COMPARISON OF EFFICACY OF NEPAFENAC 0.3% & 0.1% TO PREVENT & CONTROL POSTOPERATIVE PAIN AND CONJUNCTIVAL REDNESS AFTER CATARACT SURGERY

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ABSTRACT

Objectives: To compare the efficacy of nepafenac 0.3% with nepafenac 0.1% to control postoperative pain and conjunctival redness after cataract surgery.

Methods: It is a randomized controlled trial conducted at Ophthalmology Department, DHQ Teaching Hospital, Gujranwala from November 2020 to January 2021. A prospective review of 70 patients operated for age-related cataract was done. Patients were divided into two equal groups. Group A patients were given Ilevro eye drops (nepafenac 0.3%) once a day and group B patients were instilled Nevanac eye drops (nepafenac 0.1%) thrice a day. All patients were scored for ocular pain and conjunctival redness on basis of pre-defined scales on one day before surgery and on 1st, 7th and 14th postoperative day. Results from both groups were analyzed and compared using SPSS v 25.0.

Results: Out of 70 patients, 35 were put in group A and 35 into group B. Overall 37 (52.8%) patients were male and 33 (47.2%) were female. Patients above 40 years of age were 33 (94.3%) in group A and 35 (100%) in group B. Patients having pain score ≥5 were 30 (85.7%) in group A and 25 (71.4%) in group B on 1st postoperative day, with ≥3 were 1 (2.8%) in group A and 33 (94.2%) in group B at 7th postoperative day and zero on 14th postoperative day. Patients with conjunctival redness ≥2 were 31 (88.6%) in group A and 29 (82.9%) in group B on 1st postoperative day, with ≥1 were 18 (51.3%) in group A and 28 (79.9%) in group B on 7th postoperative day while four (11.4%) in group A and one (2.8%) in group B on 14th postoperative day.

Conclusion: Effect of once daily nepafenac 0.3% on postoperative pain and conjunctival redness was found to be sub-rated against thrice daily nepafenac 0.1% on 1st postoperative day. However, this effect became equal and then slightly superior to that of nepafenac 0.1% on 7th and 14th postoperative days.

Key Words: Cataract Surgery, Nepafenac, Postoperative Pain, Conjunctival Redness

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INTRODUCTION

Cataract is formed by opacification of crystalline lens which affects visual acuity as it matures.1 Cataract is one of the most common causes of blindness which accounts for nearly 48% of global blindness.2,3 Cataract surgery is one of the most easily assessable ophthalmic surgeries worldwide and thus a fairly commonly performed procedure in ophthalmology practice.4 There are many per-operative and post operative complications of this procedure. Post operative ocular inflammation is common after cataract surgery which causes postoperative pain and photophobia.5 Ocular inflammation can be due to
exogenous or endogenous factors. Exogenous factors include trauma and surgery. There are many complications associated with acute inflammation which include raised Intraocular pressure, inflammatory membrane, decreased visual acuity and cystoid macular edema.

As with other tissues, in ocular inflammation arachidonic acid metabolism produces prostaglandins by action of cyclooxygenase enzymes which are the most important mediators of inflammation. Surgical trauma is one of the main triggers of arachidonic acid metabolism. Ocular inflammation is manifested by redness, swelling and pain associated with irritation after surgical trauma to eyes.

There are many topical medications used after cataract surgery including antibiotics, steroids, non-steroidal anti-inflammatory agents (NSAIDs) and anti-glaucoma drops to reduce risk of postoperative complications. Many surgeons use NSAIDs for providing best surgical outcomes in patients undergoing cataract surgery and in early post operative period to reduce surgical induced inflammation. NSAIDs are safe and effective alternative to steroids in reducing post operative pain and inflammation. They are also effective in maintaining intra-operative mydriasis.

There are many different types of NSAIDs which are in clinical use for different purposes. Four topical NSAIDs currently approved for use by FDA for post operative pain and inflammation after cataract surgery are diclofenac sodium 0.1%, ketorolac 0.5% (used four times a day), nepafenac 0.1% three times a day and bromfenac twice a day.

