ORIGINAL ARTICLE

Comparison of the safety and efficacy of single injection of subtenon triamcinolone and topical dexamethasone in reducing postoperative inflammation after phacoemulsification and intraocular lens implantation

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Abstract

Objective: To compare the safety and efficacy of single injection of sub-tenon triamcinolone and topical dexamethasone in reducing post-operative inflammation after phacoemulsification and intraocular lens implantation.

Methods: The randomised controlled study was conducted at Khyber Teaching Hospital, Peshawar, Pakistan, from September 2013 to February 2014. Patients who had undergone uneventful phacoemulsification with intraocular lens implantation by the same surgeon were included. Patients in Group A received 0.1% dexamethasone eye drops and those in Group B received sub-tenon triamcinolone injection (40mg/1ml). Follow-up was at 1st day, 14th day and 6 weeks post-operatively. At follow-up visit, grades of anterior chamber cells and aqueous flare were examined with slit lamp, and intraocular pressure was recorded.

Results: Of the 108 patients, each group had 54(50%) subjects. The mean age was 58.87±9.69 years (range: 33 to 84 years) in Group A and 57.77±8.93 years (range: 30 to 78 years) in Group B (p=0.544). On the first post-operative day, all the patients in both groups had some degree of inflammation in the anterior chamber. On the 14th post-operative day, anterior chamber cells were present in 4(7.4%) eyes in Group A and in 3(5.55%) eyes in Group B (p>0.999), while aqueous flare was present in 5(9.25%) eyes in Group A and 9(16.66%) eyes in Group B (p=0.391). Six weeks after the operation, no anterior chamber cells or aqueous flare was seen in any eye in either group.

Conclusion: Sub-tenon triamcinolone injection was found to be a safe and effective alternative to topical dexamethasone for control of post-operative inflammation after phacoemulsification.

Keywords: Dexamethasone, Intraocular inflammation, Phacoemulsification, Triamcinolone. (JPMA 66: 1127; 2016)

Introduction

Phacoemulsification is the most frequently employed method of cataract extraction.[1] Although the phacoemulsification technique has improved greatly over the years, still it involves surgical trauma which predisposes the individual to post-operative inflammation.[2] Surgical trauma causes a trigger of the arachidonic acid cascade, which in turn generates prostaglandins by activation of cyclooxygenase (COX) 1 and cyclooxygenase 2. Phosoholipids in the cell membrane are the substrate for phospholipase A-2 to generate arachidonic acid from which a family of chemically distinct prostaglandins and leukotrienes are produced. Ocular effects of prostaglandins include increased or decreased intraocular pressure (IOP), local vasodilation and increased permeability of the blood-aqueous barrier and miosis.[3]

Corticosteroids effectively control ocular inflammation.[4] They interfere with the activity of phospholipase A2, thereby inhibiting the release of arachidonic acid from cell membrane phospholipids and the production of all arachidonic acid metabolites, including prostaglandins.

Topical dexamethasone 0.1% forms the mainstay of the anti-inflammatory therapy after cataract extraction.[5,6] Topical medications may be costly and can have adverse effects on the cornea, causing disruption of the tear film and subsequent irritation.[7] In addition, topical steroids have a short half-life and need to be instilled frequently for a longer duration of time and therefore patient compliance is an important issue.[7]

Triamcinolone is a potent corticosteroid that has been reported to be safe and effective for controlling post-operative inflammation when administered as a single sub-tenon injection (1ml/ 40mg) after uneventful phacoemulsification surgery.[6,9] Triamcinolone has a long half-life of 6 weeks. Sub-tenon triamcinolone remains in the intraocular tissues for more than a month and would suppress post-operative inflammation for the required period without the need for topical steroids.[10] Moreover,

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as it is given in a single dose, patient compliance is not an issue in this case.

This study was planned to compare the safety and efficacy of single injection of sub-tenon triamcinolone and topical dexamethasone in reducing postoperative inflammation after phacoemulsification and intraocular lens (IOL) implantation.

Patients and Methods

The randomised controlled study was conducted at the Department of Ophthalmology, Khyber Teaching Hospital (KTH), Peshawar, Pakistan, from September 1, 2013, to February 28, 2014. Patients were randomly divided through lottery method in dexamethasone group A and triamcinolone group B. The sample size was calculated using 97% efficacy of topical dexamethasone,[11] and 79% efficacy of sub-tenon triamcinolone[9] with 95% confidence interval (CI) and 90% power of test, under World Health Organisation (WHO) software for sample size calculation.

Sampling technique was non-probability consecutive sampling i.e. all patients who met the inclusion criteria were included. Approval was taken from institutional ethical committee. Patients who had undergone uneventful phacoemulsification with IOL implantation by the same surgeon were included. Complicated cataracts, including cataracts with uveitis, pigment dispersion syndrome (PDS), pseudoexfoliation, lens-related glaucoma i.e. phacolytic and phacomorphic glaucoma, and patients less than 25 years of age were excluded. Written informed consent was taken from all the patients.

