A Prospective Interventional Study to Evaluate the Efficacy of Nepafenac 0.1% for Prevention of Macular Oedema Associated with Cataract Surgery in Patients with Diabetes

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ABSTRACT

BACKGROUND

Pseudophakic cystoid macular oedema is a significant cause of suboptimal visual acuity post phacoemulsification. Diabetics are at greater risk of developing PCME following cataract surgery. Topical nepafenac ophthalmic suspension 0.1% is used to prevent inflammation postoperatively. We wanted to study the effect of Topical Nepafenac 0.1% eye suspension on macular thickness following phacoemulsification in patients of diabetes mellitus and correlate the final visual acuity and macular thickness.

METHODS

This prospective interventional study was conducted between January 2018 and May 2019 in the Department of Ophthalmology, MMIMSR, Mullana, Ambala. 100 patients based on the inclusion and exclusion criteria were included in the study and phacoemulsification was done. They were divided into two groups of 50 each. Group 1 received topical Nepafenac 0.1% ophthalmic suspension thrice daily along with the routine post-op medications whereas Group 2 received routine post-op medications. The groups were analysed preoperatively and at 2, 4, 6, 8 weeks postoperatively and their CMT was recorded using a SD-OCT. The change in BCVA was analysed with the help of ETDRS letter chart. The data was entered in Microsoft Excel and analysed using SPSS-PC-20 version. Quantitative data was expressed by mean and standard deviation while qualitative data was expressed as percentage. Difference between the proportions was tested with Chi Square Test or Fisher's Exact test while difference between quantitative variable between the two groups was tested with student's 't' test or Mann Whitney U test. For comparison of quantitative data between more than two groups, ANOVA or Kruskal Wallis 'H' test followed by post hoc test was used. A 'p' value of less than 0.05 was considered statistically significant.

RESULTS

A lower percentage of patients in Group 1 developed ME relative to Group 2 (2% vs. 8%; p-value= 0.36). The mean CMT was significantly lower in Group 1 at 2 (p-value<0.01), 4 (p-value<0.001), 6 (p-value<0.001) and 8 weeks (p-value<0.001). A greater percentage of patients in Group 1 (60%) experienced a gain of >15 letters as compared to the baseline (p-value<0.01).

CONCLUSIONS

Topical nepafenac helps in preventing macular oedema and improves the mean gain in letters read at 8 weeks of follow up.

KEY WORDS

Pseudophakic Cystoid Macular oedema, Irvine-Gas Syndrome, Nepafenac, NSAIDs

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BACKGROUND

Cataract surgery is a common and effective procedure which can restore the visual deficit related to cataract formation.¹ With the advent of advances in surgical techniques the incidence of complications associated with phacoemulsification has reduced dramatically; however, cystoid macular oedema (CME) presents itself as a significant cause of suboptimal visual acuity.² The incidence of pseudophakic cystoid macular oedema is thought to be around 1.17–4.2% of the patients, depending on the definitions and diagnostics modalities used.^{3,4,5,6,7,8} The incidence of clinically detectable CME following phacoemulsification is thought to be around 0.1% to 2.35%.^{5,9} Whereas when OCT is used for diagnosis, the incidence shoots up to 4% to 11%,¹⁰ some studies have also reported the incidence to be as high as 41%.¹¹

Macular oedema develops typically 4-12 weeks after surgery in 2% of the patients undergoing uneventful cataract surgery but can be close to 20% when the surgery is complicated by severe trauma to the iris or vitreous loss following rupture of the posterior lens capsule.¹² In majority of the patients CME resolves spontaneously with improvement of visual acuity within 3–12 months. If the oedema is chronic (more than 6-9 months) permanent damage to the photoreceptors with retinal thinning and fibrosis can occur.^{13,14,15,16} Fundoscopy is the gold standard in diagnosing pseudophakic CME, but treatment responses would be more conveniently monitored by bio microscopy, visual acuity and OCT. Optical coherence tomography (OCT) is used to obtain high-resolution cross-sectional imaging of the macula. Pseudophakic CME on OCT is characterized by loss of the foveal depression, retinal thickening, and cystic hyporeflective areas within the macula.

