"Comparison of subconjunctival injection of dexamethasone with intracameral injection of dexamethasone on corneal endothelial cells after phacoemulsification"

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Abstract

Introduction: Subconjunctival dexamethasone injections are used in limiting postoperative anterior segment inflammation after cataract surgery. By intracameral route, drug can be administered into the anterior chamber, being less painful and with fewer complications. Rationale of the study was to gather evidence about these two injection procedures in order to devise our local guidelines for better management of these patients.

Methodology: Fourteen hundred and sixty (n=1460) patients between age 45-65 irrespective of gender who had senile cataract having nuclear sclerosis of grade Nuclear Opalescence-2 (NO2), Nuclear Color-2 (NC2) and Nuclear Opalescence-3 (NO3), Nuclear Color-3 (NC3). Patients were equally divided into two groups. Group A received subconjunctival dexamethasone injection and Group B received intracameral dexamethasone injection. Change in endothelial count density was measured at 3 months after intervention in both groups and compared using t-test.

Results: In group A, mean percent change in endothelial count density was found to be 7.38 ± 1.06 SD, while in group B it was 7.51 ± 1.40 SD (*P*>0.05). Gender, age and phacoemulsification time based stratification showed no significant difference among both groups (*P* > 0.05).

INTRODUCTION

Cataracts are the major cause of blindness in the world. They still account for over half of the causes of blindness in Pakistan (1). Cataract extraction is one of the most routinely performed surgery on the elder population and the number of surgeries is expected to swell up in the future, due to increasing life expectancy (2). Anterior segment inflammation is a common postoperative complication. It can result in the formation of inflammatory pupillary membranes, posterior synechiae, capsular opacification and raised intraocular pressures (3). This causes patient distress

and delays visual rehabilitation (4). Steroids as anti inflammatory counteract these concerns (5). The per-operative use of steroids is well recognized in routine cataract surgery (6).

Dexamethasone is an extremely effective steroid in limiting postoperative inflammation (7). Subconjunctival dexamethasone injections are given after almost every surgery but the practice of using per-operative intracameral steroids is relatively new (8). The advantage of intracameral route is that the drug acts directly where it is required i.e. the anterior chamber, therefore the amount of drug required is less. Moreover it is less painful and complications associated with subconjunctival injections like subconjunctival hemorrhage, subdermal fat atrophy, muscle atrophy, inadvertent globe perforation and skin hypopigmentation are avoided. A study concludes that there is no significant difference in endothelial cell counts between subconjunctival and intracameral route preoperatively and postoperatively (7.55±1.19% in subconjunctival group vs. $7.63 \pm 1.10\%$ endothelial cell loss in intracameral group). Mean change in endothelial cell count at 3 months was 2496.46±171.77 in subconjunctival group and 2471.77±201.57 in intracameral dexamethasone group (9). Corneal endothelium is an exceedingly sensitive layer of the cornea; once damaged the cells have no capability of regeneration (10). A healthy cornea has approximately 2400-3200 endothelial cells/mm² (11). It is established that intracameral dexamethasone significantly reduces anterior segment inflammation but its effect on susceptible endothelial cells must be deliberated in order to determine its safety profile as a new therapeutic modality. Prior to using intraocular dexamethasone, one has to be definite that it has no undesirable effect on the endothelial cells.

MATERIALS AND METHODS

A randomized controlled trail study was conducted from January 2015 to October 2015 at the outpatient department of Al-Shifa Trust Eye Hospital Rawalpindi, Pakistan.

Sample Size: Using WHO sample size calculator,ⁱ

- ➢ Level of Significance: 5%
- > Power of Test: 80%
- Population Pooled Standard Deviation: 189.67
- Test Value of Population Mean: 2496.46
- Anticipated Population Mean: 2471.77
- Minimum Sample Size in each group: 730
- ▶ Total number of patients: 1460

Sample Technique: Non-probability Consecutive sampling technique

Sample selection criteria: The study include all patients of age 45-65 years presenting in at the OPD of Al-Shifa Trust Eye Hospital Rawalpindi, Pakistan.

