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Original Article

Ophthalmology Section

Comparison of Preoperative Topical Dexamethasone Phosphate Versus Ketorolac Tromethamine in Maintaining Intraoperative Mydriasis During Small Incision Cataract Surgery

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ABSTRACT

Introduction: Intraoperative miosis is one of the many challenges which a surgeon can face during cataract surgery. It may leads to impaired view and difficulty in delivering the nucleus. Also, it increases the chances of more serious intraoperative and postoperative complications. Therefore, maintaining adequate pupillary dilatation is of utmost importance during cataract surgery.

Aim: To study the efficacy of topical dexamethasone phosphate (0.1%) and topical ketorolac tromethamine (0.4%) in maintaining pupillary dilatation during cataract surgery.

Materials and Methods: A total of 200 patients were studied. These were randomly divided into two groups of 100 each. Group1 was given topical dexamethasone phosphate (0.1%) and Group 2, topical ketorolac tromethamine (0.4%). Medications were started 1-day before surgery in the form of one drop to be instilled every 6 hours. Pupillary diameter was measured in the horizontal meridian; 4 readings were taken - before making the incision, after nucleus delivery, following cortical clean-up and after Intraocular Lens (IOL) implantation.

Results: The two drugs showed no statistically significant difference in pupillary diameter at the commencement of surgery (p=0.435). The difference between the two drugs was statistically significant, for the mean pupillary diameter which changed from the start of surgery to after cortical clean-up. At this stage, ketorolac group showed a tendency towards larger mean pupillary diameter than dexamethasone group (6.70 ± 0.85mm and 6.32 ± 0.84mm, respectively, p=0.002). Again, ketorolac group patients had larger pupillary diameter after IOL implantation than dexamethasone group patients (the mean was 6.16± 0.97mm and 5.75 ± 0.73mm, respectively, p=0.001).

Conclusion: Both ketorolac tromethamine (0.4%) and dexamethasone phosphate (0.1%) are effective in maintaining adequate mydriasis during cataract surgery, but the comparative analysis of the two drugs concludes that ketorolac is definitely a better option in preventing surgically induced miosis.

Keywords: Corticosteroids, Miosis, Non-steroidal anti-inflammatory drugs

INTRODUCTION

Intraoperative miosis is one of the many challenges which a surgeon can encounter during cataract surgery. It may leads to impaired view and difficulty in delivering the nucleus. Also, it increases the chances of more serious intraoperative and postoperative complications [1]. Therefore, maintaining pupillary dilatation is of utmost importance during cataract surgery.

Intraoperative miosis is associated with small anterior capsulorrhexis resulting in difficult nucleus manipulation and delivery, vitreous loss, retained lens matter, high risk of iridodialysis, excessive handling of iris tissue with subsequent Prostaglandins (PGs) release, and chronic cystoid macular oedema [2].

Surgical trauma triggers a cascade of events that stimulates the production of PGs. PGs appear to play an integral role in the development of intraoperative miosis. PGs have been observed in the aqueous humour of traumatized eyes and appear to induce miosis independent of cholinergic mechanisms [3]. In many eyes, pupillary constriction starts soon after the anterior chamber is entered. This reaction is thought to be caused by PGs and other mediators that are released during surgery due to breakdown of blood-aqueous barrier [4].

Surgical trauma leads to activation of enzyme phospholipase-A2 that acts on the membrane phospholipids to produce AA and Platelet Activating Factors (PAFs). Arachidonic acid is further metabolised into endoperoxides and then to PGs by cyclo-oxygenase enzyme [5]. Endogenous PGs produce multiple deleterious effects in the eye like miosis, postoperative uveitis, and breakdown of blood-ocular barrier, conjunctival congestion, and change in intraocular pressure [6].

