Original Research Paper

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ALLAYING OCULAR PAIN: WHO WINS TOPICAL NEPAFENAC V/S TOPICAL STEROIDS IN POST CATARACT SURGERY

Manmeet Singh	Fellow, Sankara Eye Hospital, Ludhiana, Punjab.
Pritish Gupta	MBBS Final Part-I Dayanand Medical College & Hospital, Ludhiana, Punjab
Kiratmeet Singh	MBBS Final Part-I Government Medical College & Hospital, Patiala, Punjab
Ruminder Kaur	Vitreo- Retina Consultant, Sankara Eye Hospital, Ludhiana, Punjab
Manoj Gupta*	CMO & Cornea/Cataract & Refractive Consultant, Sankara Eye Hospital, Ludhiana, Punjab. *Corresponding Author

ABSTRACT **INTRODUCTION:** Cataract is the leading cause of blindness globally and is responsible for 39.1% of blindness (including refractive error) and 47.8% of total blindness (excluding refractive error).[1,2] Though the problem of cataract blindness is prevalent all over the world, it is more severe in the developing nations because of the backlog of untreated cataracts and underutilization of existing resources.[3-5] According to the latest national survey, in India 62.6% of the blindness in the population above 50 years of age is cataract related.[6]

METHODS: The study was conducted in Sankara Eye Hospital, Ludhiana, Punjab with 100 patients divided in two groups randomnly by lottery method to one receiving topical Nepafenac with steroids and the other group receiving topical steroids alone post-cataract surgery.

RESULTS: Patients were assessed on the basis of post-operative ocular pain score in group A, in which they were more pain free from day-7 onwards as compared to the group B receiving steroids alone (p=0.029)

KEYWORDS :

INTRODUCTION:

Cataract is the leading cause of blindness globally and is responsible for 39.1% of blindness (including refractive error) and 47.8% of total blindness (excluding refractive error).[1, 2] Though the problem of cataract blindness is prevalent all over the world, it is more severe in the developing nations because of the backlog of untreated cataracts and underutilization of existing resources.[3-5] According to the latest national survey, in India 62.6% of the blindness in the population above 50 years of age is cataract related.[6]

An estimated 3.8 million persons become blind from cataract each year in India and 2.5 to 5.8 million sight restoring operations are needed to be performed every year to control cataract related blindness in India.[7-8] Small incision cataract surgery (both manual and phacoemulsification) has become the widely used cataract surgery over the past two decades. The post-operative ocular pain is also experienced as an immediate discomfort after the surgery by a few patients. Another aspect is pseudophakic cystoid macular edema (CME), which is one of the important postoperative complications of cataract surgery, which can compromise the result of a cataract surgery.[9] It is recognized as the most common cause of decreased vision in patients following cataract surgery with or without the implantation of an intraocular lens.[10-18]

Despite advances in phacoemulsification for cataract extraction, pseudophakic CME remains a common cause of reduced vision following uncomplicated and complicated cataract surgery.[19] This syndrome is responsible for a greater and a more frequent loss of vision than many of the more commonly discussed postoperative complications, including retinal detachment and endophthalmitis.[11-12]

MATERIAL AND METHODS:

A prospective, randomized, interventional study was carried out at Sankara Eye Hospital, Ludhiana, Punjab. The study was carried out from the month of August-October 2021. The study was conducted on 100 patients with features suggestive of significant grade of age related senile cataract in the in-patient department of the hospital. They were divided into two groups of 50 each in Group-A receiving topical Nepafenc 0.1% in addition to topical steroids whereas in Group-B patients only topical steroids were used.

- **INCLUSION CRITERIA**:
- All patients with age related immature senile cataract were included in this study.
- Both males and females patients having age related immature senile cataract above 50 years of age.
- Patients with uncomplicated manual SICS with IOL implantation in the bag by a single surgeon

- **EXCLUSION CRITERIA**:
- Patients with central corneal opacities or any other corneal dystrophies, pseudoexfoliation of lens, lens induced glaucoma or lens subluxation or dislocation that would affect the treatment response or evaluation.
- Patients with history of uveitis, glaucoma, vascular occlusions like branch retinal vein occlusions, central retinal vein occlusion, diabetic retinopathy, hypertensive retinopathy, pre-existing macular edema due to any cause.
- Patients with history of diabetes, hypertension, bleeding disorders, blood dyscrasias or any other systemic disease, macular pathologies, signs of uveitis or allergic to topical drugs in concern in this study.

A signed informed consent was obtained from all the patients before commencing the study and an ethical clearance was taken from the hospital ethics committee for the conduct of this study. A detailed history of the patient was recorded alongwith detailed ocular examination been carried out.

STATISTICAL ANALYSIS- Statistical analysis was performed by the SPSS program for Windows, version 17.0 (SPSS inc Chicago, Illinois, USA). Data were checked for normality before statistical analysis. Categorical variables were analysed using either the chi square test or Fisher's exact test. One-way analysis of variance (ANOVA) was used to evaluate the significance of the differences in preoperative and post operative variable. For all statistical tests, a p value less than 0.05 was taken to indicate a significant difference.