Inclusion criteria: i. Patients of either gender between ages of and 45 and 65 years. ii. Senile cataract having nuclear sclerosis of grade NO2 NC2 and NO3 NC3 (Lens Opacities Classification System III/LOCS III *see annex for detail)

Exclusion criteria: i. Patients having previous history of intraocular surgery. ii. Pathologies that may contribute to corneal damage (corneal opacities, glaucoma or ocular inflammations).

iii. Preoperative endothelial cell count less than 2000 cells/mm². iv. Per-operative complication (wound burns, descemet stripping, vitreous loss).

Data Collection Procedure:

The study was conducted after approval has been accorded by the hospital ethical committee. Baseline readings included anterior segment examination and dilated fundal examination performed on slit lamp biomicroscopy. Patients were chosen according to the inclusion criteria and excluded on the basis of history and slit lamp examination. An informed written consent was taken from the patients in the study after explaining its nature. Data of each patient was collected i.e. name, age, gender and contact information. This information was noted on a specially designed proforma. The patients were divided into two groups, by lottery method, each comprising of 730 patients. **Group-A** received subconjunctival dexamethasone (2 mg/0.5 ml) whereas **Group-B** received intracameral dexamethasone (0.4 mg/0.1 ml) at the end of the surgery.

Pre-operative specular microscopy for corneal endothelial cell count was performed with SP 2000P Topcon specular microscope, by an experienced ophthalmic technician. All patients were operated by limbal incision and surgery was performed by surgeons experienced in phacoemulsification. Foldable hydrophilic acrylic intraocular lens (Auroflex) was implanted in the capsular bag. Phaco-machine, phaco-power, viscoelastic, irrigation fluid and intraocular lens were kept constant in all patients. Postoperatively, all patients received a combination of tobramycin 0.3% and dexamethasone 0.1% (Tobradex) eye drops six times per day for 6 weeks. Postoperatively, specular microscopy for corneal endothelial cell count was performed at 3 months. These readings were entered in the pre designed proforma by the principle investigator.

Data Analysis Procedure:

All the information were entered and analyzed in Statistical Package for Social Sciences (SPSS) version 17.0. Descriptive statistics was calculated for both qualitative and quantitative variables. For qualitative variables like gender and eye involved (right or left), frequencies and percentages were calculated. For quantitative variables like age mean and standard deviation was calculated. Endothelial cell count at baseline, 3 months and change in cell count presented as mean and standard deviation. Effect modifiers like age, gender and phacoemulsification time was controlled by stratification. Post stratification independent sample *t*-test was used. Data was presented in the form of tables, graphs and charts. Comparison between the two groups in terms of mean change in endothelial cell count was done by unpaired samples *t*-test. The level of statistical significance was p < 0.05.

RESULTS

Demography of the selected Population

A total of fourteen hundred and sixty (n=1460) patients were recruited in this study after the informed consent from every patient. All adult patients between age 45-65 irrespective of gender who had senile cataract having nuclear sclerosis of grade NO2 NC2 and NO3 NC3 according to Lens Opacities Classification System III (LOCS III) were included in the study. Exclusion criteria were strictly followed. After the approval from the hospital ethical committee and a written informed consent, seven hundred and thirty (n=730) patients were randomly allocated to each of the intervention groups using lottery method.

Group A comprised of 730 Patients who received subconjunctival dexamethasone injection and **Group B** comprised of 730 Patients who received intracameral dexamethasone injection. The patient were followed after 3 months of the initial treatment in both groups and evaluated for change in endothelial count density.

In **Group A**, 47.7% (n=348) patients were males with the mean age of 56.0 years \pm 6.4 Standard Deviation (SD) and 52.3% (n=382) were females with mean age of 57.3 years \pm 6.9 SD. Cumulative mean age of **Group A** was 56.7 years \pm 6.7 SD. In **Group B**, 64.9% (n=474) patients were males with the mean age of 57.3 years \pm 6.6 SD and 35.1% (n=256) were females with mean age of 55.6 years \pm 7.0 SD. Cumulative mean age of **Group B** was 56.7 years \pm 6.8 SD (Table 1&2).

