Comparative study of Prednisolone acetate 1% eye drops and Diclofenac sodium 0.1% eye drops in treatment of post-operative uveitis after uncomplicated cataract surgery

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Abstract: Eye is the most important sensory organ and it is prone to many diseases. Development of opacity of lens is called cataract. Cataract accounts for 81% among all causes of blindness in India. Cataract can be treated by surgery. Post-operative inflammation of eye (aseptic uveitis) is one of the most common complications. It can be controlled by steroid drugs, but they have got other ocular and systemic complications. To avoid this non-steroidal anti-inflammatory drugs are tried. Based on the literature and clinical study reports we wish to substantiate these findings, we undertook this study to compare Prednisolone acetate 1% eye drops and Diclofenac sodium 0.1% eye drops in the treatment of post-operative uveitis after uncomplicated cataract surgery.

Total 150 patients were taken into the study. They were divided randomly in two groups 75 patients in each group. The study was conducted up to 42nd day of post-operative period. Patients were observed up to 6 weeks. During 1st week, Predinosolone patients responded well than the patients kept on Diclofenac but in later weeks Diclofenac patients yielded better results. No adverse effects were seen in Diclofenac group but in prednisolone group raised intraocular pressure. Cost of prednisolone was more than Diclofenac. So in conclusion Diclofenac 1% eye drops were effective and safer than prednisolone 0.1% eye drops in aseptic uveitis. It could also tried in patients in whom corticosteroids were contraindicated.

Keywords: Aseptic uveitis, Diclofenac sodium, Intra ocular pressure, Predinisolone acetate, Uncomplicated cataract surgery.

I. Introduction

Development of opacity of lens is called cataract. Annual incidence of blindness due to cataract in India is 2 millions [1]. It can be treated by surgery (extra capsular cataract extraction of phaco-emulsification of lens). Post operative inflammation of eye (aseptic uveitis) is one of the most common complications. Aseptic uveitis can be controlled by steroids and non steroid drugs. Though Steroid drugs are good anti inflammatory drugs, they have ocular complications like steroid induced glaucoma, super infection, flaring of herpes, perforation of corneal ulcers. To avoid these complications, non steroid anti inflammatory drugs are tried. Wishing to substantiate these findings, we undertook a study to compare Prednisolone acetate 1% eye drops and Diclofenac sodium 0.1% eye drops in the treatment of post operative uveitis (aseptic uveitis) after uncomplicated cataract surgery.

II. Aims and objectives

• To compare the anti inflammatory effect and the outcome of clinical features with Prednisolone 1% eye drops and Diclofenac Sodium 0.1% eye drops in post operative uveitis (aseptic uveitis) after uncomplicated cataract surgery.
• To study the adverse effects of both drugs.
• To compare the cost of both the drugs.

III. Methodology

It was a comparative, prospective randomized study done at Government General Hospital, Vijayawada. The protocol was approved by Institutional Ethics Committee and written consent in local language was taken from patients.

Inclusion criteria.
• Both sexes, male and female
• Age above 45 years
• Patient with senile mature or hyper mature cataract are included.
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Exclusion criteria:
- Patients with congenital and traumatic cataract.
- Cataracts associated with seasonal allergic conjunctivitis, rhinitis or iritis
- Patients with diabetes mellitus, hypertension, lichen planus, erythema nodosum.
- Patients with auto-immune diseases like Rheumatoid arthritis, psoriasis, systemic lupus erythematosus
- Patients with ear, nose, throat infections, tuberculosis, HIV and glaucoma.
- History of Hypersensitivity of Diclofenac and Prednisolone.

Total 150 patients were taken into study. They were selected randomly in 2 groups, 75 patients in each group. The first group was given prednisolone and the second group was given Diclofenac. Each ml prednisolone contained 10 mg prednisolone acetate and each ml of diclofenac contains 10 mg diclofenac sodium. The patients who underwent extra capsular cataract extraction surgery (ECCE) were taken prednisolone 1% eye drops i.e., 1 drop 4th hourly was given in the respected group from 1st to 7th post operative day in the operated eye. Afterwards 1 drop every 6th hourly from 8th to 42nd post operative days in the respected groups. Each patient in the above mentioned 2 groups were examined in the following way:
1) Slit lamp, 2) Fundoscopic examination 3) vision was checked by snellen’s chart on 42nd post operative day 4) Intra ocular pressure was measured by schotz tonometer on 42nd post operative day 5) observation of adverse effects

On slit lamp examination the various parameters like conjunctival congestion, corneal edema, striate keratopathy, keratic precipitates, Hypopyon, flare and residual lens matter in anterior chamber, pupil shape, posterior synechiae, reaction to light, papillary capture, papillary block, posterior capsular opacification and clarity of vitreous.