Pre-Operatively- An topical antibiotic preparation and topical NSAIDS was started a day prior to surgery as assigned to the group. Operative procedure done was manual small incision cataract surgery with single surgeon.

PRE-OPERATIVE PREPARATION

- Each patient was given a scrub bath including face and hair with soap and water in the morning of the day of surgery. Each patient was instructed to comb their hair properly.
- One day prior to surgery, the eye to be operated received the assigned drug (topical NSAID) as one drop every 2 hourly
- In all the patients, mydriasis was obtained by instilling one drop of 10 percent phenylephrine hydrochloride ophthalmic solution and 1% tropicamide ophthalmic solution every 30 minutes starting two hours before surgery.

OPERATIVE PROCEDURE

The skin of eyelids, lid margins and around the eyes was cleaned with

10 percent povidone-iodine solutions. A drop of povidone-iodine 5% solution was instilled into the conjunctival sac to make it sterile.

Anaesthesia :
Peribulbar anaesthesia was obtained by infiltration of 5 ml of anaesthetic solution in the peribulbar space. The solution contain 2 percent lignocaine / xylocaine, 75 IU (1 tab) hyalouronidase. Of this solution, 3 ml is injected at the inferior orbital rim 1 cm medial to the lateral canthus and the remaining 2ml just palpating the supra-orbital notch within the peribulbar space.

To soften the eye, digital pressure was exerted against the closed eyelids for 5 minutes by intermittent massage with release of pressure every 30 second.

Retraction of globe : The lid was retracted by using universal eye speculum.

Fixation of eyeball : The superior rectus bridle suture was passed under the insertion point of superior rectus muscle 7.7 mm behind the limbus.

Conjunctival flap : A fornix-based conjunctival flap was raised and hemostasis was obtained by bipolar heat cautery.

INCISION : A 6 mm incision was made depending upon the grade of cataract 1.5-2.0 mm behind the limbus followed by a sclerocorneal tunnel with the help of a crescent knife. Due care was being taken for making good side-pockets for ease in the nucleus delivery.

Side-port entry : A side - port entry was made with the help of 15 side port knife following which dye was injected for staining the anterior capsule. This was followed by thorough washing of the dye from the anterior chamber and then filling it with visco-elastic substance.

Continuous curvilinear capsulorhexis (CCC) : The anterior chamber was filled with visco-elastic and a 6 mm capsulorhexis was performed with the help of a bent 26 G cystitome.

Hydrodissection : A small amount of BSS was injected between the anterior capsular rim and the cortex of the lens at 3 to 4 places for separation of peripheral cortex from the capsule.

Hydrodelineation : To obtain the separation of firm nucleus from the epinucleus, a small quantity of BSS was injected into the substance of the nucleus.

Nuclear Management : The nucleus was then prolapsed in the anterior chamber using Sinsky's Hook taking care for maintaining the anterior chamber using visco-elastic substance. This was followed by the delivery of the nucleus outside through the corneo-scleral tunnel using irrigating wire vectis technique.

Aspiration of Cortex : The left out cortical matter after the nucleus delivery was aspirated out using a 23 G Simco's two-way irrigation and aspiration canula from the main incision and/or side port entry.

IOL implantation : A posterior chamber IOL (PMMA) was then implanted in the capsular bag after filling the bag with visco-elastic substance, thus making sure that the implantation was being done in the bag using IOL dialer.

Removal of visco-elastic material : It was done thoroughly from the anterior chamber and capsular bag with the help of 23 G Simco's two-way irrigation and aspiration canula.

Wound Closure : An intra-cameral moxifloxacin 0.5% was injected into the anterior chamber followed by proper hydration of the wounds making sure the anterior chamber was deepened using BSS through side-port entry, leading to self sealing of the sclero-corneal tunnel, incision due to its valve effect.

Repositioning of conjunctival flap : The conjunctival flap was reposited back using Lim's forceps and a gentle cautery was done to reposit the flap back to its position.

Patching : Patching of the eye was done at the end of the surgery and topical moxifloxacin 0.5% was put before the operated eye being patched. Patient was put on regular post-operative treatment as follows:

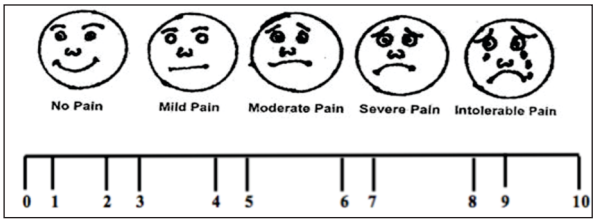
- Tab Ciprofloxacin 750 mg stat and then 500mg HS then 500mg 12 hourly for 5 days
- E/d Oloxacin + Dexamethasone 8t/d from post-operative day-1 subsequently tapered weekly over 6 weeks

A detailed examination was done on post-operative day-1 and then the patient was discharged. Follow-up examination was done on post-operative day-1, 7, 28, 90.

