

EFFICACY OF BROMFENAC IN PREVENTION OF MACULAR EDEMA FOLLOWING CATARACT SURGERY- A PROSPECTIVE STUDY

A.A. Mohamed Yasir Arafath*¹, B. Jayaprakash², B. Arul³, Juby. O. Chacko⁴, R. Kathirvel⁴ and Krishna K. B.⁴

¹Assistant Professor, Department of Pharmacy Practice, Vinayaka Mission's College of Pharmacy, Yercaud main road, Kondappanaickenpatty, Salem, Tamilnadu, India.

²Assistant Professor, Department of Ophthalmology, Vinayakka Mission's Kirupananda Variyar Medical and College Hospitals, Salem.

³Professor and Head, Department of Pharmacy Practice, Vinayaka Mission's College of Pharmacy, Yercaud main road, Kondappanaickenpatty, Salem, Tamilnadu, India.

⁴V Year Pharm. D Students, Vinayaka mission's college of Pharmacy, Yercaud main road, Kondappanaickenpatty, Salem, Tamilnadu, India.

*Corresponding Author: A. A. Mohamed Yasir Arafath

Assistant Professor, Department of Pharmacy Practice, Vinayaka Mission's College of Pharmacy, Yercaud main road, Kondappanaickenpatty, Salem, Tamilnadu, India.

Article Received on 15/09/2017

Article Revised on 06/10/2017

Article Accepted on 27/10/2017

ABSTRACT

A placebo controlled, prospective, randomized, clinical trial was carried out in our hospital to evaluate the efficacy of bromfenac 0.1% in prevention of macular edema following cataract surgery (Phacoemulsification). 120 eyes of 120 patients who underwent cataract surgery with phacoemulsification under topical anesthesia in the ophthalmology department were collected during the period of six months. A thorough literature survey was done on the area of the project to review the past work. From this study, we have concluded that bromfenac 0.1% was found to be effective in prevention of macular edema as none of the patients who were subjected to bromfenac developed macular edema. It can be considered as safe and no complications developed in patients subjected to bromfenac following cataract surgery.

KEYWORDS: Cataract, Macular edema, Bromfenac.

INTRODUCTION

Cataract is defined as a painless clouding or loss of transparency of the lens in the eye as a result of tissue breakdown and protein clumping which results in the decrease in vision and may lead to eventual blindness. In short cataract refers to any opacity of various degree of the crystalline lens, which is normally almost completely transparent. Cataract blocks the light from passing through the lens and is progressive in nature.

The World Health Organization (WHO) estimates that there are 20 million people blinded by cataract, which is approximately 51% of all blindness. It has been estimated that the cost of blindness in India is more than four billion dollars every year. Approximately half of this cost is due to cataract. The cataract surgical rate is a simple measure of the delivery of cataract surgery to a population. Currently the CSR varies from over 5000 in parts of North America to less than 100 in some African countries. The CSR needed to eliminate cataract blindness will vary according to the number of elderly people in a population and the perceived visual requirements of that population, but it is thought that the

minimum required is about 2000 operations per million people per year.

Cataract surgery has progressed over centuries and evolved into a modern technique called phacoemulsification (phaco). This method uses an ultrasonically-driven tip to fragment the cataract nucleus before emulsifying the pieces and removing them via an automated irrigation aspiration system. Phaco incisions and techniques are minimally invasive; allowing for fewer wound-related complications, faster healing and more rapid visual rehabilitation than procedures that create larger incisions. Additionally, phaco maintains a relatively closed system throughout surgery to control anterior chamber depth and safeguard against positive vitreous pressure and choroid haemorrhage.^[1-3]

Cystoid Macular Edema (CME) is defined as retinal thickening of the macula due to a disruption of the normal blood-retinal barrier; this causes leakage from the perifoveal retinal capillaries and accumulation of fluid within the intracellular spaces of the retina, primarily in the outer plexiform layer. Visual loss occurs from retinal

thickening and fluid collection that distorts the architecture of the photoreceptors. CME is a leading cause of central vision loss in the developed world.^[4-5]

MATERIALS AND METHODS

A prospective study was carried out in department of ophthalmology over a period of six months from November to April a tertiary care hospital at Salem, Tamil Nadu. A suitable data collection form was designed to collect and document the data. The patients are to be selected as per selection criteria and their consents will be taken. Data's were collected from the case sheets of medical records. All demographic data's includes mainly name, age, gender, diagnosis, treatment and follow up was also recorded. The demographic data's were recorded in the data entry form (PROFORMA). And the macular thickness and SLE findings follow up data's were studied and analysed.

