Original Research Article

A comparative study in cataract patients of south India undergoing manual small incision cataract surgery between topical dexamethasone 0.1% and topical nepafenac 0.1% ophthalmic solutions

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Abstract

Aim: To study the effect of topical dexamethasone 0.1% and topical nepafenac 0.1% ophthalmic solutions in cataract patients, undergoing manual small incision cataract surgery. **Method:** The effect of nepafenac 0.1% following cataract surgery was studied and compared to routine corticosteroid, dexamethasone 0.1% in a randomized prospective clinical trial. Both groups were similar in baseline parameters. Postoperative inflammatory response, intraocular pressure, corneal thickness following manual small incision cataract extraction were assessed in both groups in the initial 8 weeks and the severity of these were graded at 1, 2, 7, 28 and 56 days. Intraocular pressure, anterior chamber reaction, corneal thickness at baseline and endpoint were compared and statistically analyzed. **Results:** The two groups did not differ much in treatment effect for any of the variables. However there seemed to be a little increase in IOP and not very significant reduction in corneal thickness with dexamethasone. **Conclusion:** Topical nepafenac is as effective as topical dexamethasone and can be used as an alternative in routine postoperative treatment following cataract surgery
Key Word: cataract.

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INTRODUCTION

Ocular inflammation after intraocular surgery can prolong patient's recovery time. Current postoperative pharmacological treatment consists of topical corticosteroids and cycloplegics to reduce post-operative inflammation. In recent years the operative technique in cataract surgery has improved and the operation has become less traumatic to the eye. As a result there is less postoperative inflammatory reaction and less breakdown of the blood-aqueous barrier (BAB). refined surgical techniques as well as more biocompatible intraocular lenses (IOL) have contributed to this development. Topical corticosteroids are commonly used as a routine treatment during several weeks postoperatively in order to reduce the inflammatory reaction. However, the adverse effects of steroids are well known and include elevation of intraocular pressure, inhibition of wound healing, and facilitation of infections. As an alternative treatment non-steroidal anti-inflammatory drugs (NSAIDs) such as nepafenac have been tried and also found to be efficient

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in reducing BAB breakdown[1]. The present study is carried out to compare the effect of topical steroids (dexamethasone) and NSAIDS (Nepafenac) in controlling postoperative inflammation following manual small incision cataract surgery (MSICS).Many surgeons have found NSAIDs to be an indispensable tool for providing the best surgical outcomes in both routine and complicated cataract procedures. As a class of drugs, NSAIDs have been proven to be a safe and effective alternative to corticosteroids in the topical prevention and management of noninfectious ocular inflammation and cystoid macular edema (CME).2 Nepafenac has a unique prodrug structure and is converted to a potent cyclo-oxygenase inhibitor, amfenac, by intraocular hydrolases.[3,4] Upon ocular dosing, nepafenac permeates the cornea, is metabolised by intraocular tissue and is converted into amfenac for optimal efficacy. The prodrug mechanism of action maximises bioactivation to amfenac in the iris, ciliary body, retina, choroid and cornea to a lesser extent, making nepafenac a target-specific NSAID. experimental studies on nepafenac demonstrated properties of enhanced permeability and rapid bioactivation to amfenac, to inhibit PG synthesis in the anterior and posterior eye segments, Nepafenac and amfenac are potent inhibitors of the COX enzymes COX-1 and COX-2. The bioconversion of nepafenac is greatest in vascularized tissues.[5] The present study is carried out to compare the effect of topical steroids (dexamethasone) and NSAIDS (Nepafenac)in controlling postoperative inflammation following manual small incision cataract surgery (MSICS).

MATERIAL AND METHODS

A randomised, prospective clinical trial was conducted at Ophthalmology department of melmaruvathur adhiaparasakthi institute of medical sciences and research. An informed consent was taken from every patient. 50 patients were taken up for this study and were randomly assigned to two groups. Group A-Twenty five patients were assigned to this group randomly and received topical dexamethasone 0.1% postoperatively. Group B - Twenty five patients were assigned to this group randomly and received topical nepafenac 0.1% postoperatively.