We wanted to evaluate efficacy of nepafenac 0.1% in the prevention of macular oedema (defined as $\geq 30\%$ increase in central subfield macular thickness from baseline) when used for 60 days following cataract surgery in patients with history of diabetes for a minimum of 5 year^{17,18}

METHODS

This is a prospective interventional study, which was conducted in the Department of Ophthalmology, MM Institute of Medical Sciences and Research Mullana, Ambala from January 2018 to May 2019. All patients of any gender above the age of 40 years with history of diabetes mellitus for more than 5 years having visually significant cataract requiring surgery during the study period.

Exclusion Criteria

1. Patients younger than 40 years of age.
2. Patients with high myopia.
3. Patients with history of use of steroids, immunosuppressants and NSAIDs 14 days prior to surgery.
4. Patients with known hypersensitivity to any component of study drug. (Based on history)
5. Patients with history of bleeding disorders or patients on anti-coagulant therapy.

6. Patients having undergone intraocular surgery, retinal laser photocoagulation, intravitreal injections, and complicated cataract surgery due to loss of vitreous or rupture of the posterior capsule.
7. Patients suffering from uveitis, glaucoma, prostaglandin use or any other ocular pathology that could cause macular oedema.
8. Patients with systemic diseases apart from diabetes.
9. Patients not giving consent.

A total of hundred eyes of hundred patients who were known cases of diabetes mellitus (type 1 & type 2) and fitted the inclusion criteria were selected and phacoemulsification with posterior chamber intraocular lens implantation was done in all the patients, following this they were divided in two groups (1:1). The following data was collected after an informed and written consent was taken from all the patients before surgery in accordance with the declaration of Helsinki. Slit lamp examination of the eye was done and the cornea was assessed for any preoperative pathologies like punctate keratitis which is a known complication of long duration nepafenac therapy. All patients were given oral antibiotics twice daily for 5 days, oral analgesics were given on need basis, topical antibiotics (eye drop moxifloxacin 0.5%) which were given on 2 hourly basis for the first 7 days and were tapered to 4 times daily for 3 weeks following which it was stopped and topical steroids (ophthalmic suspension of prednisolone acetate 1%) were given 6 times for 2 weeks and then stopped. The patients in Group 1 were given topical nepafenac 0.1% drops thrice daily started one day prior to surgery, on the day of surgery one drop was put in the designated eye 60 minutes before surgery and was continued for the duration of the study. Group 2 consisted of controls and were given all the post-operative medications in the same manner as Group 1 except for topical nepafenac 0.1% for the entire duration of the study. Both groups were assessed for their macular thickness with the help of swept source optical coherence tomography first preoperatively (which was taken as the baseline macular thickness), followed by consecutive assessments at 2 weeks, 4 weeks, 6 weeks and 8 weeks of follow up. Patients presenting with dense cataracts whose macular thickness could not be assessed by an OCT on presentation due to media opacity were subjected to an OCT on the first post-operative day and that macular thickness was considered the baseline value.

OCT used was a spectral domain OCT with a scan speed of 27,000 A-Scans/sec, with A-Scan depth of 2 mm (in tissue), axial resolution of 5 μ and transverse resolution of 15 μ (in tissue). Slit lamp examination was also carried out to look for any adverse reactions related to the long-term use of the drug on days 1, 7, 14, 30, 45 and 60.

Visual Acuity

ETDRS chart was used to assess the visual acuity in the patients and letters read out were recorded preoperatively and post operatively at 1, 2, 4, 6 and 8 weeks. The baseline visual acuity was considered to be the best corrected visual acuity on the 7th post-op day. As improvement in vision would have been attained by this time and patient would not have developed any macular oedema by that time¹⁹

Statistical Analysis

The collected data was entered in Microsoft Excel and then analysed and statistically evaluated using SPSS-PC-20 version. Quantitative data was expressed by mean, standard deviation while qualitative data was expressed in percentage. Difference between the proportions was tested by chi square test or Fisher's exact test while difference between quantitative variable between two groups were tested by Students 't' test or Mann Whitney U test. For comparison of quantitative data between more than two groups, ANOVA or Kruskal Wallis 'H' test followed by post hoc test was used. 'p' value less than 0.05 was considered statistically significant.

RESULTS

The baseline characteristics in the two groups were broadly similar. More than two third of the study subjects in both the groups were females $n=35$ (70.0%) in group 1 and $n=34$ (68.0%) in group 2 (p -value=0.82). The mean age of group 1 was 63.75 ± 5.94 years with the majority of the patients falling in the age group of 56-65 years ($n=35$, 70%) and in group 2 the mean age was 64.82 ± 7.47 years, the majority of the patients belonged to the age group of 56-65 years ($n=28$, 56%) (p -value=0.43).