RESULTS

A total of 120 cases of cataract surgery patients were collected and analyzed. The Cataract patients were classified according to their gender to know which group is more prone to the Cataract. Out of the selected 120 cataract patients, 61(50.83%) were male and 59(49.17%) patients were female. From this, males are more in

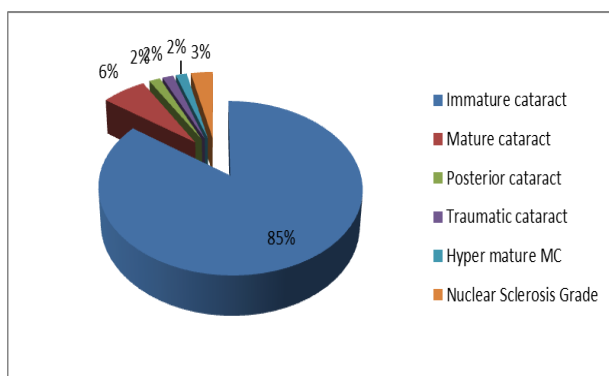
numbers than females. The age wise distribution was made for the patients with different age groups such as 20-30, 31-40, 41-50, 51-60, and 61-70. The number of patients present in each age group was found to be 1, 5, 33, 35 and 46 respectively. From this age wise analysis, the age group of 61-70 is having more number of patients than other age group patients.

Month wise analysis of number of patients undergone cataract surgery during the study period was also conducted. The total number of Cataract surgery patients was found to be 20, 19, 16, 18, 25 and 22 for the months of November, December, January, February, March and April respectively. From the month wise analysis of cataract surgery patients, we found that the cataract patients are admitted more during March month than other months.

The total number of patients according to the eye in which the surgery has done was calculated. The details were calculated separately for male and female patients. Surgery was done for 26 male and 36 female patients in right eye and 35 male and 23 female patients underwent surgery in left eye. From this analysis, we found that the cataract surgery has done more in right eye than the left eye.

Classification of patients according to the diagnosis

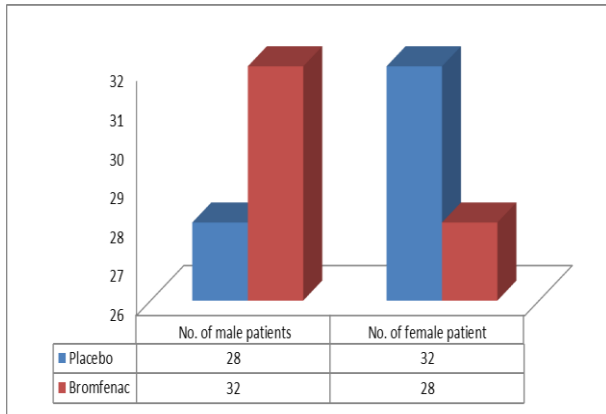
S. no.	Diagnosis	Male	Female	Total no. of patients	Percentage (%)
1	Immature cataract	52	51	103	85.8
2	Mature cataract	4	8	12	10
3	Posterior cataract	1	0	1	0.83
4	Traumatic cataract	1	0	1	0.83
5	Hyper mature cataract	1	0	1	0.83
6	Nuclear Sclerosis Grade	2	0	2	1.67
	Total	61	59	120	100



Number of Patients Administered With Placebo and Bromfenac

We have classified the total number of patients on the basis of the drug administered that is bromfenac and placebo. The details were calculated separately for male and female patients.

