone eye drops used individually and in combination in post-operative period of cataract surgery by estimating anterior chamber cell count (ACCC) and pain in visual analogue scale (VAS).

Materials and Methods: A total of 156 subjects after cataract surgery were allocated through lottery to 3 groups (n=52 each). Group A: with topical nepafenac: 1 drop thrice daily for 3 weeks, Group B with topical prednisolone: 1 drop four times daily for 3 weeks. Group C with combination of nepafenac and prednisolone as per the schedule for group A and B respectively. Drugs were continued for 22 consecutive days and there were four follow-up visits on day 4, day 8, day 15 and day 22. Anterior chamber cell count (ACCC) and pain were determined by slit lamp bio microscope and visual analogue scale respectively.

Results: End results of group A for ACCC and pain were 5.41 ± 0.44 and 1.27 ± 0.41 respectively. In case of group B, ACCC and pain were 1.09 ± 0.32 and 0. Group C showed the best results where for ACCC and pain were 0.40 ± 0.22 and 0 respectively.

Conclusion: Combination of Prednisolone and nepafenac eye drops was the most efficacious in reducing inflammation and pain after cataract surgery.

Key Words: Cataract surgery, prednisolone and nepafenac.

Introduction

Senile cataract is the leading cause of blindness all over the world.^[1,2] Of the world's total blind people, cataracts affects about half and about a third of these are in India.^[3,4] Cataract is responsible for blindness and visual impairment in 55% cases of our country. Cataract related morbidity like pain, inflammation, cystoid macular edema, corneal edema and chronic irritable eye may also occur.^[5,6,7] To counter such complications, a number of non steroidal anti inflammatory drugs (NSAID) and steroids in the form of eye drops are available at present in Indian market.^[8-17] Nepafenac eye drop is one of

such latest NSAID used commonly in post-operative inflammation of cataract surgery.^[8-11] Nepafenac eye drops are also used to maintain intraoperative mydriasis and to prevent cystoid macular oedema (CME). Another important drug which at present used routinely to prevent post-operative inflammation of cataract surgery is prednisolone, a steroid.^[16,17] Several studies were conducted with prednisolone acetate eye drop used to prevent post-operative inflammation of cataract surgery and the treatment was very effective without any adverse event.^[18] Ophthalmic corticosteroids have long been used as first-line therapy for the treatment of ophthalmic

inflammatory conditions prior to the increased use of ophthalmic NSAIDs.^[99] The ophthalmic NSAIDs offer equivalent anti-inflammatory efficacy for post-operative inflammation. There are no data to suggest a significant advantage for any one product in either subclass in terms of clinical effectiveness or adverse effect profile, nor are there data that show a difference between agents in different subclasses. There exists paucity of Indian study with nepafenac and prednisolone eye drop. Considering these facts a study was planned to compare the analgesic and anti-inflammatory efficacy of nepafenac eye drop and prednisolone eye drop used individually and in combination for the post-operative inflammation of cataract surgery in eastern India.

Materials and Methods

This prospective, parallel, single masked (assessor blind), randomized, unicentric study was performed in a tertiary care hospital (Government Medical College) in eastern India. Prior to the study and the protocol was approved by IEC. After patients were screened as per inclusion and exclusion criteria 156 patients were randomly selected by the computer generated random number and the written informed consent were obtained from each of them. Individual case record form (CRF) was properly filled up by interrogation of the patients. Healthy patients of either sex , 50 years or above with cataract of either eye were included in the study. Patients with evidence of severe uveitis, suspected endophthalmitis, corneal edema, Diabetes mellitus, psychiatric illness or patients using steroids or analgesic for any ailments and hypersensitivity to nepafenac or prednisolone were excluded. All the patients were operated by single surgery and underwent small incision cataract surgery (SICS). Patients were divided into three groups, each comprised of 52 patients. Group A received nepafenac (0.1%) eye drop 1 drop thrice daily for 3 weeks. Group B received prednisolone (1%) eye drop 1 drop four times daily for 3 weeks . Group C patients were given

the combination of nepafenac and prednisolone as per the schedule for group A and B respectively. All three groups got moxifloxacin eye drop in addition. Patients were asked to come on 4th, 8th, 15th and 22nd post operative day for follow ups. On each follow up the subject was placed before the slit lamp bio microscope. Fixing the magnification at 1 mm x 1 mm level anterior chamber cell count (ACCC) were estimated and the flare status was graded. The pain was graded according to visual analogue scale (VAS) gradation. First postoperative day findings of cataract surgery was considered as baseline data.

