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Research Article

### COMPARISON OF THE ANTI-INFLAMMATORY EFFECTS OF FLUOROMETHOLONE 0.1% COMBINED WITH LEVOFLOXACIN 0.5% AND TOBRAMYCIN/ DEXAMETHASONE EYE DROPS AFTER CATARACT SURGERY

Dr. Hadia Yousif<sup>1</sup>, Dr. Muhammad Ahsan<sup>2</sup>, Dr. Aisha Chohan<sup>3</sup>

<sup>1</sup>Jinnah Hospital Lahore Email: [hadiayousaf786@gmail.com](mailto:hadiayousaf786@gmail.com), <sup>2</sup>RHC Daud Khel District Mianwali, Email: [drmuhammadahsanttc@gmail.com](mailto:drmuhammadahsanttc@gmail.com), <sup>3</sup>Women Medical Officer at Civil Hospital, Hyderabad, Sindh, Email: [aishachohan86@gmail.com](mailto:aishachohan86@gmail.com)

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**Abstract:**

**Introduction:** Cataracts are a leading cause of vision impairment in older people. Since phacoemulsification surgery has become the most frequently employed method of cataract extraction, cataract surgery outcomes have improved significantly, while the extent of ocular injuries has decreased. However, ocular inflammatory reactions, which may be induced by surgical trauma, have not been eliminated, and the inflammation may cause unwanted complications including corneal edema, cystoid macular edema, and excessive cicatrization. Furthermore, perioperative incision infections or endophthalmitis are serious complications with cataract surgery due to their devastating consequences.

**Methodology:** Sixty eyes from 60 patients undergoing cataract phacoemulsification were randomized into two groups; half of the patients were treated with fluorometholone (6 times/d) combined with levofloxacin (4 times/d), while the other half were treated with tobramycin/dexamethasone (4 times/d) eye drops for one week. Preoperative and postoperative intraocular pressure, aqueous flare, corneal thickness, and signs and symptoms were recorded before the operation and 1wk following treatments.

**Results:**

At randomization the treatment groups were similar for age, sex, and race. Seven eyes of 4 patients were excluded from the per protocol analysis. In total, 60 patients were enrolled in this study and were randomized into two groups of 30. All of the patients completed both the study and the follow-up period. The patients in both groups had similar lens nuclear density and mean energy used during the surgery.

**Corresponding author:****Dr. Hadia Yousif,**Jinnah Hospital Lahore Email: [hadiayousaf786@gmail.com](mailto:hadiayousaf786@gmail.com).

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**INTRODUCTION:**

Cataracts are a leading cause of vision impairment in older people[1]–[2]. Since phacoemulsification surgery has become the most frequently employed method of cataract extraction, cataract surgery outcomes have improved significantly, while the extent of ocular injuries has decreased[3]. However, ocular inflammatory reactions, which may be induced by surgical trauma, have not been eliminated, and the inflammation may cause unwanted complications including corneal edema, cystoid macular edema, and excessive cicatrization[4]. Furthermore, perioperative incision infections or endophthalmitis are serious complications with cataract surgery due to their devastating consequences.

Topical corticosteroids are used to prevent or suppress postoperative inflammation, and antibiotic ophthalmic solution administration is a standard treatment in prophylactic regimens for wound infection or endophthalmitis[5]. As a topical steroid/antibiotic fixed combination, tobramycin/dexamethasone (TobraDex) ophthalmic drops have been used effectively to control inflammation and prevent infection[6]. However, dexamethasone may cause certain side effects including corticosteroid-induced ocular hypertension (OHT) and secondary glaucoma[7]. In a previous study, fluorometholone was not as potent as commonly used steroids in reducing post-operative inflammation[9], but other inconsistent results have been reported[10]–[11]. Therefore, the efficacy of fluorometholone in reducing inflammation after phacoemulsification is unclear.

In this study, we determined the differences in the treatment effects of tobramycin/dexamethasone and fluorometholone combined with levofloxacin, a broad-spectrum antibiotic drug, on postsurgical inflammation suppression and infection prevention.

