A retrospective randomized comparative study was carried out in 100 patients to compare efficacy between moxifloxacin-dexamethasone (group A-50 patients) vs. moxifloxacin-difluprednate (group B-50 patients) eye drops to reduce post cataract inflammation in terms of reduction in anterior chamber cells and flares and pain relief and were followed up on day 1, 3, 5, 7, 45 and 90.

On 5th postoperative day, cell count decreased from baseline by 96.75% in group B vs. 99.24% in group A. As well 100% reduction from baseline in anterior chamber flare found in group A as compared to 85.7% in group B.

Our study showed that speed of recovery from inflammation is more with moxifloxacin-difluprednate than moxifloxacin-dexamethasone. Study also showed that moxifloxacin-difluprednate is more efficacious than moxifloxacin-dexamethasone although costlier.

INTRODUCTION:
A Cataract is any opacity of lens, whether an small opacity or diffuse general loss of transparency causing significant reduction in visual acuity or functional impairment. It is one of leading cause of blindness in the world, accounting for 50% of blindness worldwide.[1]

In cataract surgery there occur manipulation of anterior segment structures, which in turn trigger the release of arachidonic acid from cell membranes, leading to production of prostaglandins and leukotrienes. These inflammatory mediators, in turn, lead to cellular reaction and protein leakage. Although often self limited, untreated inflammation can lead to complications such as pain/discomfort, photophobia, corneal edema, synechiae, glaucoma and cystoid macular edema endophthalmitis.[2,3] The Mean Annual Incidence of post-operative endophthalmitis among cataract patient range from 0.05 to 0.14%.[4-6]

In the immediate postoperative period, topical corticosteroids and antibiotic combined eye drops are effective in preventing infection and controlling inflammation after surgery of cataract extraction and IOL implantation.[7] A fixed combination eye preparation not only help in cutting costs but improve compliance of patient in dosing and application.[8] Moxifloxacin, fourth generation fluoroquinolol, advantages of broad spectrum, excellent penetration & deliver contraction thousand times minimal inhibitory concentration.[9,10]

Dexamethasone or difluprednate are steroid which act by inhibiting the release of arachidonic acid from cell membrane phospholipids, corticosteroids prevent the formation of both leukotrienes and prostaglandins, disrupting the inflammatory cascade. These agents are continued until the anterior chamber (AC) reaction has resoled and blood-aqueous barrier has been re-established.[11]

AIMS AND OBJECTIVES:
To evaluate efficacy of moxifloxacin-dexamethasone and moxifloxacin-difluprednate eye drops in reducing ocular inflammation and pain in patients who had undergone cataract extraction.

PHARMACOLOGY:
At molecular level corticosteroids freely penetrate cell membrane and bind to a specific steroid binding protein receptor in the cytoplasm, forming a steroid-receptor complex.[12-15] This complex then moves into the nucleus and bind to chromatin, signaling the production of messenger RNA and coding for enzymes and proteins that determine the responses of that particular cell to hormone.[16]

These molecular and cellular changes result in steroid-induced inhibition of all the cardinal signs of inflammation, such as pain, heat, redness and edema.[16,17]

Corticosteroid has dual property of both being anti-inflammatory and immunosuppressant.[18]

Difluprednate, a novel steroid, is classified as a very strong steroid. In June 2008, Difluprednate ophthalmic emulsion 0.05% was approved by US Food and Drug Administration for treatment of inflammation and pain associated with ocular surgery.[19]

Difluprednate potency:
Difluprednate is a derivative of prednisone but differs substantially due to structural modifications. The first is addition of fluorine atoms at C6 and C9 positions. It is well known that fluorination of steroids greatly enhances specificity for the glucocorticoid receptors.[20] Its anti-inflammatory activity is further augmented by replacing 17-hydroxyl group with butyrate ester. This has been shown to further increase the potency of difluprednate,[21] while its lipophilicity and hence corneal penetration is enhanced by substituting the 21-hydroxyl group with acetate group.[22] In fact, glucocorticoids with 17,21- double esters, such as difluprednate, generally penetrate tissue better than moxesters derivatives.[23]

Difluprednate dose uniformity:
Due to lipophilic nature of the steroid molecules, and so their inability to dissolve in a solution, the majority of steroid preparations are formulated as suspensions.

Ophthalmic suspensions tend to settle over time, and as a result, must be shaken by the patient prior to instillation to ensure a homogenous distribution of active drug within the aqueous phase of suspension.

Unfortunately, as most clinicians know, patients are not very compliant when it comes to shaking their medications. This was borne out of a study of steroid preparations, in which only 37% of patients followed the prescribed shaking instructions.[14]
Difluprednate ophthalmic emulsion was formulated as stable oil-in-water to achieve optimum dosage consistencies. Difluprednate ophthalmic emulsion demonstrated excellent and consistent dose uniformity compared with suspensions, suggesting that clinical use of difluprednate may produce more predictable efficacy and safety.

