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A Comparison of Efficacy of Nepafenac 0.1% with Nepafenac 0.3% Drops for the Management of Post-Operative Inflammation and CME in Uneventful Phacoemulsification

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ABSTRACT

Aim: To compare the efficacy of two topical nonsteroidal anti-inflammatory drops (NSAIDs) used in isolation in controlling inflammation and preventing cystoid macular edema (CME) after uneventful phacoemulsification.
Design: Single armed randomized prospective study
Methods: 200 patients who underwent uneventful phacoemulsification from December 2020 to March 2021 by a single surgeon were randomly assigned to be given one of the two NSAID drops. Among the 200 individuals those were included in the study, 192 patients completed follow up visits at 1 and 6 weeks and were included for analysis of the results. The efficacy of the drugs was evaluated by comparing the grade of pain score, conjunctival hyperemia, anterior chamber (AC) cells, along with best corrected visual acuity (BCVA), central macular thickness (CMT) and intraocular pressure (IOP) recorded at 1 and 6 weeks after surgery.
Results: Between the two NSAID groups, there was no significant difference in pain ratings, AC cell grade, or visual acuity. There was no significant difference in the number of patients experiencing CME at 6 weeks. At 1 and 6 weeks, however, the mean rise in central macular thickness and conjunctival hyperemia in nepafenac 0.3 percent was much smaller.
Conclusion: The efficacy of both the topical NSAIDs was found to be comparable in terms of pain score, AC cells grade and visual acuity. Though occurrence of CME after surgery was similar in both the NSAID's, subclinical CME was less in Nepafenac 0.3% group both at 1st and 6th week follow up.

Key Words: non-steroidal anti-inflammatory drugs, visual acuity, central macular thickness, cystoid macular edema, phacoemulsification.

INTRODUCTION

Cataract extraction is among the most frequent ocular surgeries done across the globe. Recent advances in instruments, lens design, and surgical technique have improved the results of cataract surgery.[1] Currently, phacoemulsification with a tiny incision and intraocular lens implantation is the recommended method.[2]

The use of topical medicines both before and after contemporary cataract and lens surgery improves the procedure's success. topical therapies include Antibiotics, Steroids, Nonsteroidal Anti-Inflammatory Drug (NSAIDs), and the whole range of glaucoma treatments are used to modulate intra ocular pressure (IOP) and provide perioperative period care. Many surgeons have discovered that nonsteroidal anti-inflammatory drugs (NSAIDs) are an essential tool for achieving the best surgical results in both regular and difficult cataract surgeries. Topical NSAIDs have been

shown to be a safe and effective alternative to corticosteroids in the prevention and therapy of non-infectious ocular inflammation and cystoid macular edema as a class of medications (CME). They've also been proposed as a means to manage intraoperative mydriasis and alleviate postoperative pain. As a treatment for high-risk eyes with CME, NSAIDs alone or with corticosteroids seem to be effective.[3,4,5]

Nepafenac is a prodrug that rapidly penetrates the cornea. When nepafenac and diclofenac were compared in vitro, nepafenac entered the cornea 6 times quicker.[6] Intraocular hydrolases deaminate the molecule to amfenac, a strong COX-1 and COX-2 inhibitor, once it reaches the aqueous.[7] According to studies, nepafenac is more powerful than ketorolac or diclofenac.[8] 0.1 percent nepafenac ophthalmic suspension (Nevanac) is a topical ocular nonsteroidal anti-inflammatory drug (NSAID) used to relieve discomfort and prevent inflammation after cataract surgery.[9]

The USFDA-approved nepafenac 0.3 percent (Ilevro) which can be administered once a day to prevent and cure ocular inflammation and discomfort following cataract surgery.

Not many literatures are available comparing the safety and efficacy of both the drugs especially in Indian eyes. Thus, we compared the safety and efficacy of topical Nepafenac 0.1 % (Nevanac) with Nepafenac 0.3% (Ilevro) used as a sole agent in controlling postoperative inflammation and preventing CME after uneventful phacoemulsification.

