Study on Efficacy of Steroids and Acyclovir Treatment in Bell's Palsy

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ABSTRACT

Background: Bells palsy is an idiopathic disease of the seventh cranial nerve. This is the most frequent cranial mononeuropathy with an annual incidence of 10 to 40 cases per 100,000 population with geographical variations. Aim: To assess the efficacy of Steroids and Acyclovir in the management of Bell’s palsy. Methods: All the patients with Bell's palsy, without clinical evidence of other cranial nerve damage or central nervous system diseases were included. Patients were divided into 4 groups, control, steroid alone, steroid with acyclovir and acyclovir alone. The study groups of patients were clinically tested in a periodic manner within twelve months at various intervals. The severity of the facial nerve involvement is assessed with House- Brackmann grading (HB) system. Results: In 101 patients, Majority of patients come under grade IV (43.6%) and next comes to grade V (31.7%). 86% of the percentage of patients improved in grade IV, and 68.8% of patients improved in grade V. None of the patients from grade VI showed improvement. Combination of Steroids and acyclovir is definitely useful when compared to the control group. The combination scores over the control group by 1.37 times which is statistically significant (P value= 0.031668). Conclusion: Steroids are safe and are probably effective in the management of bells palsy which improves the rate of recovery. Acyclovir in combination with prednisolone is safe and has a definite role in improving facial functional outcomes in patients with Bell’s palsy than using the drug alone.

Keywords: Bells Palsy, Steroids, Acyclovir.

INTRODUCTION

Bell’s palsy is the most frequent disease of the seventh cranial nerve, with a good prognosis. More than 70% of patients attain complete clinical recovery, with no noticeable residua 1. Persistent sequelae are usually noted in cases with the profound axonal loss only. Treatment of Bell’s palsy is still controversial. Therapy is difficult to evaluate, because as many as two-thirds of patients with Bell’s palsy spontaneously recover and achieve near-normal function. Many patients begin to improve as early as 10 days after the onset, even without treatment 3. Drug therapy mainly consists of corticosteroids with or without an antiviral (acyclovir). These drugs hasten the recovery and lessen the ultimate degree of dysfunction. One hundred and one patients with clinical signs of Bell’s palsy were included in this study. Clinical signs were recorded (the degree of facial muscle palsy) and treated with steroids and acyclovir in combination or separately. The results were analyzed in regard to which combination of drugs is most useful in the management of Bell’s palsy.

Aim

To assess the efficacy of Steroids and Acyclovir in the management of Bell’s palsy.

MATERIALS AND METHODS

This prospective study was done on 101 patients with clinical signs of Bell’s palsy, of both sexes, in various age groups who attended the Neurology Outpatient department, Institute of Neurology, Madras Medical College and Government General Hospital, Chennai. All the patients underwent Neurological and ENT evaluation.

Inclusion criteria:

All the patients with Bell's palsy, without clinical evidence of other cranial nerve damage or central nervous system diseases.

Exclusion criteria:

Patients with: Middle ear disease or posterior cranial fossa disease, Chronic illness like Diabetes mellitus, Hypertension and Malignancy. Patients were divided into 4 groups...
Group 1—Patients who received only physiotherapy (Control)

Group 2—Patients who received steroids and physiotherapy.

Group 3—Patients who received steroids, acyclovir and physiotherapy.

Group 4—Patients who received Acyclovir and physiotherapy.

In the treatment group, the dosage of steroids used was 1 mg/kg (45 to 60) mg for 5 days then tapered over the next 5 days. Acyclovir is used in a dose of 1 gm/day for 10 days. The severity of the facial nerve involvement is assessed with House-Brackmann grading (HB) system.

RESULTS

One hundred and one patients with signs of Bell's palsy were included in this study. Most of the cases belong to the age group of 31-40. Only 2.9% of patients belonged to the age group of 61-70. In the present study, the sex ratio was almost even. 47 were females (46.6%) and 54 were males (53.4%).

Table 1: Distribution of Grading

<table>
<thead>
<tr>
<th>Grade</th>
<th>Control</th>
<th>Steroids</th>
<th>Steroid + Acyclovir</th>
<th>Acyclovir</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>5</td>
</tr>
<tr>
<td>II</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>III</td>
<td>5</td>
<td>7</td>
<td>6</td>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td>IV</td>
<td>11</td>
<td>18</td>
<td>13</td>
<td>2</td>
<td>44</td>
</tr>
<tr>
<td>V</td>
<td>7</td>
<td>12</td>
<td>8</td>
<td>5</td>
<td>32</td>
</tr>
<tr>
<td>VI</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>-</td>
<td>05</td>
</tr>
<tr>
<td>Total</td>
<td>23</td>
<td>40</td>
<td>29</td>
<td>9</td>
<td>101</td>
</tr>
</tbody>
</table>

Majority of patients come under grade IV (43.6%) and next comes grade V (31.7%), III (19.8%), and the least in grade VI (4.9%).

In the various age groups, one out of three in 10-20 years, four out of five in 21-30 yrs, seven out of eight in 31-40 yrs, one out of two in 41-50 yrs, three out of four in 51-60 yrs and none in 61-70 yrs age groups improved.

In the various age groups, nine out of twelve in 10-20 years, eleven out of twelve in 21-30 yrs, eight out of eight in 31-40 yrs, four out of five in 41-50 yrs, one out of two in 51-60 yrs and none in 61-70 yrs age groups improved.

In the various age groups, all the patients in 10-20 years, 21-30 yrs, 31-40 yrs, 41-50 yrs, improved and none of the patients in 51-60 yrs and 61-70 yrs age groups showed improvement.