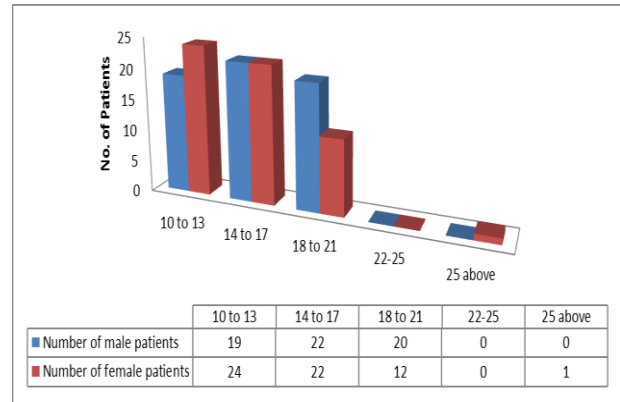
S. no.	Drugs administered	No. of male patients	No. of female patient
1	Placebo	28	32
2	Bromfenac	32	28



Pre-Operative Intra-Ocular Pressure in Patients Undergoing Cataract Surgery

The pre-operative intra ocular pressure was calculated in patients undergoing cataract surgery. The details were calculated separately for male and female patients. The IOP values of patients were classified as 10-13, 14-17, 18-21, 22-25 & above 25.

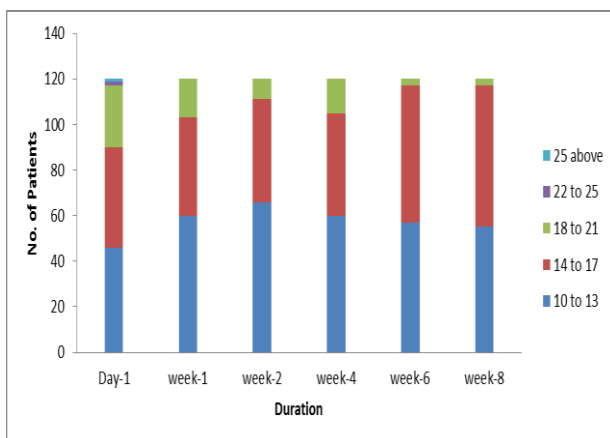
IOP value	Number of male patients	Number of female patients	Total number of patients
10-13	19	24	43
14-17	22	22	44
18-21	20	12	32
22-25	00	00	00
25 above	00	01	01
Total	61	59	120



Post-Operative Intra-Ocular Pressure in Patients Who Underwent Cataract Surgery

The post-operative intra ocular pressure was calculated in patients who underwent cataract surgery. The IOP values of patients were classified as 10-13, 14- 17, 18-21, 22-25 and 25 above.

IOP value	1 day	1 st week	2 nd week	4 th week	6 th week	8 th week
10-13	46	60	66	60	57	55
14-17	44	43	45	45	60	62
18-21	27	17	09	15	03	03
22-25	2	0	0	0	0	0
25 above	1	0	0	0	0	0
Total	120	120	120	120	120	120

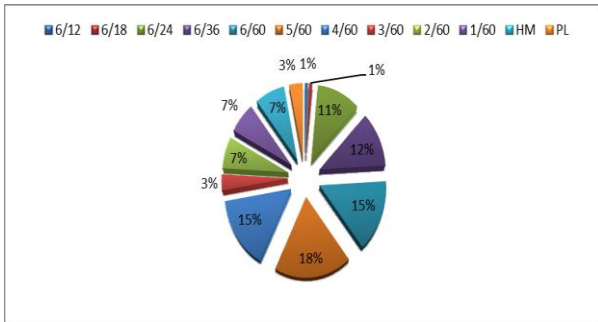


Different Ranges of Visual Acuity in Pre-Operative Cataract Surgery Patients

The pre-operative range of visual acuity was calculated in patients undergoing cataract surgery. The details were

calculated among the total number of patients. The visual acuity ranges of patients were classified as 6/12, 6/18, 6/24, 6/36, 6/60, 5/60, 4/60, 3/60, 2/60, 1/60, HM and PL.

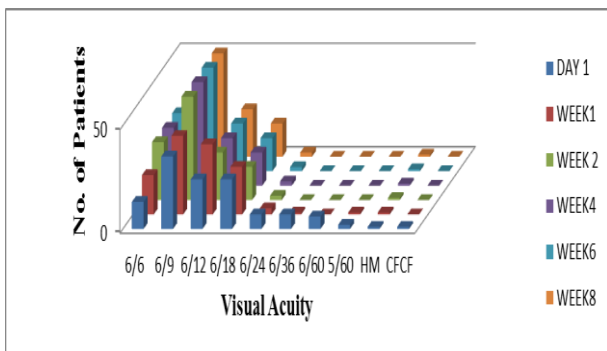
Visual acuity	No. of Patients	Percentage (%)
6/12	1	0.83
6/18	1	0.83
6/24	13	10.83
6/36	14	11.67
6/60	18	15.00
5/60	22	18.3
4/60	18	15.00
3/60	4	3.33
2/60	8	6.69
1/60	8	6.69
HM	9	7.5
PL	4	3.33



Different Ranges of Visual Acuity In Post-Operative Cataract Surgery Patients

The post-operative range of visual acuity was calculated in patients underwent cataract surgery. The details were calculated among the total number of patients. The visual acuity ranges of patients were classified as 6/6, 6/9, 6/12, 6/18, 6/24, 6/36, 6/60, 5/60, HM(hand movement), CFCF(counting fingers close to the face).