In **Group A**, 57.0% (n=416) of surgeries performed were found in right eye and 43.0% (n=314) in left eye. In **Group B** the percentages were 64.9% (n=474) and 35.1% (n=256) for right and left eye respectively (Table 3).

Mean phacoemulsification time in **Group A** was 26.6 sec \pm 9.5 SD and was 26.4 sec \pm 9.7 SD in **Group B** (Table 4).

Mean endothelial count density at baseline in **Group A** was 2430.8 ± 266.1 SD and was 2425.9 ± 263.8 SD in **Group B** (Table 5).

Mean endothelial count density at 3 months in **Group A** was 2251.4 ± 248.6 SD and was 2243.6 ± 246.6 SD in **Group B** (Table 6).

Outcomes of treatment in both groups

In **Group A**, after 3 months of treatment mean percent change in endothelial count density was found to be 7.38 ± 1.06 SD, while in **Group B**, it was 7.51 ± 1.40 SD. Independent t-test test was employed to assess the statistical significance of observed difference. *P*-value was found to be 0.06 implying no significant difference in change in endothelial count density among both the treatment groups at 3 months (Table 7).

Stratification with respect to gender in both groups

In males of **Group A**, among males, mean percent change in endothelial count density was found to be 7.35 ± 1.02 SD, and in males of **Group B**, it was found to be 7.48 ± 1.41 SD. Mean endothelial cell count in males of group B was significantly higher as compared to that of males of group A (p < 0.02). In females of **Group A**, mean change in endothelial cell count was 7.42 \pm 1.09 while in females of **Group B**, it was found to be. 7.54 ± 1.39 . *P*-value was found to be 0.79, implying no significant difference between the two groups. Overall there was no

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significant difference in mean change in endothelial cell count in males and females of the two groups (p < 0.07) (Table 8).

Stratification with respect to age in both groups

In **Group A**, among age group 45-55 years, mean percent change in endothelial count density was found to be 7.46 ± 1.05 SD. in the **Group B** patients of this age group, mean percent change in endothelial count density was found to be 7.47 ± 1.43 SD. *P*-value was found to be 0.863 implying no significant difference.

In patients of age between 56-65 years in **Group A**, mean percent change in endothelial cell count was 7.33 ± 1.06 while it was 7.53 ± 1.37 in patients of **Group B**. Mean percent change in endothelial cell count in patients having age 56-65 years in Group B was significantly higher as compared to that of Group A in the same age category (p < 0.021). Over all there was no significant difference in mean change of endothelial cell count between the two age groups (p < 0.65) (Table 9).

Stratification with respect to phacoemulsification time in both groups

In the patients with phacoemulsification time <20 sec in **Group A**, mean percent change in endothelial count density was found to be 7.37 ± 1.09 SD, while for patients in **Group B**, it was 7.51 ± 1.44 SD. There was no significant difference between the two groups (p < 0.129). In patient group with phacoemulsification time >20 sec in **Group A**, mean percent change in endothelial count density was 7.39 ± 1.02 SD, while in **Group B** it was 7.49 ± 1.35 SD. No significant difference was found between the two groups (p < 0.276). Over all there was no significant difference in mean change in endothelial cell count in patients having phacoemulsification time more or less than 20 seconds (p < 0.063) (Table 10).