Patients of group B received sub-tenon injection of triamcinolone at the end of surgery. Sub-tenon injection was performed at the inferotemporal quadrant in a single 40mg (1.0 ml) dose. Patients of group A were started on dexamethasone (0.1%) eye drops on the 1st post-operative day, according to the following schedule: 4 times/day (week 1), 3 times/day (week 2), 2 times/day (week 3) and once daily (week 4). Both groups were also given tobramycin (0.3 %) eye drops four times per day for 2 weeks.

All the patients were examined on 1st day, 14th day and 6 weeks post-operatively. Post-operative inflammation was measured in terms of grades of anterior chamber (AC) cells and grades of aqueous flare seen on slit lamp examination (Takagi, Japan), with a 2mm long and 1mm wide slit beam with maximal light intensity (Table-1).

Intraocular pressure was also recorded at each visit with Goldmann applanation tonometer (Takagi, Japan).

Data was recorded on a pre-designed proforma. SPSS 11 was used for data analysis. Chi-square test was used to compare the efficacy in both the groups and t-test was used for comparison of IOP in the 2 groups. P 0.05 was considered significant.

Results

Of the 108 patients, there were 54(50%) in each of the two groups. The mean age was 58.87±9.69 years (range: 33 to 84 years) in Group A and 57.77±8.93 years (range: 30 to 78 years) in Group B (p=0.544). In Group A there were

Table-1: Grades of anterior chamber (AC) cells and aqueous flare.

Grades of AC Cells		Grades of Aqueous Flare	
Grade	**Cells in field**	**Grades**	**Description**
0	<1	0	Nil
+0.5	1-5	+1	Faint
Cut-off point		**Cut-off point**	
+1	6-15	+2	Moderate (Iris and lens detail clear)
+2	16-25	+3	Marked (Iris and lens detail hazy)
+3	26-50	+4	Severe
+4	>50		

Table-2: Anterior chamber cells and aqueous flare on 1st post-operative day.

	Presence of AC* cells		Presence of aqueous flare	
	≥ +1	< +1	≥ +2	< +2
Group A				
Number	37	17	54	0
Percent	68.51%	31.48%	100%	-
Group B				
Number	35	19	54	0
Percent	64.81%	35.18%	100%	-
P value	0.838		1	

*AC: Anterior chamber.

Table-3: Anterior chamber cells and aqueous flare on 14th post-operative day.

	Presence of AC* cells		Presence of aqueous flare	
	≥ +1	< +1	≥ +2	< +2
Group A				
Number	4	50	5	49
Percent	7.40%	92.59%	9.25%	90.74%
Group B				
Number	3	51	9	45
Percent	5.55%	94.44%	16.66%	83.33%
P value	1		0.391	

*AC: Anterior chamber.

Table-4: Pre-operative and post-operative IOP* (mmHg) in both groups.

	Group A		Group B		P value
	Range	Mean ± SD	Range	Mean ± SD	
Pre-op	10-20	14.94 ± 2.24	11-20	14.52 ± 2.33	0.361
1st day	09-21	13.82 ± 1.95	10-19	14.28 ± 2.01	0.249
14th day	11-18	15.40 ± 2.44	11-20	14.74 ± 1.87	0.132
6th week	11-19	14.42 ± 2.15	12-21	15.00 ± 1.95	0.163

*IOP: Intraocular pressure
+SD: Standard deviation
Pre-op: Pre-operative.

37(68.52%) men and 17(31.48%) women and in Group B there were 35(64.81%) men and 19(35.19%) women (p=0.838).

On the first post-operative day, all the patients in both groups had some degree of inflammation in the AC. AC cells were present in the eyes of 37(68.52%) participants in Group A and in 35(64.81%) in Group B (p=0.838). Aqueous flare was present in all eyes in both the groups (p>0.999) (Table-2).

On the 14th post-operative day, AC cells were present in 4(7.4%) eyes in Group A and in 3(5.55%) eyes in Group B (p>0.999), while aqueous flare was present in 5(9.25%) eyes in Group A and 9(16.66%) eyes in Group B (p=0.391) (Table-3).

Six weeks after operation, no AC cells or aqueous flare was seen in any eye in either group.

There was some degree of intraocular inflammation in all eyes in both the groups on the 1st post-operative day, which was markedly reduced in both groups on the 14th day and 6 weeks, but the difference was not significant (p=0.391; p=1.00).

The mean values for IOP before the operation and on the 1st and 14th day and 6th week after the operation were 14.94±2.24, 13.82±1.95, 15.40±2.44 and 14.42±2.15, respectively, in Group A, and 14.52±2.33, 14.28±2.01, 14.74±1.87, 15.00±1.95, respectively, in Group B; (p=0.361, 0.249, 0.132 and 0.163).

There was no significant difference in IOP between the groups pre-operatively and at 1st day, 14th day and 6 weeks post-operatively (Table-4).