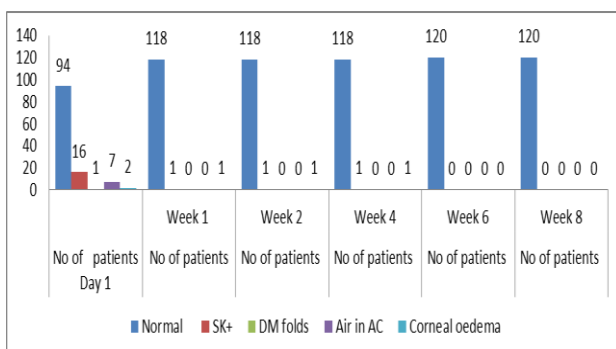
Visual acuity	No. of patients on 1 st Day	No. of patients on 1 st week	No. of patients on 2 nd week	No. of patients on 4 th week	No. of patients on 6 th week	No. of patients on 8 th week
6/6	13	19	28	28	28	28
6/9	35	38	50	50	50	50
6/12	24	34	23	23	23	23
6/18	24	23	16	16	16	16
6/24	7	3	2	2	2	2
6/36	7	1	0	0	0	0
6/60	6	0	0	0	0	0
5/60	2	1	0	0	0	0
HM	1	1	1	1	1	1
CFCF	1	0	0	0	0	0
TOTAL	120	120	120	120	120	120



Different Ranges of SLE Findings Post-Operative Cataract Surgery

The post-operative range of SLE findings was calculated in patients underwent cataract surgery. The details were calculated among the total number of patients along with their follow up visits in the next weeks. The SLE findings of patients were classified as normal, SK+, DM folds, Air in AC, Corneal oedema (K oedema).

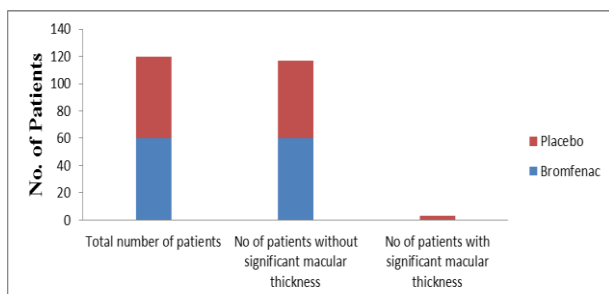
SLE findings	No of patients Day 1	No of patients Week 1	No of patients Week 2	No of patients Week 4	No of patients Week 6	No of patients Week 8
Normal	94	118	118	118	120	120
SK+	16	1	1	1	0	0
DM folds	1	0	0	0	0	0
Air in AC	7	0	0	0	0	0
K oedema	2	1	1	1	0	0
Total	120	120	120	120	120	120



Comparison of Patients with Significant Macular Thickness After Administered With Bromfenac and Placebo

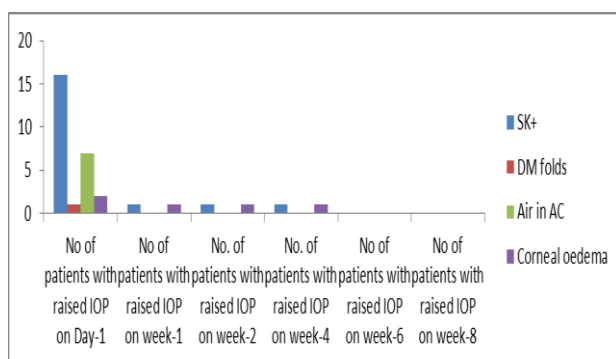
The comparison of patients with significant macular thickness after administered with post-operative treatment of placebo and bromfenac. The patients were grouped into patients who are taking bromfenac and placebo. The details were calculated among the total number of patients without significant macular thickness and number of patients with macular thickness after using bromfenac and placebo.

