

Pre-Operative Diclofenac Sodium Eye Drops Vs Intra-Operative Adrenaline Irrigation in Maintaining Mydriasis during Extracapsular Cataract Extraction

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Pak J Ophthalmol 2014, Vol. 30 No. 4

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Purpose: To compare the effectiveness of pre-operative diclofenac sodium eye drops with per-operative intraocular irrigation with adrenaline 1:1,000,000 (one in one million) solution in maintaining mydriasis during cataract surgery.

Material and Methods: It was a randomized control trial and was conducted in the department of Ophthalmology, Khyber Teaching Hospital Peshawar from September 2010 to March 2011. 210 patients with senile mature cataracts were divided into two groups "A" and "B" with 105 patients in each group. Group "A" received pre-operative diclofenac eye drops for 24 hours and group "B" received per-operative irrigation with 1:1,000,000 of adrenaline solution. In all patients pupillary size was measured after cortical matter removal during extracapsular cataract extraction.

Results: The mean age of patients in group "A" was 59.87 ± 6.54 SD years and in group "B" was 61.38 ± 6.30 SD. The mean pupillary size after cortical matter removal in group "A" was $7.0667 \text{ mm} \pm 1.78$ SD while that in group "B" was $8.3371 \text{ mm} \pm 1.94$ SD. The difference between the two was statistically significant after applying independent sample 't' test with p value of <0.000 .

Conclusion: Per-operative irrigation of adrenaline 1:1,000,000 solution keeps better pupillary size as compared to pre-operative diclofenac sodium for patients undergoing extracapsular cataract extraction,

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Key Words: Adrenaline, Extra capsular Cataract Extraction, Diclofenac sodium

Cataract surgery is one of the most common surgical procedures in patients over the age of 60 years.¹ Over the past decade operative technique in cataract surgery has improved and the operation has become less traumatic to the eye.²

Pupillary constriction during cataract surgery is found to be the major cause of iris damage, incomplete cortex removal, posterior capsular rupture, vitreous loss, and even posterior lens matter dislocation.^{3,4} Cataract surgery can be performed more easily and safely if mydriasis can be maintained until intraocular lens implantation.⁵ Different drugs e.g. cyclopentolate, tropicamide and diclofenac sodium have been used

pre-operatively to maintain per-operative pupillary dilatation.^{6,7}

Per-operative intraocular irrigation with adrenaline 1:1,000,000 solution has been found to be safe and effective in maintaining mydriasis during cataract surgery.⁶ Pre-operative diclofenac sodium eye drops have also been used and have found effective in maintaining mydriasis during cataract surgery.⁸

Purpose of the study was to determine the outcome of per-operative intraocular irrigation with adrenaline 1:1,000,000 solution is better than pre-operative diclofenac sodium eye drops in maintaining

mydriasis during cataract surgery that help in prevention of complication. It is also cost effective and compliance is better than diclofenac sodium eye drops. No local study with such a sample size had been carried out on this topic and this will help in changing the protocol used for maintaining mydriasis during cataract surgery.

MATERIAL AND METHODS

This was a randomized control trial and was conducted at the department of Ophthalmology of Khyber Teaching Hospital, Peshawar from September 2010 to March 2011. All patients with age related cataracts that undergone extracapsular cataract extractions by the same surgeon were enrolled in the study. Patients with complicated cataracts including cataracts with uveitis, pigment dispersion syndrome, pseudoexfoliation, lens related glaucoma, traumatic cataracts and patients with cardiac diseases, diabetes and hypertension were excluded from the study to avoid biased in the study results. Patients were diagnosed with slit - lamp examination and ophthalmoscopy. Written informed consent was taken from all patients. Pupil in patients of both groups was dilated with topical Tropicamide 1% eye drops (1 drop every 10 minutes for 45 minutes- 1 hour before surgery). These patients were randomly allocated into "A" (diclofenac group) and "B" (adrenaline group) by lottery method. Adrenaline 1:1,000,000 solution was made by diluting one adrenaline ampule 1:1000 in 1 liter (1000 ml) of ringer lactate. Patients in group "A" had mydriasis with pre-operative diclofenac sodium for 24 hours before surgery and patients in group "B" were irrigated pre-operatively with adrenaline 1:1,000,000 solution. Intra-operatively pupil size was measured with a caliper after cortical lens matter removal during surgery. Exclusion criteria were followed strictly to avoid any confounder and bias in study results. All the statistical analysis was carried out using SPSS version 11.0. Student t-test was applied between the pupil sizes of both the drugs to see their effects. P-value of ≤ 0.05 was considered significant.