PARAMETERS STUDIED

1. Intra-ocular pressure (IOP)
2. Slit lamp examination for inflammation
3. Pain assessment according to visual analogue pain scale, where[15]

VAS Score	Intensity of pain
0– 2	No pain to slight pain
3–5	Mild pain.
6–7	Moderate pain.
8–9	Severe pain.
10	Worst possible pain.



Visual Analog Scale

4. Slit lamp Biomicroscopic examination with 90 D for CME
5. OCT Examination if required for confirmation of CME.

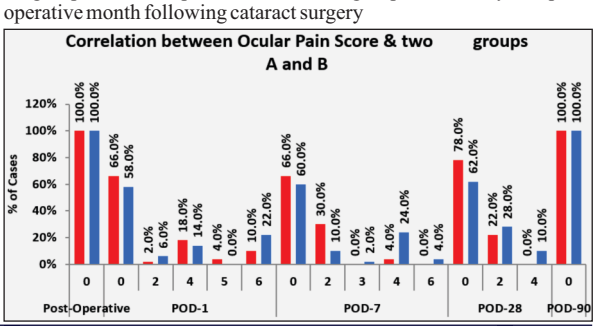
RESULTS:

Ocular Pain Score		Group A Frequency (%)	Group B Frequency (%)	p value	Significance
Post- Operative	0	n=50 (100%)	n=50 (100%)	–	-
POD-1	0	33 (66.0%)	29 (58.0%)	0.410	NS
	2	1 (2.0%)	3 (6.0%)	0.307	NS
	4	9 (18.0%)	7 (14.0%)	0.585	NS
	5	2 (4.0%)	0 (0.0%)	0.153	NS
	6	5 (10.0%)	11 (22.0%)	0.102	NS
POD-7	0	40 (80.0%)	30 (60.0%)	0.029	S
	2	6 (12.0%)	8 (16.0%)	0.564	NS
	3	0 (0.0%)	1 (2.0%)	0.315	NS
	4	4 (8.0%)	9 (18.0%)	0.137	NS
	6	0 (0.0%)	2 (4.0%)	0.153	NS
POD-28	0	39 (78.0%)	31 (62.0%)	0.043	S
	2	11 (22.0%)	17 (34.0%)	0.181	NS
	4	0 (0.0%)	2 (4.0%)	0.153	NS
POD-90	0	50 (100%)	50 (100%)	–	-

Inference

- At POD-7, the association between group A and group B having no pain has been found to be significant(p=0.029)
- At POD-28, group A patients have been found to be having no pain, ocular pain score (grade 0) (78%) as compared to group B (62%) and the association has been found to be significant(p=0.043)

The above observations are suggestive of better pain relief in patients of group A as compared to those of group B in early first post-operative month following cataract surgery



DISCUSSION:

Now a days, in this era of recent advances in techniques of cataract surgeries and newer drugs, safer alternatives and non-steroidal anti-inflammatory drugs have gradually gained popularity for comparable benefits, lack of henius side effects and some additional features of prophylaxis of cystoid macular edema and beneficial role in intra-operative mydriasis.

Incidence of CME depends on complications during or after surgery, diagnostic method and the time of diagnosis. It can even occur after an uneventful cataract extraction, but the incidence rapidly increases after a complicated surgery.[15,20] The detection of CME can be either through clinical examination, angiographic examination or optical coherence tomography examination. The incidence of CME measured by OCT and fluorescein angiogram after uneventful cataract surgery is up to 41 percent and 30 percent, respectively.[21, 22] The detection of CME with these sensitive instruments does not always correlate to visual acuity. In the past, clinical pseudophakic CME was defined as reduced visual acuity in the presence of angiographic petaloid CME following cataract extraction, and the reported incidence was 1 percent to 2 percent.[23] The incidence of pseudophakic CME with reduced vision as measured by OCT is up to 14 percent.[24]

Author (Year)	No. of patients	% age of pain free patients who received Nepafenac	% age of pain free patients who received steroids alone	p-value
Lane SS et al [25] (2007)	476	62.6	17.2	p <0.001
Nardi et al [26] (2007)	227	85.5	63.2	p=0.0016
Present study (2021)	100	78	62	p=0.043

In the above studies, the percentage of patients with no ocular pain were more in the Nepafenac group as compared to Group-B which was in accordance to the present study. Also, in the study by Nardi et al [94] (2007), more patients were pain free at each point of time from day three post-operatively with Nepafenac than with placebo,($p<0.05$). In our study also there more patients who were pain free from Day-7 onwards in Nepafenac Group as compared to Group B ($p=0.029$).

CONCLUSION AND SUMMARY :

The use of topical NSAIDS in post-cataract surgery not only helps to shun away ocular pain as seen in the present study in the immediate post operative period but also it gives patients, a better comfort and pain free period. Neverthless, the use of only steroids in the other group has also successfully yielded similar results as in the Nepafenac group but time was a constraint in regard.

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