INTRODUCTION

Surgical manipulation during phacoemulsification leads to the disruption of the blood aqueous barrier, resulting in intraocular inflammation. This can cause increased intraocular pressure, adhesion of iris to angle, to the lens implant or lens capsule, deposits on implant, opacification of posterior capsule and visual impairment.1

Topical corticosteroids are known to be effective in suppressing postoperative inflammation.2 However, they have many side effects, like impaired wound healing, elevation of intraocular pressure and increased tendency of infections, tear-film instability, epithelial toxicity, crystalline keratopathy and ptosis.3,4

Recent studies suggest that topical non-steroidal anti-inflammatory drugs (NSAIDs) are as effective as corticosteroids in preventing disruption of or re-establishing the blood aqueous barrier following cataract surgery.5,6,7 Polansky has reported that the adverse effects seen with topical corticosteroid have not been seen with NSAIDs.8 In spite of the side effects, corticosteroids are used routinely by almost all ophthalmic surgeons to control post-cataract surgery inflammation.9,10

The objective of this study was to compare postoperative anti-inflammatory effects of 0.1% diclofenac sodium and 0.1% dexamethasone eye drops in patients, following uneventful phacoemulsification surgery, using posterior chamber intraocular lens implants.

METHODOLOGY

This study was conducted in the Department of Ophthalmology, PNS Shifa Hospital, Karachi, from June 2006 to March 2007.

The study design was quasi-experimental. A non-probability, purposive sampling technique was used. Uncomplicated, senile cataract patients undergoing planned phacoemulsification surgery with posterior chamber IOL implants were included in the study. Any operative or postoperative complication, those taking topical/oral steroids or NSAIDs, patients requiring postoperative additional medication, ocular or systemic diseases, and patients having history of ocular trauma were excluded.

Pre-operative evaluation included written, informed consent from the subjects. They were admitted one day before surgery. A note of medical and ocular history was taken including use of NSAIDs, steroids, ocular trauma, inflammation, amblyopia, glaucoma and corneal diseases etc. All the subjects underwent a comprehensive ophthalmic examination.

Pre-operative medications were started a night prior to the surgery. Acetazolamide 250 mg and diazepam 5 mg...
were given to all the patients. Pre-operative mydriasis was achieved with 1% tropicamide and 10% phenylephrine hydrochloride eye drops, four times in one hour at regular intervals. For local anaesthesia, 5 ml of 1:1 mixture of 2% Xylocaine (lignocaine HCL) and 0.5% Bupicain (bupivacaine hydrochloride) was made; out of which 3 ml was used for facial block and 2 ml was used for peribulbar anaesthesia. The eye was padded for 10-15 minutes.

The operative area was draped after cleaning with antiseptic lotion. The exposed eye ball/conjunctival sac were irrigated with Ringer’s lactate solution. The anterior chamber was entered at superotemporal limbus with a 3.2 mm stainless steel angled keratome and filled with 2% hydroxypropylmethylcellulose. Continuous curvilinear capsulorrhexis was done with cystitome. A 2 mm side-port incision for a second instrument was made at the 2 o’clock limbus. Hydrodissection and hydrodelineation was performed with a Balanced Electrolyte Solution (BES). Endocapsular phacoemulsification and the nucleus aspiration were carried out. Aspiration of the residual cortical matter was done with Simco cannula. The anterior chamber was reformed with 2% methylcellulose. The foldable acrylic lens was loaded to the syringe insert and the lens slowly injected into the bag. Viscoelastic material was aspirated out. Intraocular Miostat 0.01% (carbachol) was used for miosis. The wound was left un stitched and anti-septic dressing done. All patients were operated upon by the same surgeon with same technique.

Postoperative cases were randomized via assignment to one of the two groups; “P-group” (dexamethasone) and “S-group” (diclofenac sodium), by a doctor not otherwise involved in the management of the patients. There were 50 eyes in each group to reduce the observer bias, the observer and the patients were masked from the contents of the bottle. On the first postoperative day, after removing the dressing, the patient’s vision was checked and evaluated on slit lamp for corneal transparency, wound apposition, depth of anterior chamber, cells and flare and the position of the intraocular lens. The cells and flare were graded from 0 to 4. A uniform dosage schedule of one drop four hourly during the first week in the operated eye, followed by one drop six hourly during subsequent weeks was observed. The patients were discharged next day and instructed as to the regular use of prescribed medicines.

During follow-up, ocular examination was done on the first postoperative day and then at the end of the first, third and fifth week postoperatively for visual acuity, striate keratopathy, anterior chamber cells and anterior chamber flare. The findings so obtained were entered in a pre-designed proforma.