Recently a new drug formulation, nepafenac 0.3% is available with once-a-day dosing to serve the same purpose. The rationale of this study is to compare the efficacy of 0.3% nepafenac given only once a day with 0.1% nepafenac given three times a day for controlling post operative pain and inflammation.

Methods:
This was a randomized control trial conducted at DHQ Teaching Hospital, Gujranwala from November 2020 to January 2021. This study was approved by Ethical Review Committee of above-mentioned hospital. Informed consent was taken from all the participants. A total of 70 patients were included in the study. They were selected randomly by simple random technique. They were divided into two groups. Group A included 35 patients who received nepafenac 0.3% (Ilevro Eye Drops, Alcon laboratories, Inc.) used only once a day while group B included 35 patients who received nepafenac 0.1% (Nevanac Eye Drops, Alcon laboratories, Inc.) three times a day. All patients in group A started nepafenac 0.3% one day before surgery, continued it twice a day on per op day in patients 1 drop early morning and 1 drop of drug half hour before surgery and continued in once daily dose for 14 days post operatively. Patients in group B were given nepafenac 0.1% three times a day, one day pre-operatively and continued for 14 days postoperatively. All the patients were 35 years or older, having age-related cataracts and underwent phacoemulsification surgery for cataract extraction. Patients having traumatic cataracts, complicated cataracts, patients with severe retinal pathologies and who had poor surgical outcomes based on per-operative evaluation were excluded from the study. The study was conducted to find out effect of nepafenac 0.3% versus nepafenac 0.1% in controlling pain and redness after cataract surgery.

Pain was assessed on commonly used pain score criteria in which patients rated their pain on a scale of 0 to 10. Zero meant no pain and 9 or 10 meant worst possible pain. Following is table given for pain assessment. (Taken from https://www.pinterest.com/pin/691795192749246549/)

<table>
<thead>
<tr>
<th>Pain Severity Scale</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 <strong>Unable to Move</strong></td>
<td>I am in bed and can’t move because of my pain. I need someone to take me to the emergency room.</td>
</tr>
<tr>
<td>9 <strong>Severe</strong></td>
<td>My pain is all that I can think about. I can barely talk or move because of the pain.</td>
</tr>
<tr>
<td>8 <strong>Intense</strong></td>
<td>My pain is so severe that it is hard to think of anything else. Talking and listening are difficult.</td>
</tr>
<tr>
<td>7 <strong>Unmanageable</strong></td>
<td>I am in pain all of the time. It keeps me from starting most activities.</td>
</tr>
<tr>
<td>6 <strong>Distressing</strong></td>
<td>I think about my pain all of the time. I have to stop during most activities because of my pain.</td>
</tr>
<tr>
<td>5 <strong>Distracting</strong></td>
<td>I think about my pain most of the time. I cannot do some activities because of my pain.</td>
</tr>
<tr>
<td>4 <strong>Moderate</strong></td>
<td>I am constantly aware of my pain but I can continue most of my activities.</td>
</tr>
<tr>
<td>3 <strong>Uncomfortable</strong></td>
<td>My pain bothers me but I can ignore it most of the time.</td>
</tr>
<tr>
<td>2 <strong>Mild</strong></td>
<td>I have a low level of pain. I am aware of my pain only when I pay attention to it.</td>
</tr>
<tr>
<td>1 <strong>Minimal</strong></td>
<td>My pain is hardly noticeable.</td>
</tr>
<tr>
<td>0 <strong>No Pain</strong></td>
<td>I have no pain.</td>
</tr>
</tbody>
</table>

 Conjunctival redness was described as follows. Diffuse conjunctival injection scored as 3, moderate redness scored as 2 and mild redness to no injection as 1. Pain and redness were two outcome variables noted preoperatively, on 1st post operative day, 7th post operative and 14th post operative day. Results of both study groups were analyzed and compared using SPSS v 25.0.
COMPARISON OF EFFICACY OF NEPAFENAC 0.3% & 0.1% TO PREVENT & CONTROL POSTOPERATIVE