Drugs that inhibit either phospholipase-A2 enzyme or cyclo-oxygenase enzyme, thereby interfering with endogenous PGs production, can be used topically to prevent intraoperative miosis. The former enzyme is inhibited by corticosteroids and the latter by Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These two groups of drugs are also used postoperatively to reduce vascular permeability of the blood-aqueous barrier and to control pain and inflammation [7-10]. The mechanism of action of corticosteroids and NSAIDs overlap in that the corticosteroids indirectly inhibit the synthesis of PGs at an earlier stage by preventing the release of AA from membrane phospholipids by inhibiting the enzyme phospholipase-A2 [11,12].

The first NSAIDs approved by the Food and Drug Administration (FDA) to inhibit intraoperative miosis during cataract surgery are flurbiprofen 0.03% and suprofen 1%. Several clinical studies have supported the fact that topical NSAIDs are highly effective in maintaining mydriasis during cataract surgery. All the commercially available topical NSAID formulations share this therapeutic effect [13].

Very few studies are found in literature for the role of topical corticosteroids (prednisolone acetate 1%, dexamethasone acetate

0.1%) in inhibiting the release of endogenous PGs induced by surgical trauma, and thereby preventing excessive intraoperative miosis [14-16].

AIM

A prospective cross-sectional study was conducted to compare the efficacy of topical dexamethasone phosphate (0.1%) with topical ketorolac tromethamine (0.4%) in maintaining pupillary dilatation during cataract surgery.

MATERIALS AND METHODS

The present prospective, randomized, hospital based, cross-sectional, and comparative study included 200 patients with senile cataract in whom cataract surgery was indicated. The study was conducted over a period of 1-year from November 2014 to October 2015. Due approval from the Ethics Committee of the Institution was taken prior to initiating the study.

Sample size was calculated by taking confidence interval (two-sided) as 95%, power 80%, and ratio of sample sizes between two groups as 1. The difference of means was assumed as 0.3 mm. The standard deviations for dexamethasone and ketorolac tromethamine were taken from the previous study as 0.71 and 0.80mm, respectively [17]. After applying appropriate formula, the sample size for the study found to be 100 in each of the two groups.

Inclusion criteria: Patients of either sex, ≥ 40 years of age with senile cataract and who were scheduled to undergo cataract surgery by manual Small Incision Cataract Surgery (SICS) technique with posterior chamber IOL implantation.

Exclusion criteria included: a) glaucoma; b) ocular inflammation; c) previous history of intraocular surgery or trauma; d) pseudoexfolitation; e) local pupil abnormalities such as iris atrophy, Marfan's syndrome, synechiae, etc.; f) pupil size <6 mm at the start of surgery; g) diabetes mellitus, hypertension; h) patients allergic to topical NSAIDs, preservatives, or any other component of the study medication; i) use of topical PG analogous, topical or systemic steroids and NSAIDs within 30 days prior to enrolment in the study; j) use of tamsulosin or other analogous systemic medications for benign hypertrophy of prostate; k) history of any neuro-ophthalmological diseases; l) immunocompromised patients; m) ocular surface disorders (dry eye); and n) any operative complication such as premature entry into the anterior chamber, iris trauma, iridodialysis, posterior capsular rent, etc.

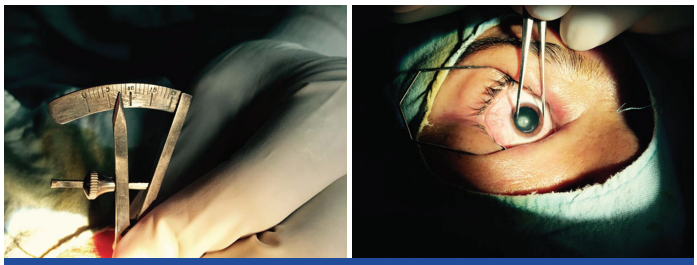
All the patients were admitted 1-day prior to the surgery and were supervised by a junior resident. An informed written consent for the study was taken before surgery. Details regarding ophthalmic history and any relevant medical complaints were recorded. Also, details regarding use of any systemic/ topical medications at the time of study were elicited. General physical examination and detailed local examination of eyes was done including uncorrected and best corrected visual acuity with Snellen's vision drum, slit-lamp examination, fundoscopy, and tonometry. Other investigations included: a) routine urine examination, b) haematological examination such as Haemoglobin (Hb), Bleeding Time (BT) and Clotting Time (CT); c) fasting blood sugar; d) serum urea, creatinine and electrolytes; e) chest X-ray; and f) ECG (all leads).