RESULTS

A total of 210 patients were enrolled in the study and were randomly distributed in two groups A and B with 105 patients in each group. In group A there were 71 (68.6%) male and 34 (32.4%) female patients, whereas in group B there were 74 (70.5%) male and 31

(29.5%) female patients. All patients enrolled have age range of 51 - 71 years with a mean of 59.87 ± 6.54 SD in group A and 61.38 ± 6.30 SD in group B. Average pupillary size in group A was $7.0667 \text{ mm} \pm 1.78$ SD and in group B was $8.3371 \text{ mm} \pm 1.94$ SD which was highly significant with p-value = 0.000 (Table 1).

The efficacy of group A was 29 (27.6%) and group B was 63 (60%) (p-value = 0.000) (Table 2).

Age wise distribution of efficacy shows that 25 (27.2%) of efficacy belongs to patients with age equal to or less than 55 years while 18 (19.6%) in age group of 56 - 60 years, 24 (26.1%) in 61 - 65 years while 25 (27.2%) efficacy was seen in above 66 years of age, which is significant with p-value = 0.254 (Table 3).

Efficacy in male patients was 58 (63%) while in females it was observed in 34 (37%). Majority of efficacy was shown in male as compared to female, although it was not significant statistically with p-value = 0.097 (Table 4).

DISCUSSION

Cataract extraction in majority of cases is a safe and effective procedure, but maintenance of mydriasis can contribute to the ease with which surgery can be performed.⁷ A small pupil during surgery may increase the risk of damage to the iris, incomplete removal of soft lens matter and more importantly, rupture of the posterior capsule with vitreous loss.⁸ To maintain mydriasis during surgery, various drugs have been used but it depends upon the surgeons choice and available authentic literature⁹. The persistence of good mydriasis is a prerequisite for cataract surgery.¹⁰ Adequate use of preoperative mydriatics, subconjunctival mydricaine, preservative-free intracameral adrenaline, iris retractors and sphincterotomies are some of the methods to combat poor mydriasis.¹¹ In spite of all these measures, the problem of poor mydriasis is still a problem for surgeons.¹² Hence we undertook this study, creating a new local data regarding the best mydriatic among diclofenac sodium and adrenaline regimen to enable us to achieve better mydriasis during cataract surgery.

The present study demonstrates that adrenaline 1:1,000,000 in the intraocular infusion is of significant benefit in maintaining mydriasis during cataract surgery compared to diclofenac sodium. The mean age of patient in diclofenac sodium group was 59.87 ± 6.54 SD while that in the adrenaline group was 61.38 ± 6.30 SD. The mean pupillary size at the time of cortical matter removal in diclofenac sodium group was

Table 1: Papillary size wise distribution of patients in both groups

Groups		N	Mean	Std. Deviation	p-value
Pupillary size (mm)	A	105	7.0667	1.78146	0.000
	B	108	8.3371	1.94211	

Table 2: Efficacy wise comparison in both groups

		Group				Total	%	p-value
		A	%	B	%			
Efficacy	No	76	72.40	42	40	118	56.20	0.000
	Yes	29	27.60	63	60.0	92	43.80	
Total		105	100.0	105	100.0	210	100.0	