	GR	OVER ALL	
GENDER	R GROUP A GROUP E (SUBCONJUNCTIVAL (INTRACAME DEXAMETHASONE) DEXAMETHAS		
MALES	348	474	822
MALES	47.7%	64.9%	56.3%
FEMALES	382	256	638
FEMALES	52.3%	35.1%	43.7%
TOTAL	730	730	1460
TOTAL	100.0%	100.0%	100.0%

Table 1: Demographic Profile of the study Population (gender distribution)



GROUPS	GENDER	MEAN (YEARS)	STD. DEVIATION
GROUP A	MALES	56.0	6.4
(SUBCONJUNCTIVAL	FEMALES	57.3	6.9
DEXAMETHASONE)	TOTAL	56.7	6.7
GROUP B	MALES	57.3	6.6
(INTRACAMERAL	FEMALES	55.6	7.0
DEXAMETHASONE)	TOTAL	56.7	6.8
	MALES	56.7	6.5
OVER ALL	FEMALES	56.2	6.9
	TOTAL	56.7	6.7
	SI	_	

Table 2: Demographic Profile of the study Population (age distribution)

	GRO	OVER ALL	
LOCATION OF LESION	GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)	GROUP B (INTRACAMERAL DEXAMETHASONE)	
DICUTEVE	416	474	890
RIGHT EYE	57.0%	64.9%	61.0%
LEFT EYE	314	256	570
	43.0%	35.1%	39.0%
TOTAL	730	730	1460
IOTAL	100.0%	100.0%	100.0%
	JS	ER	

Table 3: Demographic Profile of the study Population (site of lesion distribution)

Table 4: Phacoemulsification time in both groups

GROUPS	MEAN (SECONDS)	STD. DEVIATION
GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)	26.6	9.5
GROUP B (INTRACAMERAL DEXAMETHASONE)	26.4	9.7
TOTAL	26.5	9.6
IJ5		

GROUPS	MEAN (COUNTS)	STD. DEVIATION	
GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)	2430.8	266.1	
GROUP B (INTRACAMERAL DEXAMETHASONE)	2425.9	263.8	
TOTAL	2428.4	264.8	
IJS		R	

Table 5: Mean endothelial count density at baseline

GROUPS	MEAN (COUNTS)	STD. DEVIATION
GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)	2251.4	248.6
GROUP B (INTRACAMERAL DEXAMETHASONE)	2243.6	246.6
TOTAL	2247.6	247.5
IJS		R

Table 6: Mean endothelial count density at 3 months

Table 7: Comparison of mean percent change in endothelial count density at 3 months in both groups

GROUPS	MEAN PERCENT CHANGE	STD. DEVIATION	P-VALUE t-test	
GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)	7.38	1.06	0.06	
GROUP B (INTRACAMERAL DEXAMETHASONE)	7.51 1.40		0.00	
J	SE			

Table 8: Stratification of mean change in endothelial cell count with respect to gender(n=1460)

GENDER	GROUPS	MEAN CHANGE IN ENDOTHELIAL CELL COUNT		P- VLAUE
		n	Mean ± SD	
MALES	GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)	348	7.35 ± 1.02	0.02
	GROUP B (INTRACAMERAL DEXAMETHASONE)	474	7.48 ± 1.41	
FEMALES	GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)	382	7.42 ± 1.09	0.79
	GROUP B (INTRACAMERAL DEXAMETHASONE)	256	7.54 ± 1.39	
OVER ALL	MALES	822	7.39 ± 1.06	0.07
	FEMALES	638	7.50 ± 1.40	

Table 9: Stratification of mean change in endothelial cell count with respect to age

(n=1460)

GROUPS	END	OTHELIAL CELL	P-VALUE	
	Ν	MEAN ±SD		
GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)	323	7.46 ± 1.05	0.863	
GROUP B (INTRACAMERAL DEXAMETHASONE)	324	7.47 ± 1.43	2	
GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)	407	7.33 ±1.06	0.021	
GROUP B (INTRACAMERAL DEXAMETHASONE)	406	7.53 ± 1.37		
45-55 YEARS 56-65 YEARS	647 813	7.46 ± 1.26 7.43 ± 1.23	0.65	
	GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE) GROUP B (INTRACAMERAL DEXAMETHASONE) GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE) GROUP B (INTRACAMERAL DEXAMETHASONE) 45-55 YEARS	END COUGROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)323GROUP B (INTRACAMERAL DEXAMETHASONE)324GROUP B (INTRACAMERAL DEXAMETHASONE)407GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)407GROUP B (INTRACAMERAL DEXAMETHASONE)406GROUP B (INTRACAMERAL DEXAMETHASONE)406GROUP B (INTRACAMERAL DEXAMETHASONE)406GROUP B (INTRACAMERAL DEXAMETHASONE)406GROUP B (INTRACAMERAL DEXAMETHASONE)406	ENDUTHELIAL CELL COUNTIAL MEAN ±SDGROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)3237.46 ± 1.05GROUP B (INTRACAMERAL DEXAMETHASONE)3247.47 ± 1.43GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)4077.33 ± 1.06GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)4077.53 ± 1.37GROUP B (INTRACAMERAL DEXAMETHASONE)4067.53 ± 1.37GROUP B 	