Inclusion Criteria

Cases who underwent manual small incision cataract surgery and did not have any other previous ocular surgery and any other ocular pathology (glaucoma, iritis, retinal disorders etc) except cataract.

Patients between 45-60 yr were taken in the study.

Exclusion Criteria

Post-operative inflammation of grade 2 or more (cell count 16-25 cells or, more, and moderate flare on slit lamp with a beam of 3 mm length 1 mm width on maximum light intensity and magnification) on first post operative day in group B.

Post-operative hyphaema.

Patient requiring resurgery in immediate post-operative period.

Any intra-operative complications.

Any other ocular pathology.

History of previous ocular surgery

Other supplementary drugs needed were same in both the groups. The patient in both the groups were operated by single surgeon *and* similar procedure (MSICS). Incision size was kept 6 mm *and* 6 mm polymethyl methacrylate (PMMA) IOL was implanted in the bag under peribulbar anaesthesia in both the groups. The patients who fit into the inclusion criteria were randomly selected and assigned into any of the two groups. Group A consisted of patients receiving topical dexamethasone 0.1% which was instilled 1drop 6 times a day for 2 weeks then four times a day for next 4 weeks. Group B consisted of patients receiving topical nepafenac 0.1% which was instilled 1 drop four times a day for 6 weeks beginning from 1st post operative day. Treatment failure is defined as patient presenting any time in post-operative visit with more than grade 2 inflammation [i.e. cells>16-25] in number and very dense flare on slit lamp examination with beam size of 1x3 mm and such patient was discontinued from study. Patient was considered cured if the sum of their aqueous cells and flare rating was 0 (i.e. absence of cells *and* flare) and clinical success was defined as an aqueous cells rating of 0 (none) or .5+ (1-5 cells) and an aqueous flare rating of 0 (none) at the current and all subsequent study visit.[6] Post-operative examinations were conducted on 1stday, 2nd day, 1st week, 4th week and 8th week.

Evaluation Parameters

Variables examined and compared were

1. Intraocular pressure [Nct-Reichert]
2. Corneal thickness [Sonomed-Pscan]
3. Aqueous flare and cells in Ac [Carl Zeiss Slitlamp] Statistical Method

To find arithmetic mean and standard deviation of parameters under study at different point of time.

- To apply repeated ANOVA test to measure significant difference of corneal thickness, intraocular pressure and anterior chamber reaction at different points of time at 5% level of significance.
- To compare efficacy *and* significant difference between two drugs under study.

RESULTS

The Results have been Analysed in the following tables. The study was carried out to compare the efficacy of two

drugs dexamethasone *and* nepafenac in terms of postoperative inflammation and intra-ocular tension. Postoperative IOP after 8 weeks of surgery in group A (dexamethasone) showed an average of 16 mmHg (2 mm rise from baseline IOP) *and* in group B (nepafenac) showed an average of 12 mmHg (same as baseline IOP), hence the results indicate that dexamethasone causes an increase in IOP, whereas nepafenac do not affect IOP. Both drugs were equally effective in controlling the postoperative inflammatory reaction. Corneal thickness did not show significant alteration with use of both drugs postoperatively.