**METHODOLOGY:**

All patients were informed about the study design and provided their written informed consent. Sixty male or female age-related cataract patients undergoing phacoemulsification with posterior chamber intraocular lens (IOL) implantation between October 2020 and January 2021 were enrolled in DHQ Hospital Kasur. Preoperatively, all patients underwent a routine ophthalmological examination, i.e. slit-lamp examination, measurement of best corrected visual acuity (BCVA), IOP, funduscopy, and a complete medical history.

Sixty eyes from 60 patients undergoing cataract phacoemulsification were randomized into two groups; half of the patients were treated with fluorometholone (6 times/d) combined with levofloxacin (4 times/d), while the other half were treated with tobramycin/dexamethasone (4 times/d) eye drops for one week. Preoperative and postoperative intraocular pressure, aqueous flare, corneal thickness, and signs and symptoms were recorded before the operation and 1wk following treatments.

**RESULTS:**

At randomization the treatment groups were similar for age, sex, and race. Seven eyes of 4 patients were excluded from the per protocol analysis. In total, 60 patients were enrolled in this study and were randomized into two groups of 30. All of the patients completed both the study and the follow-up period. The patients in both groups had similar lens nuclear density and mean energy used during the surgery. The effective phacoemulsification time (EPT) of the two groups were  $9.41 \pm 1.37$ s (group A) and  $9.57 \pm 1.39$ s (group B), respectively.

Table 1 shows IOP (mm Hg) comparison between groups over time

Groups	Preoperative	1 day	1 week
A	14.68 $\pm$ 3.08	15.89 $\pm$ 4.90	13.24 $\pm$ 3.23
B	14.21 $\pm$ 2.45	15.61 $\pm$ 3.87	13.86 $\pm$ 3.23
P	0.404	0.378	0.590

**DISCUSSION:**

It is widely accepted that surgical trauma of the ocular surface can induce an inflammatory response that may include the release of prostaglandins and the recruitment of neutrophils and macrophages. This process culminates in the production of chemical inflammatory mediators including proteolytic

enzymes, oxygen-free radicals, and cyclooxygenase and lipoxygenase metabolites of arachidonic acid, leading to the observation of inflammation-related signs including corneal edema, conjunctival hyperemia, and anterior chamber flare and cells[10],[12]–[13]. Several studies have confirmed

the significant role of corticosteroids in the reduction of inflammation after cataract surgery through the inhibition of the cyclooxygenase pathway and the lipoxygenase pathway of the arachidonic acid cascade[14]–[15].

Wound infections and endophthalmitis are also potentially vision-threatening complications of cataract surgery. Endophthalmitis is a severe inflammation of the anterior and/or posterior chambers of the eye and may be associated with infections[1],[16].

Among ophthalmic antibiotics, the most prescribed are aminoglycosides and fluoroquinolones, as they provide excellent coverage against most Gram-positive and Gram-negative organisms[21]. Levofloxacin, a third-generation fluoroquinolone, has a low rate of bacterial resistance compared with other commonly used antibiotics, and its antibacterial activity is two-fold greater than that of ofloxacin[22]. The effect of ophthalmic antibiotics depends largely on the antibiotic permeability of the eyes. Stuart Elborn *et al*[23] found that ofloxacin has better aqueous penetration in human eyes compared with tobramycin; thus, this report suggests that ofloxacin could be the better choice for the prevention and treatment of endophthalmitis. There were no infections observed in either group in our study, and the results support the idea that levofloxacin is a better antibiotic in cataract surgery.

## CONCLUSION:

In the present study, we found that a combined medication, fluorometholone 0.1% combined with levofloxacin 0.5%, had a comparable efficacy, but possibly a lower tendency to increase IOP, when compared to tobramycin/dexamethasone. However, this study has some limitations. First, due to the small sample size, the statistical power was limited. Second, due to the short follow-up time, we cannot compare the effect on IOP modifications of the two steroids under long-term administration.

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