For data analysis, SPSS version-10 was used. Frequencies and percentages were computed to present all categorical variables. The chi-square test was applied to compare the proportions of postoperative outcome with that of pre-operative findings (to test alternate hypothesis) between two groups at p < 0.05 level of significance for qualitative factors. Baseline comparisons of quantitative data between groups were made using the independent sample t-test. Alpha for significance was set at p ≤ 0.05. All tests of hypotheses were two-tailed.

**RESULTS**

One hundred patients participated in the study; fifty received dexamethasone 0.1% eye drops and another fifty received diclofenac sodium 0.1% eye drops topically. In the diclofenac group, 3 patients had severe anterior segment inflammation and had to be given oral steroids and excluded from the study.

The dexamethasone group consisted of 32 males (64%) and 18 females (36%) while the diclofenac group included 27 males (57.4%) and 20 females (42.6%). Two groups were similar in gender distribution (p = 0.539).

The mean (SD) age in the dexamethasone group was 61.68 (±9.78) years and in the diclofenac group was 59.915 (±10.734) years. The two groups were comparable in age (t = 0.847, df = 95, p = 0.399).

The visual acuity (Table I) was comparable pre-operatively between the two groups (chi-square = 4.450, df = 6, p = 0.616). The visual acuity distribution did not vary significantly between the two groups after the first day (chi-square = 7.448, df = 8, p = 0.489), first week (chi-square = 5.469, df = 6, p = 0.485), three weeks (chi-square = 1.926, df = 4, p = 0.749) or five weeks postoperatively (chi-square = 2.157, df = 4, p = 0.707).

The anterior chamber cell count (Table II) was not comparable postoperatively between the two groups on the first day (chi-square = 7.448, df = 8, p = 0.489), first week (chi-square = 5.469, df = 6, p = 0.485), three weeks (chi-square = 1.926, df = 4, p = 0.749) or five weeks postoperatively (chi-square = 2.157, df = 4, p = 0.707).

The flare (Table III) between the two groups was not different when analyzed at the first postoperative day (chi-square = 5.579, df = 2, p = 0.061) and the first postoperative week (p = 0.426) while flare was not present on the third week postoperatively and beyond.

On the first day and first week postoperatively, the striate keratopathy (Table IV) distributions were not the
same- with dexamethasone showing a better response than the diclofenac group (first day chi-square = 15.876, df = 2, p < .001, first week p = 0.028. The response of both the drugs became similar from 3 weeks onwards (third week chi-square = 4.660, df = 8, p = 0.793; fifth week chi-square = 5.639, df = 8, p = 0.688).

The patients were divided into grades of severity (Table V), which was a composite variable including anterior chamber cells and flare. It was found that the response of dexamethasone was better in terms of decreasing the overall severity than diclofenac (chi-square = 10.923, df = 2, p < 0.005).

Table I: Visual acuity: analysis between the two groups.

Table II: AC cells: analysis between the two groups.
DISCUSSION

Studies have shown that some of the NSAIDs are as effective as steroids in controlling inflammation after cataract surgery. This study was done on Pakistani patients with brown irises and demonstrated beneficial effects with both diclofenac sodium (0.1%) and dexamethasone phosphate (0.1%). This showed that topically applied diclofenac sodium suppresses postoperative inflammation effectively but to a lesser magnitude than topically applied dexamethasone drops. Moreover, topical corticosteroids need not be routinely used in uncomplicated cataract surgery. However, in moderate to severe cases, dexamethasone appeared to be superior. Farooq and Ali found that in mild cases of postoperative inflammation, ophthalmic Flurbiprofen is comparable to ophthalmic dexamethasone but for moderate to severe cases of postoperative inflammation dexamethasone is superior to the former. Joint use of both in postoperative cases is more efficacious than either of them in resolution of both of the AC activity as well as striate keratopathy.

In a study between diclofenac sodium and dexamethasone, Reddy et al. found that the treatment effects for any of the variables including aqueous cells, flare, ciliary congestion, descemets' folds and intraocular pressure did not show statistical difference three weeks postoperatively. However, there was a trend towards quicker improvement in the dexamethasone group when cells in the anterior chamber were considered. In another study by Missotten et al. a difference in the postoperative signs was in favour of indomethacin, but hyperemia was less pronounced in the dexamethasone group one month postoperatively. Diestelhorst et al. showed that flurbiprofen was less effective than diclofenac and indomethacin, in a postoperative period.

This study included patients having no preoperative inflammatory disease and surgery was uneventful in all the patients of both groups, the effectiveness of topical diclofenac versus dexamethasone in complicated cataract surgery remained undetermined and therefore, would need a separate study.

CONCLUSION

The resolution of inflammation was quicker in the dexamethasone group than in the diclofenac group. This effect was more marked in moderate to severe cases. Although dexamethasone seemed to be superior in the resolution of anti-inflammatory activity, the use of diclofenac sodium may be considered in mild cases of postoperative inflammation.

REFERENCES


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