Discussion

Cataract surgery always causes a certain degree of post-surgical ocular inflammation that is essentially beneficial as it produces the mediators required for tissue healing.[12] Corticosteroids have been the mainstay in controlling ocular inflammation in a number of conditions including post-operative inflammation. Topical corticosteroid drops are routinely administered for approximately 1 month after uneventful cataract surgery in order to reduce an inflammatory reaction.

Although topical corticosteroid drops are very effective in controlling post-operative inflammation, they have several disadvantages: the intraocular levels of topically applied preparations are low and unreliable, with concentrations fluctuating between instillations and reaching peak concentrations approximately 1 hour after application.[13-15] In addition, the number of drops required during the post-operative period often creates compliance issues, particularly in the elderly patients; topical medications have an undesirable effect on the cornea, causing disruption of the tear film and subsequent irritation, and the cost to the patient can be substantial.[15]

To avoid the problems associated with topical therapy, intravitreal, sub-tenon, sub-conjunctival, and intracameral administration of steroids have also been employed, each with its own indications, advantages and disadvantages.[16]

The use of triamcinolone acetonide has been gaining popularity in ophthalmic practice. Triamcinolone acetonide stays longer in intraocular fluids, making it ideal for controlling the inflammatory process if used intravitreally, intracamerally, or via sub-tenon's injection. Some studies have reported traces of triamcinolone in the AC for as long as 6 months after intravitreal injection.[17]

In this study we compared the safety and efficacy of sub-tenon triamcinolone injection and topical dexamethasone in the treatment of post-operative inflammation after phacoemulsification in otherwise normal eyes. The efficacy variables of this study included signs of the anterior segment inflammation i.e. cells and flare in the AC as observed by slit lamp examination. Safety was assessed in terms of IOP changes.

The efficacy of drug in reducing post-operative inflammation at 14th post-operative day was 90.74 % in Group A and 83.33 % in Group B and 100% in both groups at 6 weeks post-operatively. P-value for difference of drug efficacy between the two groups at 14th post-operative day was 0.391. At 6 weeks there were no flare and cells in the AC in both groups therefore application of chi-square test was invalid. There was no significant difference in IOP between the 2 groups pre-

operatively and at 1st day, 14th day and 6 weeks post-operatively (p=0.361, 0.249, 0.132 and 0.163, respectively). No IOP elevation or any other side effect was seen in any eye in either group.

These results showed that sub-tenon triamcinolone injection is as effective and safe in the control of post-operative inflammation after phacoemulsification as topical 0.1% dexamethasone. A number of other studies have also shown single sub-tenon triamcinolone injection to be as safe and effective as topical steroids in controlling intraocular inflammation after uneventful cataract surgery. [8,9,18]

Paganelli et al. compared the therapeutic effect of intra-operative 40 mg triamcinolone acetonide sub-tenon injection with 1% prednisolone acetate eye drops. Triamcinolone acetonide was shown to have anti-inflammatory efficacy clinically equivalent to 1% prednisolone acetate eye drops in reducing intraocular inflammation. Triamcinolone was found to be as safe as the prednisolone in terms of adverse effects, changes in visual acuity, IOP, and biomicroscopic and ophthalmoscopic variables.[9]

In another study, Paganelli et al. compared sub-tenon triamcinolone (25mg) + ciprofloxacin (2 mg) injection with topical prednisolone (1%) + ciprofloxacin (0.3%) eye drops. No significant differences were observed between the groups in anterior chamber cell (p>0.14) and flare (p>0.02) at any post-operative visits and no infection was seen in any patient in either group.[4]

Negi et al. also compared the safety and efficacy of a single peri-operative sub-tenon's injection of triamcinolone (30mg) with topical steroid therapy following cataract surgery. They used flare meter to assess the anterior chamber inflammation and performed fluorescein angiography at 30 and 90 days post-operatively to detect angiographic cystoid macular oedema (CME). No significant difference was seen in the 2 groups in terms of all the efficacy variables.[8] Different studies have shown that measurement of AC inflammation with laser flare/ cell meter is highly accurate and reproducible.[19,20] As laser flare/ cell meter was not available in our hospital, we measured the anterior chamber inflammation (cells and flare) by clinical method, using slit lamp biomicroscopy (with a 2 mm long and 1 mm wide slit beam with maximal light intensity).

The results of the current study suggest that topical drops and sub-tenon triamcinolone injection may be equally safe and effective in controlling post-operative intraocular inflammation. Sub-tenon triamcinolone injection may help to eliminate noncompliance associated with eye drops.

Conclusion

Single injection of sub-tenon triamcinolone is a very safe and effective alternative to topical dexamethasone in reducing post-operative inflammation after uncomplicated phacoemulsification and intraocular lens implantation. However, whether sub-tenon triamcinolone alone is equally effective to dexamethasone in control of severe AC inflammation after prolonged or complicated surgery, remains uncertain.

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