Table 1

			Acr_pod1					Total		
			Cells0	Cells1+	Cells1+	Cells2+	Cells2+		Chi square Period	Chi square for Group
Dexamethasone group	1 POD	No	0	14	8	10	4	36	95.756**	0.898 Non Significant
		%	0.0%	38.9%	22.2%	27.8%	11.1%	100%		
	2 POD	No	6	10	7	13	0	36		
		%	16.7%	27.8%	19.4%	36.1%	0.0%	100%		
	WEEK1	No	17	13	5	1	0	36		
		%	47.2%	36.1%	13.9%	2.8%	0.0%	100%		
	WEEK4	No	31	5	0	0	0	36		
		%	86.1%	13.9%	0.0%	0.0%	0.0%	100%		
	WEEK 8	No	36	0	0	0	0	36		
		%	100.0%	0.0%	0.0%	0.0%	0.0%	100%		
Nepafenac group	1 POD	No	0	14	4	12	6	36		
		%	0.0%	38.9%	11.1%	33.3%	16.7%	100%		
	2 POD	No	9	13	3	11	0	36		
		%	25.0%	36.1%	8.3%	30.6%	0.0%	100%		
	WEEK1	No	15	15	5	1	0	36		
		%	41.7%	41.7%	13.9%	2.8%	0.0%	100%		
	WEEK4	No	34	2	0	0	0	36		
		%	94.4%	5.6%	0.0%	0.0%	0.0%	100%		
	WEEK 8	No	36	0	0	0	0	36		
		%	100.0%	0.0%	0.0%	0.0%	0.0%	100%		

Table 2

GROUP	Frequency	%
Dexamethasone group	36	50.0
Nepafenac group	36	50.0
Total	72	100.0

Table 3: Descriptive Statistics

	N	Minimum	Maximum	Mean	SD
AGE	72	56.00	81.00	69.9583	7.81915

Table 4: Independent Samples Test

	GROUP	N	Mean	Std. Deviation	Std. Error Mean	t value	P value
AGE	Dexamethasone group	36	68.3889	7.06006	1.17668	1.727	0.089
	Nepafenac group	36	71.5278	8.31345	1.38558		Non significant

Table 5: Independent Samples Test

	SEX	N	Mean	Std. Deviation	Std. Error Mean	t value	P value
AGE	MALE	37	68.2703	8.38865	1.37908	1.919	0.059
	FEMALE	35	71.7429	6.83995	1.15616		Non significant

Table 6: SEX * GROUP Crosstabulation

			GROUP		
			Dexamethasone group	Nepafenac group	Total
SEX	MALE	Count	18	19	37
		% within SEX	48.6%	51.4%	100.0%
	FEMALE	Count	18	17	35
		% within SEX	51.4%	48.6%	100.0%
Total		Count	36	36	72
		% within SEX	50.0%	50.0%	100.0%

Table 8

Group		NO CHANGE	1+	2+	3+	4+	5+	1-	Total	Chi square Period	Chi square for Group
Dexamethasone Group	1 POD	0	10	9	3	13	1	0	36		
		0.00%	27.78%	25.00%	8.33%	36.11%	2.78%	0.00%	100%		
	2 POD	0	9	10	4	13	0	0	36		
		0.00%	25.00%	27.78%	11.11%	36.11%	0.00%	0.00%	100%		
	WEEK1	0	11	13	5	7	0	0	36		
		0.00%	30.56%	36.11%	13.89%	19.44%	0.00%	0.00%	100%		
	WEEK4	10	13	11	2	0	0	0	36		
		27.78%	36.11%	30.56%	5.56%	0.00%	0.00%	0.00%	100%		
	WEEK 8	8	11	14	3	0	0	0	36		
		22.22%	30.56%	38.89%	8.33%	0.00%	0.00%	0.00%	100%	29.594**	3.162 Non Significant
Nepafenac Group	1 POD	0	9	7	2	13	5	0	36		
		0.00%	25.00%	19.44%	5.56%	36.11%	13.89%	0.00%	100%		
	2 POD	0	8	10	2	10	0	6	36		
		0.00%	22.22%	27.78%	5.56%	27.78%	0.00%	16.67%	100%		
	WEEK1	0	10	12	4	8	2	2	38		
		0.00%	27.78%	33.33%	11.11%	22.22%	5.56%	5.56%	106%		
	WEEK4	15	4	12	5	0	0	0	36		
		41.67%	11.11%	33.33%	13.89%	0.00%	0.00%	0.00%	100%		
	WEEK 8	5	14	12	5	0	0	0	36		
		13.89%	38.89%	33.33%	13.89%	0.00%	0.00%	0.00%	100%		

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