RESULTS
Total patients included in the study were 70 (n=70) out
of which 37 (52.8%) were male and 33 (47.2%) were
female. For the sake of comparison, patients were
divided into two groups. Group A included 35 patients
who received Ilevro (nepafenac 0.3%) eye drops used
only once a day. Group B included 35 patients who
received Nevanac (nepafenac 0.1%) eye drops three
times a day. In group A, out of 35, 18 (51.4%) were
male and 17 (48.6%) were female. In group B, 19
(54.3%) were male and 16 (45.7%) were female. (Table 1)

Table 1: Frequency Distribution of Gender

<table>
<thead>
<tr>
<th>Gender</th>
<th>Group A (n=35)</th>
<th>Group B (n=35)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>18 (51.4%)</td>
<td>19 (54.3%)</td>
</tr>
<tr>
<td>Female</td>
<td>17 (48.6%)</td>
<td>16 (45.7%)</td>
</tr>
<tr>
<td>Total</td>
<td>35 (100%)</td>
<td>35 (100%)</td>
</tr>
</tbody>
</table>

In age groups, patients aged 40 years or less were 2
(5.7%) in group A and 0 (0%) in group B. Patients
below age of 41-60 years were 23 (65.7%) in group
A and 13 (37.1%) in group B. Patients above age of 60
were 10 (28.5%) in group A and 22 (62.9%) in group B. (Table 2)

Table 2: Frequency Distribution of Age Groups

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Group A (n=35)</th>
<th>Group B (n=35)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤40</td>
<td>2 (5.7%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>41-60</td>
<td>23 (65.7%)</td>
<td>13 (37.1%)</td>
</tr>
<tr>
<td>&gt;60</td>
<td>10 (28.5%)</td>
<td>22 (62.9%)</td>
</tr>
<tr>
<td>Total</td>
<td>35 (100%)</td>
<td>35 (100%)</td>
</tr>
</tbody>
</table>

As implied above, the comparative efficacy of both
drug groups was noted in terms of pain as well as
redness at 1 day before surgery, at 1st postoperative day,
7th postoperative day and on 14th postoperative day.
Obviously, no group had any pain or redness at 1 day
before surgery. However, on rest of occasions
following results were documented. (Table 3,4)

Table 3: Frequency Distribution of Pain Score in Both Groups

<table>
<thead>
<tr>
<th>Pain Score at 1st Postoperative Day</th>
<th>Pain Score at 7th Postoperative Day</th>
<th>Pain Score at 14th Postoperative Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain Score</td>
<td>Group A (n=35)</td>
<td>Group B (n=35)</td>
</tr>
<tr>
<td>1-10</td>
<td>(n=35)</td>
<td>(n=35)</td>
</tr>
<tr>
<td>&gt;6</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>6</td>
<td>7 (20%)</td>
<td>7 (20%)</td>
</tr>
<tr>
<td>5</td>
<td>23 (65.7%)</td>
<td>18 (51.4%)</td>
</tr>
<tr>
<td>4</td>
<td>5 (14.3%)</td>
<td>8 (22.8%)</td>
</tr>
<tr>
<td>3</td>
<td>0 (0%)</td>
<td>2 (5.6%)</td>
</tr>
<tr>
<td>&lt;3</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Total</td>
<td>35 (100%)</td>
<td>35 (100%)</td>
</tr>
</tbody>
</table>