A total of 200 patients who met the inclusion/exclusion criteria were randomly divided into two groups with 100 eyes in each group: a) Dexamethasone group – Group 1 and b) Ketorolac group – Group 2. The process of randomization was based on random number table prepared by using GraphPad random number generator.

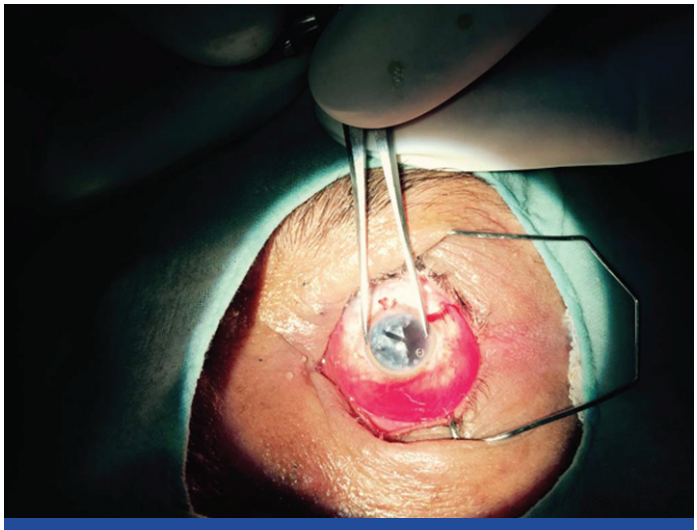
All the patients were advised to start medications one day prior to surgery. In Group 1, patients were given preoperative dexamethasone phosphate (0.1%) and moxifloxacin (0.5%) combination eye drops and in Group 2, ketorolac tromethamine (0.4%) and moxifloxacin (0.5%) combination drops. Dosage of the medications was advised as one drop to be instilled 6 hourly for a total of 4 drops. The administration of preoperative topical medications was advised by the junior resident. The operating surgeon had no information regarding the randomisation process and the type of drug administered in the two groups. A single drug formulation containing 0.8% tropicamide and 5% phenylephrine was used 60, 45 and 30 minutes prior to the surgery to dilate the pupil. Peribulbar anaesthesia was used with 50:50 mixtures of 5ml each of 2% lignocaine and 0.5% bupivacaine with 150 units/ml of hyaluronidase injection.

All cases were operated by a single surgeon using SICS technique with posterior chamber IOL implantation [18]. A chevron external incision was given about 6.5 mm in size with No. 11 Bard-Parker (B.P.) blade and the sclerocorneal tunnel was dissected with crescent knife. Side-port was created with MVR blade and continuous curvilinear capsulorrhexis was done. Anterior chamber was entered and internal incision was enlarged with 2.8 mm keratome. Disposable B.P. blade, crescent, keratome, and MVR blade of the same manufacturer were used in all the patients. Nucleus was delivered by viscoexpression and the same viscoelastic material (hydroxylpropyl methylcellulose 2%) was used in every patient. A single piece polymethyl methacrylate IOL of a single brand and type was implanted in the posterior chamber (in the bag) in all the cases. Pupillary dilation was not supplemented by the use of adrenaline in the irrigating ocular solutions. Also, intracameral use of pilocarpine was strictly avoided.