IV. Results

The following results were noted on 7th, 21st, 42nd post operative days. No of patients responded on 7th, 21st, 42nd post operative day:

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Prednisolone acetate No%</th>
<th>Diclofenac sodium No %</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7th Day</td>
<td>21st Day</td>
<td>42th Day</td>
</tr>
<tr>
<td>Conjunctival congestion</td>
<td>14/23(60.8%)</td>
<td>22/23(95.8%)</td>
<td>23/23(100%)</td>
</tr>
<tr>
<td>Striate keratopathy</td>
<td>7/19(36.84%)</td>
<td>13/19(68.4%)</td>
<td>18/19(94.7%)</td>
</tr>
<tr>
<td>Corneal edema</td>
<td>22/13(73.3%)</td>
<td>29/30(96.6%)</td>
<td>30/30(100%)</td>
</tr>
<tr>
<td>Hypopyon</td>
<td>2/23</td>
<td>3/3</td>
<td>3/3(100%)</td>
</tr>
<tr>
<td>Keratic precipitates</td>
<td>1/3</td>
<td>2/3</td>
<td>3/3 (100%)</td>
</tr>
<tr>
<td>Flare</td>
<td>1/1</td>
<td>1/1</td>
<td>1/1(100%)</td>
</tr>
<tr>
<td>Cells in anterior chamber</td>
<td>4/5</td>
<td>5/5</td>
<td>5/5</td>
</tr>
<tr>
<td>Pigmentary deposits</td>
<td>18/17</td>
<td>31/57</td>
<td>51/17</td>
</tr>
<tr>
<td>Residual lens matter</td>
<td>11/46</td>
<td>29/46</td>
<td>41/46</td>
</tr>
</tbody>
</table>

At the end of 42 days there was no change to pupil shape, reaction to light. No posterior synechiae, papillary capture or block in either group. The fundus was normal and vitreous was clear in either group. Results were tabulated; comparison and significance were tested by chisquare test. P value was noted. Result were shown graphically in bar and pie charts.

During 1st week prednisolone worked better, but in later weeks Diclofenac 0.1% eye drops were good than prednisolone 0.1% eye drops. But there results were statistically not significant.

In steroid group raised intra ocular pressure was seen. No adverse reactions were seen in Diclofenac groups.
V. Figures

7th post operative day: No. of patients responded:

21st post operative day: No. of patients responded:
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42\textsuperscript{nd} post operative day: No of patients responded:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Prednisolone</th>
<th>Diclofenac</th>
</tr>
</thead>
<tbody>
<tr>
<td>residual lens matter</td>
<td>89</td>
<td>91</td>
</tr>
<tr>
<td>posterior opacification</td>
<td>70</td>
<td>73</td>
</tr>
<tr>
<td>pigmentary deposits</td>
<td>90</td>
<td>92</td>
</tr>
<tr>
<td>cells in anterior chamber</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>flare</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>keratic precipitates</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>hypopyon</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>corneal edema</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>striate keratopathy</td>
<td>94</td>
<td>94</td>
</tr>
<tr>
<td>conjunctival congestion</td>
<td>100</td>
<td>96</td>
</tr>
</tbody>
</table>

7\textsuperscript{th} post operative day: Percent of patients responded:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percent Responded</th>
</tr>
</thead>
<tbody>
<tr>
<td>residual lens matter</td>
<td>5%</td>
</tr>
<tr>
<td>posterior opacification</td>
<td>3%</td>
</tr>
<tr>
<td>pigmentary deposits</td>
<td>6%</td>
</tr>
<tr>
<td>cells in anterior chamber</td>
<td>15%</td>
</tr>
<tr>
<td>flare</td>
<td>19%</td>
</tr>
<tr>
<td>keratic precipitates</td>
<td>6%</td>
</tr>
<tr>
<td>hypopyon</td>
<td>13%</td>
</tr>
<tr>
<td>corneal edema</td>
<td>14%</td>
</tr>
<tr>
<td>striate keratopathy</td>
<td>7%</td>
</tr>
<tr>
<td>conjunctival congestion</td>
<td>12%</td>
</tr>
</tbody>
</table>
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21st post operative day: Percent of patients responded:

**Diclofenac**

- residual lens matter: 5%
- posterior opacification: 6%
- pigmentary deposits: 9%
- cells in anterior chamber: 20%
- flare: 0%
- keratic precipitates: 7%
- hypopyon: 0%
- corneal edema: 29%
- striae keratopathy: 13%
- conjunctival congestion: 13%

**Prednisolone**

- residual lens matter: 8%
- posterior opacification: 4%
- pigmentary deposits: 7%
- cells in anterior chamber: 13%
- flare: 13%
- keratic precipitates: 9%
- hypopyon: 13%
- corneal edema: 12%
- striae keratopathy: 9%
- conjunctival congestion: 12%
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42nd post operative day Percent of patients responded:

**Diclofenac**
- residual lens matter: 11%
- posterior specification: 8%
- pigmented deposits: 10%
- cells in anterior chamber: 17%
- flare: 0%
- keratic precipitates: 4%
- hypopyon: 0%
- corneal edema: 18%
- stralate keratopathy: 16%
- conjunctival congestion: 16%

**Prednisolone**
- residual lens matter: 9%
- posterior specification: 8%
- pigmented deposits: 9%
- cells in anterior chamber: 11%
- flare: 11%
- keratic precipitates: 11%
- hypopyon: 11%
- corneal edema: 10%
- stralate keratopathy: 10%
- conjunctival congestion: 10%
VI. Discussion

In our study during 1\textsuperscript{st} week Prednisolone eye drops yielded better results than Diclofenac sodium. But in later weeks Diclofenac did better than Prednisolone. But the results were not statistically significant. So, both have got the anti inflammatory effect. Similar results were observed by Brennan KM, Brown RM, Roberts CW [2].

Diclofenac sodium 0.1\% eye drops was effective, safe and did not raise the intra ocular pressure. Similar results were seen by Strelow SM, Shenwood MB, Bron Cat to LJ [3]

Diclofenac Sodium eye drops decreases the inflammation after cataract surgery. This is similar to the study of Onakoya A.O., Majekondiu AA, Adecate [4]

Topical Diclofenac sodium effectively decreases the post surgical inflammation. This is consistent with Matsuo K, Hojou H, Honbou M and Manjoo S, Reddy, M.S, Suneetha N, M.S, Reji [5,6]

VII. Conclusion:

Post operative uveitis (aseptic uveitis) is a common problem after uncomplicated cataract surgery. Routinely steroids are used to control it. But they possess many adverse effects and contra indications. So other anti inflammatory drugs which belongs to non steroidal anti inflammatory drugs are tried.

The present study compared the efficacy of prednisolone acetate 1\% eye drops with Diclofenac Sodium 0.1\% eye drops in the treatment of Aceptic Uveitus.

Total 150 patients were taken for study. They were allotted randomly in 2 groups i.e. prednisolone group and Diclofenac group, 75 patients in each group.

The study was conducted up to 42\textsuperscript{nd} post operative day. They were particularly observed on 7\textsuperscript{th}, 21\textsuperscript{st} and 42\textsuperscript{nd} days and full eye examination was done using various instruments. Both the drugs suppressed the post operative inflammation. But in the steroids group, raised intra ocular pressure was seen. During the 1\textsuperscript{st} week prednisolone 1\% eye drops yielded better results, but in later weeks Diclofenac Sodium 0.1\% eye drops yielded good results than prednisolone 1\% eye drops. But there results were statistically not significant.

In steroid group raised intra ocular pressure was seen. No adverse effect in Diclofenac group was noted.

Cost of the prednisolone acetate 1\% eye drops (Rs 2) was more than Diclofenac Sodium(Rs 1.50).

Though statistically not significant, on the whole Diclofenac Sodium 0.1\% eye drops was effective, safer, than prednisolone 1\% eye drops will no adverse effects in controlling aseptic uveitis. Cost was also less. It could also be tried in patients in whom corticosteroids were contraindicated.

Acknowledgments

I am thankful to all the patients who participated and co-operated in this study. I am thankful to statistician who helped me with diagrams and tables.
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References