Table 3: Age wise distribution of efficacy

Age (in Years)	Efficacy				Total	%	p-value
	No	%	Yes	%			
≤ 55	34	28.80	25	27.20	59	28.10	0.254
56 - 60	33	28.00	18	19.60	51	24.30	
61 - 65	19	16.10	24	26.10	43	20.50	
66 ≥	32	27.10	25	27.20	57	27.10	
Total	118	100	92	100	210	100	

Table 4: Gender wise comparison of the efficacy

Gender	Efficacy of Procedure				Total	%	p-value
	No	%	Yes	%			
Male	37	73.70	58	63.00	145	69.00	0.097
Female	31	26.30	34	37.00	65	31.00	
Total	118	100.0	92	100.0	210	100.0	

7.0667 mm ± 1.78 SD while that in adrenaline group was 8.3371 mm ± 1.94 SD. The difference was statistically significant after applying independent sample t-test with p-value of < 0.000. The results of our study clearly verified that adrenaline 1:1000000 solution is quite effective in maintaining mydriasis during cataract extraction along with IOL insertion for age related senile cataract.

A study conducted by Flach AJ comparing the pupillary sizes at various stages of extracapsular

cataract extraction. The average dilation in adrenaline group at 45minutes was 7.13 mm and that in diclofenac group was 5.88 mm.¹³ The difference achieved in both the dilating regimens was 1.25 mm which was statistically significant using the unpaired t-test (p < 0.001). The results of this study were quite comparable and in close approximation to what are achieved in our study.

Similar results were obtained in a study conducted by Ong-Ton L, he concluded his results showing better

efficacy of adrenaline over diclofenac sodium as mean pupil diameter after cortical lens matter removal was $8.14 \text{ mm} \pm 0.85$ for adrenaline and $7.87 \text{ mm} \pm 1.03$ for diclofenac sodium and the difference was statistically significant ($p < 0.002$).⁶ These results were quite closer to what we found in our study.

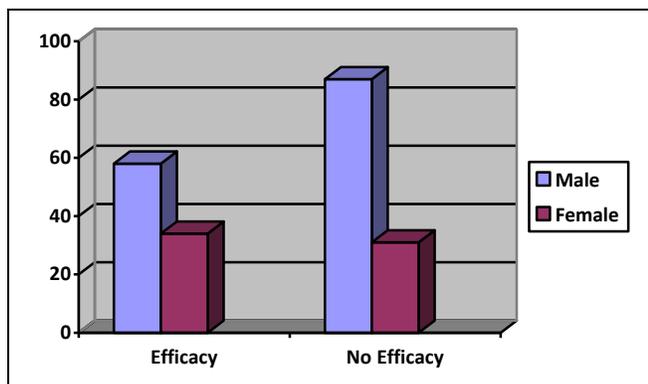


Fig. 1: Ender wise comparison of efficacy

Fahimi MS et al also demonstrated similar results in his study for pupillary size during ECCE with a p-value of < 0.04 proving that the difference between in pupillary size is statistically significant.¹³ And even a much stronger difference has been quoted by Guadalupe Cervantes-Coste with the mean pupil size at the end of surgery, between diclofenac sodium ($6.84 \pm 0.93 \text{ mm}$) and adrenaline group ($7.91 \pm 0.74 \text{ mm}$) was statistically significant ($p < 0.001$).¹⁴

Similarly in a study conducted by Bäckström G, showed that there was a greater degree of contraction in the absence of adrenaline in the irrigation solution ($2.3 \pm 1.0 \text{ mm}$ in the intracameral mydriatics (ICM) group and $3.2 \pm 0.7 \text{ mm}$ in the placebo group ($p = 0.015$)).¹⁵

Our study has shown that per-operative intraocular irrigation with adrenaline 1:1000,000 has significant benefit in maintaining mydriasis during cataract surgery.

CONCLUSION

Per operative irrigation of adrenaline 1:1,000,000 solution keeps better pupillary size compared to pre operative diclofenac sodium for patient undergoing extracapsular cataract extraction.

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