**FIXED DRUG COMBINATION:**
In the immediate postoperative period, topical corticosteroids and antibiotic combined eye drops are effective in preventing infection and controlling inflammation after surgery of cataract extraction and IOL implantation.[3]

A fixed combination eye preparation not only help in cutting costs but improve compliance of patient in dosing and application.[4]

**METHOD & MATERIOLOGY**
The study design is retrospective, comparative study. In study we are going to collect data of 100 patients, coming to ophthalmology department GGH, Jamnagar had diagnosed as a case of cataract and need cataract extraction and IOL implantation.

**EXCLUSION CRITERIA:** - Adult (>18 year) with diagnosis of cataract.

**EXCLUSION CRITERIA:** - Uncontrolled glaucoma, Steroid responder, diabetes mellitus, History of corticosteroid allergy. Ocular inflammatory condition like iritis, uveitis, dacrocystitis, fungal or viral infection.

Data will be collected after 60 days of discharge of patient. Preoperative assessment of patient was done which include torch light examination, slit lamp examination, fundus examination, A-scan, keratometry, intraocular pressure measurement. Systemic examination was done to rule out disease like hypertension, diabetes.

Patients had been undergone cataract extraction either by SICS-small incision cataract surgery or phacoemulcification and IOL implantation.

Patient had advised either moxifloxacin-dexamethasone or moxifloxacin-difluprednate eye drop post operative period. Patients had been examined post operatively on day 1,3,5,7,45,60. At each visit, patients were examined for sign of infection, inflammation and ocular pain. Best corrected visual acuity and intraocular pressure measured & recorded.

Grading scheme was achieved for standardization of grading anterior chamber cells and flare. The first international Workshop on the Standardization of Uveitis Nomenclature(SUN) was held in 2004 to standardize some aspects of uveitis, including classification criteria, inflammation grading scheme, and evaluation of outcomes.[5]

AC (anterior chamber) inflammation, major criterion of effectiveness, were evaluated based on number of cells per high power field measure using narrowest (0.5 at height of 8 mm) slit beam of lamp and recorded as SUN CLASSIFICATION:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Cells in Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>&lt; 5</td>
</tr>
<tr>
<td>1+</td>
<td>6-15</td>
</tr>
<tr>
<td>2+</td>
<td>16-25</td>
</tr>
<tr>
<td>3+</td>
<td>26-50</td>
</tr>
<tr>
<td>4+</td>
<td>&gt; 50</td>
</tr>
</tbody>
</table>

**Anterior Chamber Flare Grading by SUN:**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Descriptors</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
</tr>
<tr>
<td>1+</td>
<td>Light (iridic detail present)</td>
</tr>
<tr>
<td>2+</td>
<td>Moderate (iris and lens detail clear)</td>
</tr>
<tr>
<td>3+</td>
<td>Marked (iris and lens detail hazy)</td>
</tr>
<tr>
<td>4+</td>
<td>Intense (fibrin or plastic aqueous)</td>
</tr>
</tbody>
</table>

**OBSERVATIONS AND ANALYSIS:**
In this comparative retrospective study,100 patients were underwont cataract surgery with implantation of PCIOL in eye department of our institute which were divided into two groups of 50 patients having instilled either moxifloxacin-dexamethasone(group A) or moxifloxacin-difluprednate(group B). The data was evaluated on day 1,3,5,7,45 and 60.

**Table 1: Percentage Reduction In Anterior Chamber Cell Count from Baseline.**

<table>
<thead>
<tr>
<th>Group</th>
<th>Day 1</th>
<th>Day 3</th>
<th>Day 5</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>0%</td>
<td>53.66%</td>
<td>96.75%</td>
<td>100%</td>
</tr>
<tr>
<td>Group B</td>
<td>0%</td>
<td>61.36%</td>
<td>99.24%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Above data indicates that speed of recovery from inflammation is greater with moxifloxacin-difluprednate than moxifloxacin-dexamethasone eye drops

**Table 2: Change in anterior chamber cell grade from baseline.**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage</th>
<th>Size</th>
<th>No of bottle used per patient</th>
<th>Price per bottle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moxifloxacin-dexamethasone</td>
<td>2 hourly for first 3 day, 6 times a day for 7 day, 4 times a day for 14 days</td>
<td>5 ml</td>
<td>1</td>
<td>9-15 Rs/-</td>
</tr>
<tr>
<td>Moxifloxacin-difluprednate</td>
<td>4 times a day for first 14 days, 2 times a day for next 14 days</td>
<td>5 ml</td>
<td>1</td>
<td>136-140 Rs/-</td>
</tr>
</tbody>
</table>

The above data indicate moxifloxacin difluprednate is costlier than moxifloxacin dexamethasone.

**Conclusion:**
Moxifloxacin-difluprednate and moxifloxacin- dexamethasone eye drops both are effective in reducing post cataract inflammation.

Speed of recovery from inflammation is more with Moxifloxacin-difluprednate and pain relief is also more with Moxifloxacin- difluprednate eye drops.

Good patient compliance was determined from patient accounts during follow up consultations. This can be attributed to the tolerability profile of the drug and ease of administrations of Moxifloxacin- difluprednate eye drops although Moxifloxacin -difluprednate is costlier than moxifloxacin- dexamethasone.

**References:**