Table 4: Frequency Distribution of Conjunctival Redness in Both Groups

<table>
<thead>
<tr>
<th>Conjunctival Redness at 1st Postoperative Day</th>
<th>Conjunctival Redness at 7th Postoperative Day</th>
<th>Conjunctival Redness at 14th Postoperative Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redness Score 0-3</td>
<td>Group A (n=35)</td>
<td>Group B (n=35)</td>
</tr>
<tr>
<td>3</td>
<td>5 (14.3%)</td>
<td>5 (14.3%)</td>
</tr>
<tr>
<td>2</td>
<td>26 (74.3%)</td>
<td>24 (68.6%)</td>
</tr>
<tr>
<td>1</td>
<td>4 (11.4%)</td>
<td>6 (2.8%)</td>
</tr>
<tr>
<td>0</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Total</td>
<td>35 (100%)</td>
<td>35 (100%)</td>
</tr>
</tbody>
</table>

DISCUSSION
In this study 52.8% of patients were male and 47.2%
were female. Mean age was above 32 years of age. All
patients having nuclear cataract undergoing
phacoemulsification cataract surgery were planned for
our study.

For post-operative management of pain and
inflammation topical steroids, topical and systemic non-
steroidal anti-inflammatory drugs are available and
literature shows satisfactory control of pain and
inflammation with them.

In our study pre surgery pain and inflammation has
been recorded that was zero in both groups. Taking in
account the anti-inflammatory role of nepafenac as it inhibits the release the prostaglandins literature shows various studies for the affectivity of NSAIDs in the management of post-operative inflammation. History also shows the role of NSAIDs in control of CSME, diabetes induced retinal microvascular disease, in management of intraocular pressure, control of inflammation in extra ocular surgery. For the analgesic effect of NSAIDs literature shows studies that compare topical NSAIDs with topical steroids or history shows comparison of NSAIDs or combination with ketorolac, showing that NSAIDs are equivalent to or superior to other topical or placebo management.

In our study we compare two different strengths of NSAIDs 0.1% vs. 0.3%. it showed that majority of group ‘B’ patients experience pain score of 5 at 1st post-operative day that is 51.4%, while majority of group ‘A’ patients receiving 0.3% of topical NSAIDs also experience pain score of 5 at 1st post-operative day in 65.7% of patients. While on 7th post-operative day patients of group ‘B’ experience pain of grade 4 in 48.5% of patients, while in group ‘A’ 97.1% of patients experience pain of <3 score that is much reduced as compare to group ‘B’ and is in correspondence with literature review. On 14th post-operative day both 0.1% and 0.3% NSAIDs are equivalent in terms of pain that is <3 pain score. Grade 2 conjunctival redness was mostly experienced by patient on 1st post-operative day out of which 68.6% was experienced by group ‘B’ and 74.35 was experience by group ‘A’. while on follow up at 7th and 14th post op day group ‘A’ patients shows marked decrease in conjunctival redness (42.8% and 88.5% ) as compare to group ‘B’ (71.4% and 97.2 %) respectively, this shows that nepafenac 0.3% is better in management of pain and inflammation at 14 days follow-up.

This study is limited by relatively small size for comparison and short duration of follow-up although literature shows no study showing the comparison of nepafenac 0.1% vs. nepafenac 0.3%.

CONCLUSION
Effect of nepafenac 0.3% once daily dropping in terms of controlling postoperative pain and conjunctival redness is not superior as compared to nepafenac 0.1% thrice daily dropping on 1st postoperative day. However, this effect becomes equal and then slightly superior to that of nepafenac 0.1% on 7th and 14th postoperative days after cataract surgery concluding that nepafenac 0.1% given 3 times daily offers more control of pain and redness in early postoperative days while same is true about nepafenac 0.3% given once a day after 1-2 weeks.

CONFLICT OF INTERESTS
Authors declared no conflict of interests.

FUNDING
No funding was provided for this study.

ETHICAL APPROVAL
The study was approved by the Institutional review board/ Ethical review committee of Gujranwala Medical College/ DHQ Teaching Hospital, Gujranwala. Vide IRB Reference No. 382/GMC.

REFERENCES


AUTHOR’S CONTRIBUTIONS
SJ, BB: Manuscript Writing, Data collection
ZH: Manuscript Writing, Statistical Analysis, Correspondence
IQM, AJ, AY: Supervision, Manuscript Review