MATERIAL AND METHODS

This was a single centre, randomized prospective study comparing nepafenac 0.1% with nepafenac 0.3% eye drops in patients undergoing uncomplicated phacoemulsification. The institutional ethics committee approved the study protocol. According to the principles of the Helsinki Declaration, the study was carried out. Before surgery, all patients sign a written informed consent allowing their data and outcomes to be utilised for research and publishing.

For analysis, a review of the electronic medical records of adult patients who underwent uneventful phacoemulsification with in the bag IOL placement by a single surgeon and completed six week follow up was performed over a 4 months period from December 2020 to March 2021.

Inclusion criteria: Patients who received topical nepafenac 0.1% and nepafenac 0.3% as the sole anti-inflammatory agent were selected.

Exclusion criteria: Presence of chronic ocular inflammation; presence of any ocular pathology other than cataract including severe dry eyes, history of use of topical NSAIDs or steroids or oral alpha agonists like tamsulosin or oral or inhalational steroids or NSAIDs, history of previous ocular trauma or surgery; diabetics who had retinopathy; patients with known autoimmune diseases, presence of any intra or postoperative complications, non-compliance with the scheduled follow-ups and any known hypersensitivity to the drugs administered in the study. Any procedure with a Cumulative Dissipated Energy (CDE) of more than 20 was ruled out. Out of the 100 patients selected, a total of 96 patients [96 eyes] from each group met the selection criteria and were included for analysis.

All patients received topical therapy including moxifloxacin hydrochloride 0.5% 4 times a day for 2 weeks and Carboxymethylcellulose 1% eye drop 4 times a day for 6 weeks along with the NSAID eye drop. All patients underwent a sutureless 2.2-mm clear corneal incision, continuous curvilinear capsulorhexis, phacoemulsification using the direct chop technique with Centurion Vision system (Alcon, Vernier-Geneva, Switzerland) and implantation of hydrophobic acrylic foldable IOL in bag. All surgical procedures used 1.4% hyaluronic cohesive viscoelastic

solution (Aurogel 1.4%w/v, Aurolab, Tamil Nadu, India).

Patients were divided into 2 groups based on anti-inflammatory treatment used. The treatment regimen used is as follows:

Group 1: nepafenac (0.1%) [n=96] thrice daily for 6 weeks

Group 2: nepafenac (0.3%) [n=96] once daily at bed time for 6 weeks

Data from all the patients were analyzed at baseline (before surgery) and at 1 and 6 weeks after the surgery. Since the majority of the patients were out of town, follow-up was restricted to one week and six weeks to reduce the number of patients who dropped out of the examination. Signs of postoperative inflammation were evaluated. Ocular pain was graded using a category scale as 0 indicating no pain, 1 indicating occasional pain, 2 mild but pain occurred daily, and 3 moderate to severe pain, requiring an oral analgesic. Slit-lamp assessment was performed for the following signs: Conjunctival hyperemia, which was graded as per published picture of the International Chronic Ocular Graft-vs-Host-Disease (GVHD) Consensus Group: from Grade 0 to 2 [Grade 0 = none, Grade 1 = mild/moderate, Grade 2 = severe]; and Cells in anterior chamber (AC), which were ranked from 0-4 as per the standardized uveitis nomenclature (SUN) classification of severity of uveitis. [10,11]

The visual acuity was recorded using Snellen's chart and converted into LogMAR and analyzed at each visit. The best corrected visual acuity (BCVA) less than 6/9 at last follow-up was analyzed to find the cause.

Central macular thickness and CME was assessed using a swept-source optical coherence tomography device [DRI Triton Topcon, SS-OCT (Hasunuma-cho, Itabashi-Ku, Tokyo, Japan)]. All the scans were performed by a single experienced ophthalmic technician at baseline, 7 days and 6 weeks post-surgery. A 6mm cube scan focused on the fovea was used to determine central macular thickness (CMT). CMT increases are an objective sign of macular edema and may be used to show the extent of inflammation after cataract surgery. Since it has been reported that an average increase in foveal thickness of 10 to 22 (+/- 24) microns occurs after an uncomplicated phacoemulsification, a rise in CMT by 40 or more microns from baseline value or presence of cystic spaces on OCT was considered to be significant and was referred as subclinical CME.[12]

Clinical CME was defined as significant increase in CMT along with visible cystic changes and final BCVA less than 6/9. Intraocular pressure (IOP) was measured using a non-contact pneumo-tonometer (Nidek CO., LTD. Kayoto, Japan) at all visits and included in the research to assess the effect of the drugs.