Table 10: Stratification of mean change in endothelial cell count with respect to phacoemulsification time (n=1460)

PHACOEMULSIFIC- ATION TIME (SECONDS)	GROUPS	MEAN CHANGE IN ENDOTHELIAL CELL COUNT		P-VALUE
		Ν	MEAN ±SD	
<20	GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)	385	7.37 ± 1.09	0.129
	GROUP B (INTRACAMERAL DEXAMETHASONE)	385	7.51 ± 1.44	
>20	GROUP A (SUBCONJUNCTIVAL DEXAMETHASONE)	345	7.39 ± 1.02	0.276
	GROUP B (INTRACAMERAL DEXAMETHASONE)	345	7.49 ± 1.35	
OVER ALL	<20	770	7.38 ± 1.06	0.063
	>20	690	7.51 ± 1.40	

DISCUSSION:

Intraocular inflammation after cataract surgery can prolong patient's visual rehabilitation. The peroperative use of anti-inflammatory therapy has well established role in standard cataract surgery (12). Subconjunctival dexamethasone injection is a commonly used drug for this purpose. There are many studies indicating the efficacy of intracameral dexamethasone in reducing intraocular inflammation after cataract surgery. The advantage of intracameral route is that the drug acts directly where it is required i.e. the anterior chamber, therefore the amount of drug required is less. Moreover, it is less painful and complications associated with subconjunctival injection may be avoided. The effect of intracameral dexamethasone on corneal endothelial cell count changes was not observed.

Rationale was to gather evidence about effects of intracameral dexamethasone on corneal endothelial cell count in comparison with standard subconjunctival injection in order to devise our local guidelines for better management of these patients. In this study we compared the mean change in endothelial cell count following peroperative intracameral dexamethasone opposed to subconjunctival dexamethasone after phacoemulsification. A total of fourteen hundred and sixty (n=1460) patients between age 45-65 irrespective of gender who had senile cataract having nuclear sclerosis of grade NO2 NC2 and NO3 NC3 were included in the study. Patients were equally divided into two groups. **Group A** received subconjunctival dexamethasone injection and **Group B** received intracameral dexamethasone injection. Change in endothelial count density was measured before and at 3 months after intervention in both groups and compared using t-test. Our results showed that in **Group B** it was 7.51 \pm 1.40 SD (*P*>0.05). Gender, age and phacoemulsification time based stratification showed no significant difference among both groups (*P* > 0.05).

Our results are similar to already published data on the subject. Jamil AZ, *et al* ¹³ in their quasi experimental study evaluated the effects of intracameral dexamethasone on corneal endothelium. Study subjects were adults of either gender with senile cataract who underwent phacoemulsification. They were divided in two groups, each had 110 patients. Group-A received subconjunctival injection of dexamethasone (2 mg/0.5 ml) at the end of surgery while Group-B received intracameral injection of dexamethasone (0.4 mg/0.1 ml) at the end of surgery.

Endothelial cell count was performed by specular microscopy pre-operatively and postoperatively at first week, first month and three months. Outcome measures included changes in endothelial cell count. Results were compared using t-test for means. Their results showed that after 3 months, in Group-A, there was $7.55 \pm 1.19\%$ endothelial cell loss while in Group-B, there was $7.63 \pm 1.10\%$ endothelial cell loss. The difference between the two groups was not statistically significant (p=0.614). They concluded that use of intracameral dexamethasone at the end of cataract surgery is safe for corneal endothelium.