Follow up	Group 1 CMT (μ m) (n=50)		Group 2 CMT (μ m) (n=50)		p Value
	Mean	SD	Mean	SD	
At baseline	218.92	18.41	222.06	10.59	0.38
At 2 weeks	224.94	17.96	236.98	12.01	<0.01
At 4 weeks	233.20	20.95	250.68	21.95	<0.001
At 6 weeks	233.34	20.86	251.12	23.95	<0.001
At 8 weeks	232.54	22.09	252.52	25.75	<0.001

Table 1. Comparison of Central Macular Thickness at Different Follow Up Visits

At baseline the CMT measurements were $218.92 (\pm 18.41) \mu$ m and $222.06 (\pm 10.59) \mu$ m in Group 1 and Group 2 respectively. The difference was statistically not significant ($p=0.38$). At 2 weeks post operatively, they were $224.94 (\pm 17.96)$ and $236.98 (\pm 12.01) \mu$ m. The difference was significant ($p<0.01$). At 4 weeks postoperatively, they were $233.20 (\pm 20.95)$ and $250.68 (\pm 21.95) \mu$ m. The difference was significant ($p<0.001$). At 6 weeks postoperatively, they were $233.34 (\pm 20.86) \mu$ m and $251.12 (\pm 23.95) \mu$ m. The difference was significant ($p<0.001$). At 8 weeks postoperatively, they were $232.54 (\pm 22.09) \mu$ m and $252.52 (\pm 25.75) \mu$ m. The difference was significant ($p<0.001$).

Macular oedema	Group 1 (n=50)		Group 2 (n=50)		p Value
	No.	%	No.	%	
Within 2 weeks	0	0.0	0	0.0	-
Within 4 weeks	1	2.0	4	8.0	0.36
Within 6 weeks	1	2.0	4	8.0	0.36
Within 8 weeks	1	2.0	4	8.0	0.36

Table 2. Development of Macular Oedema after Cataract Surgery

At 2 weeks, 0 patients (0%) developed macular oedema in Group 1 and Group 2. At 4 weeks, macular oedema was found to be present in 1 patient (2%) in Group 1 whereas it was found to be in 4 patients (8%) in Group 2 (p -value=0.36). At 6 weeks, macular oedema was found in 1 patient (2%) in Group 1 and in 4 patients (8%) in Group 2 (p -value=0.36). At 8 weeks, macular oedema was found to be present in 1 patient (2%) in

Group 1 whereas it was found in 4 patients (8%) in Group 2 (p -value=0.36).

Time	Group 1 (Letters Read) (n=50)		Group 2 (Letters Read) (n=50)		p Value
	Mean	SD	Mean	SD	
At baseline	72.26	3.53	72.38	3.12	0.85
At 2 weeks	76.80	2.64	73.94	2.06	<0.01
At 4 weeks	78.86	5.89	77.04	11.61	0.01
At 6 weeks	81.68	6.08	77.92	12.54	0.05
At 8 weeks	83.98	6.64	78.48	13.06	<0.01

Table 3. Comparison of BCVA Based on ETDRS Letters Read at Various Follow Up Visits

The mean baseline BCVA based on the number of ETDRS letters read at 1 week after surgery was $72.26 (\pm 3.53)$ in Group 1 and $72.38 (\pm 3.12)$ in Group 2 (p -value=0.85). The mean BCVA based on the number of ETDRS letters read at 2 weeks after surgery was $76.80 (\pm 2.64)$ in Group 1 and $73.94 (\pm 2.06)$ in Group 2 (p -value<0.01). The mean BCVA based on the number of ETDRS letters read at 4 weeks after surgery was $78.86 (\pm 5.89)$ in Group 1 and $77.94 (\pm 11.61)$ in Group 2 (p -value=0.01). The mean BCVA based on the number of ETDRS letters read at 6 weeks after surgery was $81.68 (\pm 6.08)$ in Group 1 and $77.92 (\pm 12.54)$ in Group 2 (p -value=0.05). The mean BCVA based on the number of ETDRS letters read at 8 weeks after surgery was $83.98 (\pm 6.64)$ in Group 1 and $78.48 (\pm 13.06)$ in Group 2 (p -value<0.01).