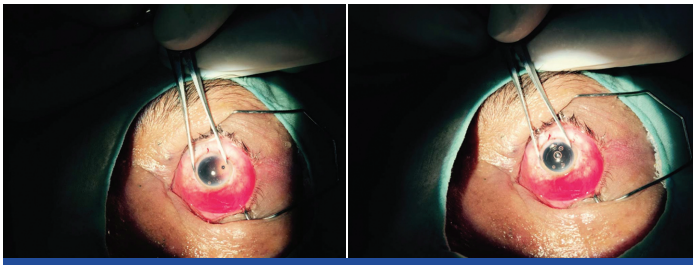
The horizontal pupillary diameter was measured using a Castroviejo-calliper [Table/Fig-1]. Measurement was made by placing the calliper in front of the cornea under standard operating microscope. Same microscope with same illumination (full) and magnification (x10) was used in all cases to ensure standardization of illumination and magnification during pupillary measurement. Readings were taken at four intervals - before making the incision, after nucleus delivery, following cortical lens matter removal, and after IOL implantation [Table/Fig-2-5]. Measurements were done in fully formed anterior chamber. The first reading taken



[Table/Fig-1]: Castroviejo-calliper showing pupillary diameter.
[Table/Fig-2]: Measurement of pupillary diameter before making the incision.



[Table/Fig-3]: Measurement of pupillary diameter after nucleus delivery.



[Table/Fig-4]: Measurement of pupillary diameter following cortical lens matter removal. **[Table/Fig-5]:** Measurement of pupillary diameter after IOL implantation.

before making the incision was labelled as basic measurement. The change in pupil size during the surgery was determined by subtracting the subsequent readings at that particular step from the initial basic reading.

STATISTICAL ANALYSIS

Statistical analysis was done by using the Statistical Package for Social Sciences version 20.0 (SPSS 20.0). Comparison between the two groups for the continuous variables (like age, pupillary diameter, and changes in pupillary diameter) was made using analysis of variance (ANOVA). Chi-square test was used to analyse nominal categorical variables (like sex, operated eye). Difference between the two groups was labelled as significant when p-value was ≤ 0.05%.

RESULTS

A total of 200 patients were randomly divided into two groups each of 100 patients to receive preoperative topical treatment with either dexamethasone phosphate 0.1% drops (Group 1) or ketorolac tromethamine 0.4% (Group 2). The demographic profile of the patients is summarized in [Table/Fig-6]. The mean age of the study population was 58.60 ±10.10 years (range, 41-80 years) in Group 1 and 60.22 ± 9.49 years (range, 42-78 years) in Group 2. Statistically, the two groups did not show any differences between age, sex and affected eyes.

Characteristics	Group 1 (n=100)	Group 2 (n=100)	p-value	Remarks
Age [Years]				
Mean ± SD	58.60 ± 10.10	60.22 ± 09.49	0.244	NS
Range	41-80	42-78		
Sex [No. (%)]				
Male	56(56)	51(51)	0.479	NS
Female	44(44)	49(49)		
Eye Affected [No. (%)]				
Right	55(55)	48(48)	0.323	NS
Left	45(45)	52(52)		

[Table/Fig-6]: Demographic profile of the study population.
[SD: Standard deviation; NS: Not significant; No.: Number of patients]

The mean pupillary diameter in horizontal meridian (M) during different stages of surgery for both the groups is depicted in [Table/Fig-7]. Differences between the two groups were tested by using t-test. At the start of surgery (M1), the mean pupillary diameter was 7.88mm ± 0.68mm in the dexamethasone treated group (Group 1) and 7.96mm ± 0.69mm in ketorolac treated group (Group 2); showing no statistically significant difference (p=0.435). The change of mean pupillary diameter from the initiation of surgery (MI) to after nucleus removal (M2) was less with ketorolac group (1.15mm ± 0.65) than with the dexamethasone group (1.24 ± 0.84mm), but the difference was not statistically significant (p=0.166). After cortical lens matter removal (M3), the change of mean pupillary diameter from the initial basic measurement (M1) was less with ketorolac group (1.26 ± 0.62mm) than with the dexamethasone group (1.56 ± 0.87mm). The ketorolac group showed a tendency towards having a larger pupil diameter. The two groups at this step attained a statistically significant difference (p=0.002).