Hasnain M, *et al*¹⁴compared the effectiveness of subconjunctival injection of dexamethasone with intracameral injection of dexamethasone in controlling immediate postoperative anterior uveitis after cataract surgery in patients of phacomorphic glaucoma. They

enrolled sixty patients of phacomorphic glaucoma underwent conventional Extra capsular cataract extraction (ECCE) with intraocular lens (IOL) implantation by same surgeon. They were divided into two groups comprising of 30 patients each. Patients in Group A, received subconjunctival injection of dexamethasone while patients in Group B received intracameral injection of dexamethasone at the end of surgery. Patients were examined on 1st and 3rd post-operative day on slit lamp for signs of anterior uveitis. Their results showed that on 1st post-operative day, in Group A findings were, cells in AC \leq +2 (17 patients, 57%), cells in AC \geq +3 (11 patients, 36%), membrane in AC (19 patients, 63%) while in Group B findings were, cells in AC \leq +2 (14 patients, 47%), cells in AC \geq +3 (13 patients, 43%), membrane in AC (21 patients, 70%). The data was analyzed statistically by applying T test using SPSS version 8. It showed that there was no statistically significant difference in results between Group A and Group B on 1st and 3rd post-operative day. They concluded that intracameral injection of dexamethasone provides an equally effective alternative to subconjunctival injection.

Wadood AC, *et al*¹⁵ compared the safety and efficacy of the dexamethasone anterior segment drug delivery and dexamethasone 0.1% eye drops in patients with inflammation after cataract surgery. Their results showed that both groups had a steady increase in laser flare meter readings postoperatively. The readings peaked at 3 days in the control group and at 7 days in the anterior chamber delivery group. This was followed by a gradual decline toward baseline values up to 28 days, after which the values remained at a similar level to 60 days in both groups. There were no significant differences in flare meter readings between the groups throughout the study. There were also no significant between-group differences in subjective assessment of intraocular inflammation and in impact on corneal endothelial cell count (P =.67). Neither group had a severe adverse event. They concluded that intracameral route appeared to be as effective as dexamethasone 0.1% eye drops in controlling intraocular inflammation after cataract surgery by phacoemulsification, and both methods had a similar safety profile.

Diane TW, *et al* ¹⁶ in their retrospective chart review of 176 consecutive eyes from 146 patients receiving uncomplicated phacoemulsification evaluated whether dexamethasone injected intracameral at the conclusion of surgery can safely and effectively reduce postoperative inflammation and improve surgical outcomes in eyes with and without glaucoma. Their results showed that intracameral dexamethasone given at the end of cataract surgery significantly reduces postoperative anterior chamber cells in eyes with and without glaucoma, and improves subjective reports of recovery in non-glaucomatous eyes. There were no statistically significant risks of intraocular pressure elevation or other complications in glaucomatous eyes.

In summary, inflammation after intraocular surgery can prolong patient recovery. Subconjunctival injection of dexamethasone is used in controlling immediate postoperative inflammation which is associated with pain and other complications like subconjunctival hemorrhage, sub-dermal fat atrophy, muscle atrophy, inadvertent globe perforation and skin hypo-pigmentation. The intracameral route seems promising as the drug can be administered directly into the anterior chamber, being less painful and complications associated with subconjunctival injection may be avoided. Outcome was found comparable with standard subconjunctival route in terms of adverse effects on corneal endothelium. Further large scale randomized controlled trials are needed to establish its definitive role in clinical settings.

CONCLUSION:

Mean percent change in endothelial count density was not found to be significantly different among both the treatment groups in this study. The intracameral route found to be less painful and complications associated with subconjunctival route may be avoided with comparable outcomes. Further large scale randomized controlled trials are needed to establish its definitive role in clinical settings.

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