Follow up	Group 1 Change in BCVA from baseline (n=50)		Group 2 Change in BCVA from baseline (n=50)		p value
	Mean	SD	Mean	SD	
At 2 weeks	4.54	2.81	1.56	4.09	<0.01
At 4 weeks	6.60	7.21	4.66	13.09	0.72
At 6 weeks	9.42	7.69	5.54	13.89	0.71
At 8 weeks	11.72	8.41	6.10	14.37	<0.01

Table 4. Changes in BCVA Based on the Number of ETDRS Letters Read from Baseline at Different Follow Up Visits

At 2 weeks the mean change in number of letters read from ETDRS chart in Group 1 was $4.54 (\pm 2.81)$ and $1.56 (\pm 4.09)$ (p -value<0.01). At 4 weeks the mean change in number of letters read from ETDRS chart in Group 1 was $6.60 (\pm 7.21)$ and $4.66 (\pm 13.09)$ (p -value=0.72). At 6 weeks the mean change in number of letters read from ETDRS chart in Group 1 was $9.42 (\pm 7.69)$ and $5.54 (\pm 13.89)$ (p -value=0.71). At 8 weeks the mean change in number of letters read from ETDRS chart in Group 1 was $11.72 (\pm 8.41)$ and $6.10 (\pm 14.37)$ (p -value<0.01).

Letters	Group 1 BCVA (n=50)		Group 2 BCVA (n=50)		p Value
	No.	%	No.	%	
Decrease					
5-9 letters	0	0.0	2	4.0	-
10-14 letters	0	0.0	1	2.0	
≥15 letters	1	2.0	4	8.0	
No change (±1-4 letters)	0	0.0	2	4.0	0.49
Increase					
5-9 letters	11	22.0	20	40.0	<0.01
10-14 letters	8	16.0	1	2.0	0.03
≥15 letters	30	60.0	20	40.0	<0.01
Table 5. Changes in Best Corrected Visual Acuity after Cataract Surgery at 8 th Postoperative Week					

Table 5. Changes in Best Corrected Visual Acuity after Cataract Surgery at 8th Postoperative Week

The BCVA decreased by 5-9 letters in 0 patients in Group 1 and 2 (4%) patients of Group 2. The BCVA decreased by 10-14 letters in 0 patients in Group 1 and 1 (2%) patient of Group 2. The BCVA decreased by ≥ 15 letters in 1 (2%) patients in Group 1 and 4 (8%) patients of Group 2. There was no change in BCVA in 0 patients in Group 1 and 2 (4%) patients of Group 2 (p -

0.49). The BCVA increased by 5-9 letters in 11 (22%) patients in Group 1 and 20 (40%) patients of Group 2. ($p < 0.01$). The BCVA increased by 10-14 letters in 0 patients in Group 1 and 1 (2%) patient of Group 2. The BCVA increased by ≥ 15 letters in 30 (60%) patients in Group 1 and 20 (40%) patients of Group 2. The difference was statistically significant ($p < 0.01$).

DISCUSSION

Central Macular Thickness

The mean central macular thickness of group 1 and group 2 when, evaluated preoperatively by OCT was statistically insignificant (p -value=0.38). However, when the mean central macular thickness was evaluated subsequently at the follow up visits, it was found that the increase in the central macular thickness at 2 weeks between the two groups was significantly lesser in Group 1 as compared with Group 2 (p -value<0.01). On subsequent follow ups at 4, 6 and 8 weeks the central macular thickness was found to have increased by a significantly lesser value in Group 1 as compared to Group 2 (p -values <0.001). We noted that a significantly larger number of patients in Group 1 [$n=37$ (74%)] returned to within $\pm 10\%$ of the baseline values as compared with Group 2 [$n=15$ (30%)] at 6 weeks of follow up (p -value of <0.01). A similar trend was observed at 8 weeks where a total of 39 patients (78%) in Group 1 returned to within $\pm 10\%$ of the baseline values as compared with a total of 27 patients (54%) in Group 2 with a significant p -value of 0.01. Thus, showing that the changes in macular thickness, when compared with the baseline values were lesser in Group 1 when compared with those of Group 2 at 6 and 8 weeks of follow up. In the study by Ayala Pollack the mean central macular thickness was found to have increased in both the groups, but it was found to be remarkably lesser in the nepafenac group compared with vehicle group.²⁰ Rishi Singh reported in their study that the central macular thickness evaluated at the 14, 30 and 60 post-operative day was significantly lesser in the nepafenac group as compared with the vehicle group with p -values <0.001.¹⁹