The change in mean pupil size from initial basic measurement (M1) at the time of commencement of surgery to the last reading taken after IOL implantation (M4) was less with Group 2 (1.80 ± 0.84mm) than with Group 1 (2.13 ± 0.84mm). The difference observed in the mean pupil size among the two groups at this stage was again statistically significant (p=0.001).

DISCUSSION

Miosis due to surgical trauma is one of the important obstacles for successful cataract surgery. It leads to difficulty in nucleus delivery and makes the eye more vulnerable to serious intraoperative and postoperative complications [1]. Topical Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) are important group of drugs which help cataract surgeons to reduce intraoperative miosis, and also are beneficial in controlling postoperative pain and inflammation [7-10,19].

Several studies compared the effects of topical NSAIDs with placebo in inhibiting miosis during cataract surgery [17]. A number of comparative studies showed similar therapeutic efficacy of various ophthalmic NSAIDs with only minor differences in preventing intraoperative miosis [13]. The timing regarding installation of NSAIDs drops is still a controversial issue, but the common practice is using topical NSAIDs prior to surgery for desired effects [20].

Several people have done comparative studies regarding the role of topical NSAIDs and corticosteroids in reducing postoperative ocular inflammation after cataract surgery [10]. But the efficacy of topical steroids in preventing intraoperative miosis is not adequately studied. There are only few studies which have documented the role of corticosteroids in the prevention of intraoperative miosis during cataract surgery [14-16].

In our study, no statistically significant difference was seen in the mean pupillary diameter between dexamethasone and ketorolac treated eyes at the start of surgery (p=0.435). The change in

M	Topical drops used (Group 1 & 2)	N	Mean	SD	95% CI		Min	Max	p-value
					Lower bound	Upper bound			
M1	Dexamethasone (Group 1)	100	7.88	0.68	7.74	8.02	7.00	9	0.435
	Ketorolac (Group 2)	100	7.96	0.69	7.82	8.09	7.00	9	
M2	Dexamethasone (Group 1)	100	6.64	0.89	6.46	6.82	5.00	8.5	0.166
	Ketorolac (Group 2)	100	6.81	0.84	6.64	6.98	5.00	8.5	
M3	Dexamethasone (Group 1)	100	6.32	0.84	6.15	6.49	5.00	8	0.002
	Ketorolac (Group 2)	100	6.70	0.85	6.53	6.87	5.00	8.50	
M4	Dexamethasone (Group 1)	100	5.75	0.73	5.61	5.89	5.00	8	0.001
	Ketorolac (Group 2)	100	6.16	0.97	5.97	6.35	5.00	8	

[Table/Fig-7]: Mean intraoperative pupillary diameters in Group 1 and Group 2.
[M: Mean pupillary diameter; M1: At the start of surgery i.e. before making the incision; M2: After nucleus delivery; M3: Following cortical clean-up; M4: Afterintraocular lens (IOL) implantation; N: Number of patients;SD: Standard deviation; 95% CI: 95% Confidence interval for mean; Min: Minimum; Max: Maximum]

