COMPARISON OF THE EFFICACY OF TOPICAL DICLOFENAC VERSUS TOPICAL BETAMETHASONE AFTER STRABISMUS SURGERY

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Abstract- Topical corticosteroids are commonly used for decreasing inflammation after strabismus surgery. However the use of topical corticosteroids may be associated with several adverse effects. The aim of this study was to compare the relative effects of topical diclofenac with betamethasone in inflammation, wound healing and intraocular pressure following strabismus surgery. A single centre, single observer, prospective, randomized and single blind clinical trial of 43 patients undergoing strabismus surgery was carried out. Both postoperative treatments were instilled four times per day in the first week and two times per day in the second week postoperatively. Patient pain and discomfort, conjunctival chemosis, injection, conjunctival gap, and intraocular pressure were assessed at one day, one week, two weeks and four weeks after surgery. Since the first postoperative week the diclofenac group showed less discomfort and less conjunctival inflammation, edema, and conjunctival gap than the betamethasone group and these differences became statistically significant at the second week after surgery. There was not any significant difference between mean intraocular pressure of the diclofenac and the betamethasone group in any postoperative measurements. Diclofenac appears to be superior to corticosteroids in controlling the inflammatory responses and surgical wound healing after strabismus surgery. The maximal effect of diclofenac occurred at 2 weeks after surgery.

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Key words: Betamethasone, diclofenac, strabismus surgery

INTRODUCTION

Topical corticosteroids are commonly used for decreasing inflammation after strabismus surgery (1). However the use of topical corticosteroids may be associated with several adverse effects such as increased intraocular pressure (IOP), decreased wound healing, raised susceptibility to infections and cataract formation (2, 3).

Non-steroidal anti inflammatory drugs (NSAIDS) have been shown to be more effective than corticosteroids after cataract and strabismus surgery in several studies (4-6). In addition, they may reduce postoperative pain by decreasing prostaglandin production by a similar pathway as corticosteroids without impairment of corneal wound healing (7).

The aim of this study was to compare efficacy of topical Diclofenac and Betamethasone on the conjunctival healing process and IOP after strabismus surgery.
Diclofenac vs. betamethasone after strabismus surgery

MATERIALS AND METHODS

The study population included 43 consecutive patients who underwent strabismus surgery at Farabi Hospital of Tehran from October 2002 through June 2003. Patients with systemic abnormalities, previous ocular surgery, intraocular pathology, family history of glaucoma, or allergic reaction to the steroidal or non-steroidal drugs or chloramphenicol were excluded.

Written informed consent was obtained from all parents or patients. For patients undergoing bilateral surgery the right eye was randomized to receive postoperative topical treatment with Diclofenac sodium 0.1%- Chloramphenicol 0.5% or Betamethasone sodium phosphate 0.1%-Chloramphenicol 0.5% while the left eye was assigned to the opposite group. In the participants with unilateral disorder the allocation was performed randomly.

All surgeries were performed by one surgeon under general anaesthesia. The rectus muscles were approached through a 5-6 mm limbal conjunctival incision or a conjunctival fornix incision. Conventional recession and resection was performed depending on the type of strabismus. Muscles were reattached after recession/resection with double armed 6-0 Vicryl sutures. The conjunctival incision was closed with 8-0 Vicryl absorbable sutures, two sutures at the limbus and one suture in the middle of each arm. Both postoperative treatments were instilled four times per day in the first week and two times per day in the second week postoperatively.

Patients were evaluated one day after surgery, at 1, 2 and 4 weeks postoperatively by a single masked investigator. Five parameters were measured: patient pain and discomfort, conjunctival chemosis, injection, conjunctival gap, and IOP (measured by Goldman – type applanation tonometer). For the first parameter, the patients were asked to rate their pain perception anywhere between 0 (no pain) to 100 (extreme disabling pain). This score was then grouped in a 5-point scale: total comfort = 0, 1 to 25=1, 26 to 50=2 and 51 to 75=3 and 76 to 100=4. The second and third parameters were rated on a 4-point scale: no chemosis or injection = 0, in incision site only = 1, extended to the hours 6 and 12 of limbus = 2, extended to fornix or eyelids = 3. The size of the postoperative conjunctival gap was measured in millimeters with slit-lamp illumination perpendicular to the incision line.

Differences between the groups in clinical characteristics and surgical parameters were statistically analyzed with $t$ and Chi square tests as necessary. The comparison between postoperative measures of two groups was done using independent samples $t$ test. Paired sample $t$ test was utilized to compare postoperative IOPs with preoperative measures.

RESULTS

A total of 65 eyes (of 43 patients) were included in the study and were randomized to Diclofenac (33 eyes) and Betamethasone groups (32 eyes).

The patients' characteristics and surgical parameters are presented in table 1. There were no statistically significant differences between the groups in age, gender, number of operated eyes. The number of muscles operated in each eye was significantly more in Diclofenac group. As depicted in table 2, since the first postoperative week the diclofenac group showed less discomfort and less conjunctival inflammation, edema and conjunctival gap than the betamethasone group and these differences became statistically significant at the second week after surgery.