Drugs used	Total number of patients	No of patients without significant macular thickness	No of patients with significant macular thickness
Bromfenac	60	60	0
Placebo	60	57	3



Comparison of Post-Operative Intra-Ocular Pressure and Post-Operative Findings of SLE

SLE findings	No of patients with raised IOP on Day-1	No of patients with raised IOP on Week-1	No of patients with raised IOP on Week-2	No of patients with raised IOP on Week-4	No of patients with raised IOP on Week-6	No of patients with raised IOP on Week-8
SK+	16	1	1	1	0	0
DM folds	1	0	0	0	0	0
Air in AC	7	0	0	0	0	0
K-oedema	2	1	1	1	0	0



CONCLUSION

The comparison of patients with significant macular thickness after administered with post-operative treatment of bromfenac and placebo was carried out. The patients were grouped into patients who are taking bromfenac and placebo. The details were calculated among the total number of patients without significant macular thickness and number of patients with significant macular thickness after using placebo and bromfenac. In patients who were treated with bromfenac the number of patients without significant macular thickness is 60 and with significant macular thickness is 0. In patients who were treated with placebo the number of patients without significant macular thickness is 57 and with significant macular thickness is 3. This proves that the use of bromfenac as post-operative treatment for the patients is much effective in prevention of macular edema.

The comparison of post-operative intra-ocular pressure and post-operative findings of SLE is done where the patients are grouped according to the SLE findings. The SLE findings are classified into SK+, DM folds, Air in AC, Corneal oedema.

The comparison of post-operative intra-ocular pressure and post-operative findings of SLE is done where the patients are grouped according to the SLE findings. The SLE findings are classified into SK+, DM folds, Air in AC, Corneal edema. The number of patients with raised IOP in different follow up visits on day-1 is 16,1,7 and 2, in week-1 is 1,0,0,1, in week-2 is 1,0,0,1, in week-4 is 1,0,0,1, and in week-6 and week-8 is zero patients. This proves that use of bromfenac will not have any effect on IOP, because the number of patients with raised IOP on week-8 with different SLE findings was found to be nil when comparing with day 1.

From this study, we have concluded that bromfenac was found to be effective in prevention of macular edema as none of the patients who were subjected to bromfenac developed macular edema. It can be considered to be safe and no complications developed in patients subjected to bromfenac following cataract surgery.

REFERENCES

- Andrew Coombes, David Gartry, Fundamentals of Clinical Ophthalmology: Cataract Surgery, Chapter 5, page no: 46-65 and Chapter BMJ Publishing Group, 2003; 13: 193.
- Renu Jogi, Basic Ophthalmology, 3rd edition, Jaypee Publications, 2003; 204-226.
- H. V. Nema, Nithin Nema, Text book of Ophthalmology, 4th edition, Jaypee Publications, 2002; 220-237.
- Cystoid Macular Edema Pooja G Garg, MD, Brad H Feldman, MD and Vinay A Shah MD International

classification of Disease ICD 9-CM 362 53 Cystoid Macular Degeneration, 2014.

5. John D Sheppard, topical bromfenac for prevention and treatment of cystoid macular edema following cataract surgery: a review. *Clinical ophthalmology*, 2016; 10: 2099-2111.
6. Walters TR, Goldberg DF, Peace JH, Gow JA, Bromfenac Ophthalmic Solution 0.07% Once Daily Study Group Bromfenac ophthalmic solution 0.07% dosed once daily for cataract surgery: results of 2 randomized controlled trials. *Ophthalmology*, 2014; 121(1): 25–33.
7. Mohamed yasir arafath, Fibimol baby, A.Helan, Issac George, ‘Comparative Study of Timolol maleate and Brimonidine tartarate in Glaucoma management in a Tertiary Care Hospital, *Ejpmr*, 2016, Volume 3, Issue 12, Page 463-468.
8. Mohamed Yasir Arafath, B. Jayapraksh, B. Arul, Linta Jose, Oliviya C.J. and Powrnami Raj, A comparative study of prophylactic use of subconjunctival gentamicin and intracameral moxifloxacin in post operative cataract surgery, *Ejpmr*, 2017, Volume 4, Issue 10, Page 241-245.