The most important result was intraocular inflammation evaluated by AC cells at 1 and 6 weeks after surgery. Secondary outcomes included conjunctival hyperemia, pain perceived by the patient, BCVA and CMT on OCT at 1 and 6 weeks after surgery. Comparison of CMT was done between diabetic and non-diabetic patients in both the groups at all visits.

Statistical Analysis

The data collected in the process were scrutinized, codified and entered into IBM SPSS Statistics 24.0, SPSS South Asia Pvt. Ltd (No.2353/1-4, Dolphin, Hennur Main Road, Opp. Harmony Apartments, Kacharakanahalli, Bangalore-560043). Significance of association of categorical variables like gender, DM, AC cell score, ocular pain score, conjunctival congestion score, CME and BCVA with Nepafenac 0.1% and 0.3% were studied by using Chi-square test of association. For both the groups, the sample size of more than 90 achieved. The post-hoc power analysis using G. Power 3.1.9.2 is made taking a combined sample of 180 in the group. Using a lower level of conventional effect size of 0.22, α err probability- 0.05, Df = 1, Power was (1-β err prob) =0.8393153. Comparison of mean age in year, BCVA pre-op, change in CMT, BCVA at baseline & 6 weeks and

change in IOP between Nepafenac 0.1% and 0.3% were analyzed by using independent sample 't' test. Association of DM within Nepafenac 0.1% and 0.3% was found using non parametric Binomial test. Comparison of mean OCT macular thickness within Nepafenac 0.1% and 0.3% was made by single paired sample 't' test.

RESULT

A total of 192 patients among the 200 patients enrolled, met the selection criteria and were included for analysis. Baseline characteristics are mentioned in table 1. There was no discernible change in the baseline characters (age, gender distribution, baseline BCVA) among the two groups.

Table 1: Baseline characteristics among both groups

Parameter	Nepafenac 0.1 % (n=96)	Nepafenac 0.3% (n=96)	'p' value
Age in year $	65.9 ± 8.5	64.0 ± 6.6	0.092*
Male : Female	1.5: 0.6	1.2: 0.8	0.381#
DM □	27(28.1%)	28(29.2%)	0.873#
BCVA pre-op (logMAR)$	1.47 ± 0.96	1.29 ± 0.76	0.081*
$ Mean ± SD			
□n(%)			
* Independent sample 't' test 'p' value			
# Chi-square test 'p' value			

Anterior chamber (AC) cells: Evaluation of AC cells at 1 week showed that 51% and 58% of patients had no or minimal AC cells (grade 0) in the nepafenac 0.1% and nepafenac 0.3% group respectively. There was no significant difference in the percentage of patients with AC cells grade of 0, 1+ and 2+ among two groups at 1 week follow up (table 2). None of the patients had AC cells at 6 weeks follow up period.

Table 2: Comparison of AC cells score among both groups

Week	Score	Cells in AC		'p' value
		Nepafenac 0.1 % (n=96)	Nepafenac 0.3% (n=96)	
1	0 n(%)	51(53.1%)	58(60.4%)	0.574
	1 n(%)	42(43.8%)	36(37.5%)	
	2 or more n(%)	3(3.1%)	2(2.1%)	
6	0 n(%)	96(100%)	96(100%)	*

Ocular pain score: Analysis of pain score at 1 week showed that 88% of patients in nepafenac 0.1% group and 92% of patients in nepafenac 0.3% group had no pain (table 3). There was no discernible change in the percentage of patients with pain score of 0 and 1 between the two groups at 1 week follow up. Patients in both the groups achieved a pain score of 0 at 6 weeks follow up period.