Table 1. Patients' characteristics*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Diclofenac (n = 33)</th>
<th>Betamethasone (n = 32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>21.24 ± 9.39</td>
<td>21.25 ± 9.4</td>
</tr>
<tr>
<td>Male/Female†</td>
<td>17/16</td>
<td>16/16</td>
</tr>
<tr>
<td>Unilateral/Bilateral†</td>
<td>11/22</td>
<td>10/22</td>
</tr>
<tr>
<td>No. Muscles operated</td>
<td>1.79 ± 0.55</td>
<td>1.47 ± 0.47‡</td>
</tr>
<tr>
<td>in each eye</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative IOP</td>
<td>13.59 ± 2.01</td>
<td>13.72 ± 1.95</td>
</tr>
</tbody>
</table>

*Data are given as mean ± SD unless specified otherwise.
† Number.
‡ $P = 0.02.$
Table 2: Postoperative measures in diclofenac (Group 1) and betamethasone (Group 2) groups*

<table>
<thead>
<tr>
<th>Measures</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 day</td>
<td>1 week</td>
<td>2 weeks</td>
<td>4 weeks</td>
<td>1 day</td>
<td>1 week</td>
</tr>
<tr>
<td>Pain and discomfort</td>
<td>40.3±10.1</td>
<td>39.1±10.9</td>
<td>18.9±6.2</td>
<td>20.7±6.3</td>
<td>4.2±2.8</td>
<td>7.2±4.0†</td>
</tr>
<tr>
<td>Chemosis</td>
<td>1.41±0.46</td>
<td>1.30±0.44</td>
<td>0.68±0.41</td>
<td>0.87±0.34</td>
<td>0.05±0.15</td>
<td>0.38±0.31††</td>
</tr>
<tr>
<td>Injection</td>
<td>1.94±0.17</td>
<td>1.92±0.18</td>
<td>1.30±0.25</td>
<td>1.39±0.21</td>
<td>0.74±0.28</td>
<td>0.89±0.21††</td>
</tr>
<tr>
<td>Conjunctival gap</td>
<td>0.69±0.76</td>
<td>0.79±0.67</td>
<td>0.43±0.56</td>
<td>0.56±0.49</td>
<td>0.13±0.23</td>
<td>0.28±0.31††</td>
</tr>
</tbody>
</table>

* Data are given as mean ± SD.
†P < 0.001.
‡P < 0.05 compared with betamethasone.

The results of the measurement of preoperative intraocular pressure are shown in table 3. The intraocular pressure was almost identical in the betamethasone groups in four postoperative time points. By contrast, it was significantly more than preoperative IOP at the first day and the fourth week after surgery in the diclofenac group. There was not any significant difference between mean IOP of the diclofenac and the betamethasone group in any postoperative measurements.

**DISCUSSION**

The present study showed that diclofenac is more effective than betamethasone for the treatment of pain and discomfort, for conjunctival chemosis, injection, and conjunctival gap.

The analgesic effect of topical diclofenac after ocular surgeries has been investigated in some studies. Morton et al. showed that diclofenac had the same analgesic effects as Oxybuprocain, especially in children (8). In the Snir et al. study, diclofenac was superior to dexamethasone in reducing pain and discomfort for a period of four weeks (6).

Like corticosteroids, diclofenac acts via decreasing the formation of the main mediators of the inflammatory response such as prostaglandins and Leukotrienes by directly modulating the cyclooxygenase pathway and indirectly modulating the lipoxygenase pathway. The anti-inflammatory effects of topical diclofenac have compared favorably with topical steroids following cataract surgery (6, 9, 10). Conversely, Apt et al. (5) and Dadeya (11) demonstrated no difference between diclofenac and steroids in the rate of resolution of the inflammatory response after strabismus surgery. The use of postoperative anti-inflammatory steroidal drops has been found to impair the quality and rate of wound healing. It seems that topical steroids decrease fibroblast activity and scar formation after corneal surgery (12). According to the results of the current study NSAIDS have not such inhibitory effects.

The routine use of postoperative topical corticosteroids may induce a high IOP, which becomes apparent after 3 to 8 weeks. Ohji et al. demonstrated that 82% of children under 10 years of age receiving topical dexamethasone 0.1% three times daily following strabismus surgery demonstrated significant elevations of IOP with half of the children having rises in IOP of greater than 15 mm Hg (13). In present study we did not find any significant difference in IOP between diclofenac and betamethasone group and all
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the post operative IOP measures were within normal range. Less increase in IOP in betamethasone group compared with the previous studies may be due to shorter treatment period in our study (5, 6, 11).

In conclusion, diclofenac appears to be superior to corticosteroids in controlling the inflammatory responses and surgical wound healing after strabismus surgery. The maximal effect of diclofenac occurred at 2 weeks after surgery.

REFERENCES