Macular Oedema

There was a 4-fold increase in the number of patients [$n=4$, (8%)] in Group 2 who developed macular oedema as compared with Group 1 [$n=1$, (2%)] at 4, 6 and 8 weeks. However, this value was found not to be statistically significant (p -values =0.36). This might be due to a small sample size or short duration of follow up. In the study by Ayala Pollack a significantly larger number of patients [$n=14/80$ (17.5%)] belonging to the vehicle group developed macular oedema within 90 days of undergoing phacoemulsification as compared with the nepafenac group [$n=4/80$ (5%)].²⁰ Rishi Singh reported that there was a statistically significant difference in the number of patients who developed macular oedema in nepafenac group as compared with vehicle group at days 30, 60 and 90 of follow up with p -values of 0.029, <0.001 and <0.001 respectively.¹⁹ Thereby suggesting that nepafenac is efficacious in the prevention of macular oedema.

Best Corrected Visual Acuity

In our study we found that there was a greater increase in the mean number of letters read off the ETDRS chart at follow up visits at 2,4,6 and 8 weeks in patients belonging to Group 1 as

compared with patients in Group 2. A statistically significant difference was found to be present at 2 weeks (p -value<0.01), 4 weeks (p -value=0.01) and at 8 weeks (p -value<0.01). Though there was a greater increase in the number of letters read at 6 weeks of follow up in Group 1 as compared with Group 2, the difference between the two groups was considered statistically insignificant (p -value=0.05). We found a significant increase in visual recovery in terms of change in letters read off the ETDRS chart at 2, 4, 6 and 8 weeks of follow up in patients belonging to Group 1 as compared with Group 2. However statistically significant difference between the groups was seen at the 2nd (p -value<0.01) and 8th (p -value<0.01) week of follow up. In our study the mean change in increase in the number of letters read from the baseline to day 60 was significantly greater in Group 1 (11.72 $\pm$ 8.41 letters) relative to Group 2 (6.10 $\pm$ 14.37 letters) (p -value <0.01). Thereby highlighting the fact that the difference between the two groups is statistically significant. Benefit of using topical nepafenac 0.1% eye drops in speeding up the process of visual recovery is seen. We found that a significantly lesser percentage of patients in Group 2 ($n=20$, 40%) experienced a gain of 15 letters or more as compared with Group 1 ($n=30$, 60%). The difference between the two groups was statistically significant at 8 weeks of follow up (p -value ≤ 0.01). Ayala Pollack's study concluded that there was a greater mean increase in change of BCVA as compared with the baseline, in the nepafenac group compared with vehicle group at 90 days of follow up. However, the difference between the two groups was not statistically significant in their study.²⁰

Rishi Singh reported that a significantly larger percentage of patients belonging to the nepafenac group experienced improvements of 15 letters or more from the postsurgical baseline to day 90 as compared with the vehicle group (56.8% vs. 41.9%; p -value=0.019).¹⁹ At 8 weeks follow up, as the macular thickness had increased much more in Group 2 compared with Group 1, the change in macular thickness was found to be strongly negatively correlated with changes in visual acuity letters read and this correlation was found to be statistically significant in Group 2 ($p < 0.01$) while in Group 1 no statistically significant correlation was observed (p -value=0.67). Thereby suggesting that patients in Group 2 experienced a greater increase in the central macular thickness and were associated with a greater loss of letters read as compared with Group 1 at 8 weeks of follow up. No adverse reactions were noted in patients in Group 1 ($n=50$) who were treated with topical nepafenac 0.1% ophthalmic suspension at 8 weeks.

The strengths of our study were that it was done prospectively, and the dropout rate was small (6 out of 106) and the limitations were a small sample size due to limited study duration and also a short period of follow up.

CONCLUSIONS

Nepafenac is a safe drug that decreases the occurrence of macular oedema when used after cataract surgery in diabetic patients. Macular oedema was 4 times less common in patients given topical nepafenac as compared to controls. Multicentric

randomized control trials should be done to determine its efficacy and safety.

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