Table 3: Comparison of ocular pain score among both groups

Week	Score	Pain score		'p' value
		Nepafenac 0.1 % (n=96)	Nepafenac 0.3% (n=96)	
1	0 n(%)	88(91.7%)	92(95.8%)	0.233
	1 n(%)	8(8.3%)	4(4.2%)	
6	0 n(%)	96(100%)	96(100%)	*

Conjunctival hyperemia: Analysis of congestion score at 1 week showed that there was a statistically significant difference in the percentage of patients with congestion at 1 week (p=0.01). 61% of patients in nepafenac 0.1% and 78% of patients in nepafenac 0.3% had no congestion (table 4). However, all the patients in both groups achieved a congestion score of 0 at 6 weeks follow up visit.

Table 4: Comparison of conjunctival congestion score among both groups

Week	Score	Congestion		'p' value
		Nepafenac 0.1 % (n=96)	Nepafenac 0.3% (n=96)	
1	0 n(%)	61(63.5%)	78(81.3%)	0.012
	1 n(%)	34(35.4%)	16(16.7%)	
	2 n(%)	1(1%)	2(2.1%)	
6	0 n(%)	96(100%)	96(100%)	*

Central macular thickness and CME: Central macular thickness (CMT) was weighed in each visit and compared between the groups (table 5a and 5b). At 1 week even though none of the cases had any cystic spaces evident in OCT, an increase in CMT by more than 40 microns was seen in 7.3% in nepafenac 0.1% group as against none in nepafenac 0.3% group. This was statistically highly significant.

Table 5a: Comparison of number of patients with CME or increase in CMT on OCT among both groups

Time of evaluation		Central macular thickness (CMT)		'p' value
		Nepafenac 0.1 % (n=96)	Nepafenac 0.3% (n=96)	
(1 week-Base line)*	n(%) of patients with subclinical CME	7(7.3%)	0(0%)	0.000*
(6 week-Base line)*	n(%) of patients with subclinical CME	8(8.3%)	3(3.1%)	0.120
(6 week-Base line)*	n(%) of patients with clinical CME	1(1.0%)	1(1.0%)	0.477
* Mean ± SD				

Table 5b: Comparison of change in mean CMT from baseline among both groups

Time of evaluation	Central macular thickness (CMT)		Independent sample 't' test 'p' value
	Nepafenac 0.1 % (n=96)	Nepafenac 0.3% (n=96)	
(1 week-Base line)*	2.8 ± 23.3	-1.1 ± 16.0	0.177
(6 week-Base line)*	12.0 ± 22.7	6.8 ± 11.6	0.045
* Mean ± SD			

However, by 6 weeks, though the number of patients with subclinical CME is more in the Nepafenac 0.1% group it was not statistically significant. 1 patient in each group had clinical CME by the 6 week follow up.

The mean (SD) change in CMT from baseline to 1-week and 6 weeks postoperative period was also compared. It was found that both at 1 week and 6 weeks the mean increase in CMT from baseline was less in nepafenac 0.3% group compared to nepafenac 0.1% group and it was less significant in the 6th week follow up.

Visual outcome: The mean (SD) of baseline BCVA and at 6 weeks follow up was statistically similar among the two groups (table 6).

Table 6: Comparison of visual outcome among both groups

Parameter	Time of evaluation	BCVA Logmar scale		p' value
		Nepafenac 0.1 % (n=96)	Nepafenac 0.3% (n=96)	
BCVA Logmar	Baseline	1.47 ± 0.96	1.29 ± 0.76	0.081*
	6 weeks	0.08 ± 0.11	0.08 ± 0.08	0.994*
n (%) patients with BCVA 6/9 or better	Baseline	3(3.12%)	2(2.1%)	0.650#
	6 weeks	90(93.8%)	93(96.9%)	0.306#
* Independent sample 't' test 'p' value				
# Chi-square test 'p' value				

The percentage of patients with BCVA better than 6/9 at baseline, was also similar in both the groups (table 6). At 6 weeks follow up, was not statistically important in percentage of patients with BCVA better than 6/9.