Author(s)	Topical drops used	N	Pupillary diameter (mm) Mean ± SD		p-value	Significance
			At the start of surgery	At the end of surgery		
Suleiman et al. [15]	Ketorolac (0.5%)	25	7.72 ± 0.54	6.28 ± 0.74	<0.0001	HS
	Prednisolone (1%)	25	7.52 ± 0.65	5.34 ± 0.72		
Mahdy [16]	Flurbiprofen (0.03%)	35	7.38 ± 0.51	6.28 ± 0.50	0.03	S
	Dexamethasone (0.1%)	35	7.28 ± 0.48	6.06 ± 0.40		
Zanetti at al ., [17]	Ketorolac (0.4%)	35	7.8 ± 0.8	6.9 ± 0.9	0.003	S
	Nepafenac (0.1%)	35	7.9 ± 0.9	6.9 ± 0.9		
	Prednisolone (1%)	35	7.9 ± 0.7	6.8 ± 0.9		
	Placebo	35	7.5 ± 0.6	6.1 ± 1.1		
Sethi et al. [21]	Nepafenac (0.1%)	20	>6* (20/20)†	>6* (17/20)†	0.003	S
	Prednisolone (1%)	20	>6* (20/20)†	>6* (16/20)†		
	Placebo	20	>6* (20/20)†	>6* (07/20)†		
Present study	Ketorolac (0.4%)	100	7.96 ± 0.69	6.16 ± 0.97	0.001	HS
	Dexamethasone (0.1%)	100	7.88 ± 0.68	5.75 ± 0.73		

[Table/Fig-8]: Comparison of results between present study and those reported by various authors in literature.
[N: Number of patients; SD: Standard deviation; HS: Highly significant; S: Significant; *Pupillary size; † Number of patients]

mean pupillary diameter from the basic measurement to after nucleus delivery was less with ketorolac group than with the dexamethasone group , but at this stage, again the difference was not significant (p=0.166). The changes in mean pupil size from the basic measurement to after cortical clean-up and IOL implantation were less with the ketorolac group than with the dexamethasone group. Ketorolac group showed larger mean pupillary diameters compared to dexamethasone group and the differences being statistically significant at these stages of surgery (p=0.002 and p=0.001, respectively). Thus, the important observation made in our study was that the ketorolac treated group showed a consistent trend towards more stable mydriasis and a significant inhibition of miosis at all comparative stages of surgery.

Our results were similar to the previous comparative studies between NSAIDs and corticosteroids as reported by various authors in the literature [Table/Fig-8]. Preoperative topical NSAIDs have been reported to be more effective than corticosteroids or placebo in maintaining mydriasis during cataract surgery [13,14,22-27].

Thus, the results of our study corroborate well with the above quoted studies that both the corticosteroids and the non-steroidal anti-inflammatory group of drugs are efficacious in inhibiting surgically induced miosis during cataract surgery since both the drugs prevent PGs release caused by ocular trauma either by inhibition of phospholipase-A2 enzyme (dexamethasone) or cyclo-oxygenase enzyme (ketorolac tromethamine), but NSAIDs are superior to corticosteroids in terms of maintaining a consistently larger pupil size and having a more prolonged effect. The hypothesis given in support of this states that dexamethasone inhibit platelet activating factors (PAFs) which probably are beneficial in maintaining mydriasis during surgery, while this mechanism of action is lacking in ketorolac tromethamine [15,16]. However, this fact needs to be supported by further studies.

LIMITATION

The limitation of the study was that only the horizontal pupillary diameter was measured, whereas vertical diameter was not taken into account which could have affected the final results. Moreover, an exclusion of diabetes and hypertensive patients from the study also limits the applicability of the results on these patients.

We could not find any study comparing preoperative topical dexamethasone phosphate and ketorolac tromethamine eye drops in maintaining mydriasis during cataract surgery in the literature. Thus, more research is needed to confirm the results of our study.

Further studies are required to evaluate the effect of these drugs in maintaining pupillary dilatation when other types of surgeries (phacoemulsification, etc.), viscoelastic material (sodium hyaluronate agents) or different types of IOLs (e.g., acrylic IOLs, accommodating IOLs, multifocal IOLs, etc.) are used.

CONCLUSION

Therefore, we may conclude that both ketorolac tromethamine (0.4%) and dexamethasone phosphate (0.1%) are effective in maintaining adequate mydriasis during cataract surgery, but the comparative analysis of two drugs have shown that ketorolac is definitely a better option in preventing surgically induced miosis.

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