Calibration

Slit lamp bio microscope (1mmx1 mm) was used to estimate the ACCC and VAS scale for assessing pain. Statistical analysis within the group was done by Friedman test (non parametric repeated measures ANOVA) followed by post hoc analysis of Dunn's multiple comparison test. Between the 3 groups (group A, group B and group C) statistical analysis was done by non parametric Kruskal Wallis test followed by Dunn's multiple comparison test. P values < 0.05 were considered significant.

Results

All 156 study subjects were recruited on an ambulatory basis. The subjects in all the three groups had comparable demographic profile as shown in table 1. Base line scores are also summarized in this table. Regarding ACCC the base line score of group A is 18.64 ± 0.89 , while the day 22 score was 5.41 ± 0.44 . For group B the base line and the day 22 scores were 19.36 ± 1.69 and 1.09 ± 0.32 respectively. Group C showed the best result as it's base line score 21.23 ± 1.69 went to 0.40 ± 0.22 on day 22. All these data are shown in table 2. The pain score in group A changed from 37 ± 2.90 to 1.27 ± 0.41 . But in case of group A and group B, base line scores 37.78 ± 2.25 and 39.84 ± 2.20 respectively went to 0 on day 22 shown in table 3.

Table 1: Demographic profile of the recruited subjects & vital parameters :

Parameters	Group 1	Group 2	Group 3	P value
Mean age(years) ± SEM	62.01 ± 1.30	61.17± 1.10	61.80 ± 1.10	NS
Sex				
Male(%)	22(42.30)	25(48.07)	29(55.77)	NS
Female(%)	30(57.70)	27(51.93)	23(44.23)	NS
Mean ACCC± SEM	18.64 ±0.89	19.36 ±1.68	21.23 ±1.69	NS
Mean Pain score(VAS) ±SEM	37.74 ±2.90	37.78±2.25	39.84±2.20	NS

SEM=Standard error of mean ,VAS=Visual analogue scale, NS=Not significant, ACCC=Anterior chamber cell count, P values from post hoc analysis Dunnett's test.

Table 2 : Change of score of anterior chamber cell count :

Visits	Group A	Group B	Group C
Day 0	18.64±0.89	19.36±1.68	21.23±1.69
Day 4	14.07±0.70	10.86±0.84	7.88±0.85
Day 8	11.07±0.58	5.78±0.56	2.88±0.62
Day 15	8.17±0.44	2.51±0.42	0.71±0.26
Day 22	5.41±0.44	1.09±0.32	0.40±0.22

Mean score of anterior chamber cell count ± standard error of mean

Table 3 : Change of score of pain in VAS :

Visits	Group A	Group B	Group C
Day 0	37.74±2.90	37.78±2.25	39.84±2.20
Day 4	20.39±1.58	17.01±1.79	13.17±2.16
Day 8	9.50±1.16	3.46±0.95	1.34±0.47
Day 15	4.21±0.78	0.57±0.29	0.00±0.00
Day 22	1.27±0.41	0.00±0.00	0.00±0.000

Mean score of pain in VAS ± standard error of mean

Discussions

In India most of the cataract patients belong to age group sixty years and above. ^[2,3] In our setting senile cataract is found at above the age of fifty years generally. That's why this age bar was included in the study. Both sex were included to avoid bias in the study result. One eyed persons were excluded as the previous pathology of the affected eye might lead to catastrophe in the existing functioning eye. Patients with post operative complications like severe uveitis, endophthalmitis and corneal edema might not be affected properly by our study drugs and not only that they would require some other special intervention. Diabetic patients could modify pain and psychiatric patients could not follow VAS or express properly. With existing uveitis and glaucoma patients were also excluded as they could also modify pain. Patients already using steroids and analgesics would be little responsive

to prednisolone and nepafenac eye drops. Patients having hypersensitivity to nepafenac and prednisolone were natural exclusion. The present study was a randomized controlled clinical trial to evaluate the efficacy of prednisolone and nepafenac in post-operative patients of cataract surgery. They were assigned to three treatment groups by randomization. The groups were comparable at baseline with a comparable scores of anterior chamber cell count through slit-lamp bio-microscope and 82 pain in VAS scale. AC cell count and pain were the primary objectives. The secondary objective was to note any adverse event.

Acknowledgements

We acknowledge the support and co operation of the Department of Pharmacology and Ophthalmology, R.G. Kar Medical College and Hospital, Kolkata-700004.

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