Analysis of causes of poor visual outcome (<6/9) was done at 6 weeks follow up. Total number of patients who had clinical CME (vision less than 6/9) was one patient in each group. Other than CME 5 patients in Nepafenac 0.1% group and 2 in Nepafenac 0.3% group had poor vision and the causes included macular scar, optic atrophy, epi-retinal membrane, age related macular degeneration, RPE atrophy due to healed CSCR.

IOP: The mean (SD) of the change in IOP from baseline to 1 week and 6 weeks postoperative period was statistically similar between the two NSAID groups (table 7).

Table 7: Comparison of change in IOP from baseline among both groups

Time of evaluation	Change in IOP		Independent sample 't' test 'p' value
	Nepafenac 0.1 % (n=96)	Nepafenac 0.3% (n=96)	
1 week-Base line	-2.2 ± 3.2	-1.5 ± 2.7	0.074
6 week-Base line	-2.6 ± 3.8	-1.1 ± 4.4	0.062

However, minimum change in IOP was observed in nepafenac 0.3% group at 1 and 6 weeks follow-up.

CMT in Diabetic and non- diabetic patients: Table 8 shows total number of diabetic and non-diabetic patients in both the groups which were similar.

Table 8: Comparison of diabetes population within both groups

Associate Condition	Nepafenac 0.1 % (n=96) n(%)	Nepafenac 0.3% (n=96) n(%)
Diabetes	27(28.1%)	28(29.2%)
Non-Diabetes	69(71.9%)	68(70.8%)
Total	96(100%)	96(100%)

CMT was compared between the diabetic and non-diabetic patients in both groups at every visit (Table 9). There was no significant difference in macular thickness between diabetics and non-diabetics in the nepafenac 0.3% group.

Table 9: Comparison of OCT macular thickness at different time point between diabetics and non-diabetics in both groups

Time point	OCT Macular Thickness					
	Nepafenac 0.1 % (n=96)		p' value*	Nepafenac 0.3 % (n=96)		p' value*
	Diabetes (n=27)	Non-Diabetes (n=69)		Diabetes (n=28)	Non-Diabetes (n=68)	
	Mean ± SD	Mean ± SD		Mean ± SD	Mean ± SD	
Base line	216.6 ± 36.0	225.3 ± 38.8	0.317	232.2 ± 30.1	230.4 ± 21.7	0.752
1 week	214.0 ± 37.8	230.2 ± 34.7	0.048	224.1 ± 27.4	232.2 ± 24.7	0.166
6 week	230.0 ± 34.5	236.8 ± 34.2	0.384	236.5 ± 27.1	238.2 ± 24.5	0.769
* Independent sample 't' test 'p' value						

However, in the nepafenac 0.1% percent group difference in CMT was significant at 1 week follow up only.

Adverse events: Both the NSAID topical preparations were well tolerated by patients. None of the patients had any corneal complications or adverse effect needing to change the medication.

DISCUSSION

Cataract surgery is one of the most frequently practiced surgical techniques in developed countries and CME is an important cause of visual loss after phacoemulsification. There are a few number of people who suffer from CME that progresses to the point where their eyesight is permanently impaired. It may show up anywhere from a few weeks to a few months after surgery has taken place.[13]

Topical NSAIDs have been used effectively to control postoperative inflammation after uneventful phacoemulsification, thereby reducing CME. NSAIDs prevent the conversion of arachidonic acid to prostacyclins, thromboxanes, and prostaglandins by inhibiting cyclo-oxygenase (COX) enzymes.

We compared the safety and efficacy of two different concentrations of NSAIDs. The primary outcome of our study was the control of post-operative intraocular inflammation evaluated by cells in the anterior chamber at 1 and 6 weeks after surgery. A progressive decrease in the cell count was found in both groups and by 1st week about 58% of patient had no or occasional cells in Nepafenac 0.3% group against 51% in Nepafenac 0.1% group. More than 88% of patients in both groups feel pain free at the end of 1 week.

At 1 week, 7(7.3%) patients developed subclinical CME in the nepafenac 0.1 % group whereas none of the patients in the nepafenac 0.3% developed subclinical CME. At 6 weeks 8(8.1%) patients and 3(3.1%) patients developed subclinical CME in nepafenac 0.1% and 0.3% groups respectively which was statistically insignificant (p=0.12). 1 case of CME was diagnosed at the end of 6 weeks in both the groups which was not significant statistically (p=0.47One (12.5%) of the eight individuals in the nepafenac 0.1 percent group who had subclinical CME had diabetes. In the nepafenac 0.3 percent group, none of the individuals who had subclinical or clinical CME had diabetes. Since a result, diabetes was not shown to be a risk factor for the development of subclinical CME in our investigation, as the difference in retinal thickness between diabetic and non-diabetic patients in both the nepafenac 0.1 percent and 0.3 percent groups at 6 weeks post-op was statistically insignificant. The impact of straightforward cataract surgery on CMT in well-controlled diabetes individuals without DR was not statistically different from healthy non-

diabetic participants following uncomplicated cataract surgery, according to a study by Guliani BP et al. In other words, following straightforward phacoemulsification, well-controlled diabetics without DR and non-diabetic patients exhibited equal intragroup thickening of the central macular region at weeks 1 and 6, while the intergroup comparison was not statistically significant.[15]

According to Altintas *et al*, both normal and diabetic people had a significant rate of increased CFT after unremarkable phacoemulsification.[14]

We found that nepafenac 0.3% started on the day of surgery was more effective than nepafenac 0.1% management of inflammation after surgery and preventing subclinical CME.

Postoperative Macular Edema incidence has been reduced significantly by 0.1 percent Nepafenac three times daily analysing angiographic leakage evidence, macular thickness and measures of visual acuity, and the treatment is well tolerated with little difference between the treatment and the vehicle only in terms of adverse events. To reduce the required frequency of dosing and improve convenience, phase III clinical trials have shown similar findings in that the higher 0.3% NPF formulation which is also equally effective in PMO prevention when used once daily.[16]

The percentage of patients who achieved clinical success was higher in patients who received once-daily nepafenac 0.3% than in those who received nepafenac 0.3% vehicle (P%.0264). This variation was seen as early as one day after surgery and remained throughout the length of the trial on days 3, 7, and 14. These results are consistent with nepafenac's mode of action and preoperative dose of nepafenac, which lowers inflammation after surgical trauma. The increased concentration of nepafenac 0.3 percent in the tissue prior to surgery is predicted to inactivate COX enzyme activity more effectively, minimise the amplitude of the inflammatory response, and speed the resolution of trauma-induced inflammation. Similarly, when nepafenac 0.1 percent was compared to the control group, considerably more patients achieved clinical success by day 3.[17]

The high clinical success rates with nepafenac 0.3% once daily and nepafenac 0.1% 3 times daily are supported by the corresponding low number of treatment failures. The lowest risk of treatment failure was related with nepafenac 0.3 percent once daily on day 14. Patients should find nepafenac 0.3 percent with once-daily administration more convenient postoperatively, with the potential to improve dose compliance.[18] In the present study also the nepafenac 0.3 % was found to be significantly effective in reducing the CMT by first week of postoperative period.

Nepafenac 0.3% is well tolerated and associated with a low incidence of treatment-related adverse events. There were no significant differences in safety between the 0.3 percent once-daily and 0.1 percent three-times-daily doses of nepafenac, as compared to the findings of prior clinical trials.[19,20,21,22] Our study also confirms the safety profile of use of both concentrations of nepafenac used for 6 weeks without any patient having any adverse effect to the drug.

CONCLUSION

Nepafenac 0.1% and nepafenac 0.3% can be used in isolation and effectively to control inflammation after uneventful phacoemulsification, thus avoiding the adverse effects of topical steroids. The efficacy of both the concentrations of nepafenac was found to be comparable in terms of pain score, AC cells grade and visual acuity. Though occurrence of CME after the surgery was similar with both the NSAID's, subclinical CME was found to be low at 1st and 6 weeks in Nepafenac 0.3%. It also was more effective in reducing conjunctival congestion in comparison to nepafenac 0.1%. Thus, in Indian eyes, nepafenac 0.3 percent is more efficient in managing postoperative

inflammation and maintaining macular thickness due to the simplicity of a once-daily dosage schedule.

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