In the various age groups, all the patients in 10-20 years, 21-30 yrs, 31-40 yrs and one out of two in 31-40 yrs, one out of three in 41-50 yrs improved.

In the control group, all the patients in group A recovered. In group B out of 10 patients 9 recovered and in group C none recovered. In the steroid group, all the patients in group A recovered and in group C none recovered. In the steroid group, all the patients in group A recovered within 2 months. In group B out of 9 patients 8 recovered and in group C out of 8 patients 2 recovered. All the patients in group A recovered within 2 months. In group B out of 7 patients 6 recovered and in group C out of 5 patients 3 recovered. All the patients in group A and B recovered within 6 months. In group C none of the cases recovered. 82 patients (81.2%) had normal latency, among these, 73 cases recovered within 6 months. Out of 17 who had prolonged latency, 7 patients recovered fully and 2 patients in group C didn’t show any improvement.

Table 3: Rate of improvement in various treatment groups and grades

<table>
<thead>
<tr>
<th>Groups</th>
<th>Total cases</th>
<th>Patients improved</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>23</td>
<td>15</td>
<td>65.2</td>
</tr>
<tr>
<td>Steroids</td>
<td>40</td>
<td>33</td>
<td>82.5</td>
</tr>
<tr>
<td>Acyclovir + Steroids</td>
<td>29</td>
<td>26</td>
<td>89.6</td>
</tr>
<tr>
<td>Acyclovir</td>
<td>9</td>
<td>6</td>
<td>66.6</td>
</tr>
</tbody>
</table>

The improvement in group 1 was 65.2%; group 2 recorded an improvement of 82.5%. Group 3 showed maximum improvement (89.6%) and group
4 the improvement is only 66.6%. In the control group the improvement started by 6-8 weeks. In the steroids group, Improvement started as early as 2-4 weeks and the majority of the patients had complete improvement within 8 weeks. In Steroids + Acyclovir, improvement started as early as 2-4 weeks and the majority of the patients had complete improvement within 8 weeks. All patients recovered within 6 months. In the Acyclovir group the improvement started by 6-8 weeks.

**Table 7 Rate of recovery**

<table>
<thead>
<tr>
<th>Groups</th>
<th>RR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steroids vs Control</td>
<td>1.265</td>
<td>0.9-1.76</td>
</tr>
<tr>
<td>Steroids +Acyclovir vs Control</td>
<td>1.374</td>
<td>0.99-1.89</td>
</tr>
<tr>
<td>Steroids vs Steroids</td>
<td>1.086</td>
<td>0.89-1.31</td>
</tr>
<tr>
<td>Acyclovir vs Steroids</td>
<td>1.022</td>
<td>0.58-1.77</td>
</tr>
</tbody>
</table>

Patients treated with steroids alone also had a better recovery when compared with the control group. The data interpretation showed that, the steroid group scored over the control group by 1.26 times. However it was not statistically significant. Patients treated with steroids and Acyclovir scored over patients treated with steroids by 1.08 times. Patients treated with Acyclovir alone scored over control by 1.02 times. The above data was not statistically significant.

**DISCUSSION**

Treatment of Bell’s palsy is still controversial. Therapy is difficult to evaluate, because as many as two-thirds of patients with Bell’s palsy spontaneously recover and achieve near-normal function. Many patients begin to improve as early as 10 days after the onset, even without treatment. Mathews WB et al in his study observed that older age could badly influence the course of the illness.4Heath et al5presented the results of their research showing that the average age of patients who had a rapid and complete recovery was 35.8 ± 15.9 years, while patients with an incomplete recovery were 55.4 ±18.8 years old. The results of this study had not shown the existence of a correlation between the age and the duration, degree of clinical recovery.

It was noted by May M et al,6 and Hauser WA et al,7 that majority of patients with signs of incomplete facial paralysis of the third and fourth degree, on the fourteenth day of the illness, had a rapid and complete recovery.

The present study shows that patients with signs of incomplete facial paralysis of the third and fourth-degree, on the fourteenth day of the illness, had a rapid and complete recovery.

These results showed that an incomplete facial paralysis had a complete clinical recovery, while a complete paralysis indicated bad prognosis, which is consistent with the literature data.8,9 An absolute bad prognostic sign was the lack of any movement of the mimic musculature during the first fourweeks. In this study, the best functional recovery was seen in patients who were treated with steroids and Acyclovir. The above data was statistically significant when compared to control group with ‘P’ value of 0.031668.

These observations correlated with other studies which says that steroids hasten clinical recovery in bell’s palsy.8,9 Wolf et al have suggested that patients with complete facial palsy benefit most from steroids.10

Combination of Steroids and acyclovir is definitely useful when compared to the control group. The combination scores over the control group by times which is statistically significant (P value= 0.031668). This observation correlated with the study made by Adour and colleagues.11 The present study did not find any beneficial effect in treating the patients with Acyclovir alone. Even though the study sample is small this observation concurs with the observation made by De Diego JI, et all in the study comparing prednisolone vs acyclovir. They found that patients treated with prednisolone had better complete recovery rates, 93.6% vs 77.7%.12

The observations made in the present study shows that the combination of steroid and acyclovir is definitely useful in Bell’s palsy. Steroids are probably effective in the management of bells palsy as they improve the rate of recovery. The outcome in patients in whom Acyclovir alone (group 4) was used didn’t score over the control group.
Rate of recovery
These studies correlated with other studies which said that steroids hasten clinical recovery in bell’s palsy. Wolf et al have suggested that patients with complete facial palsy benefit most from steroids. The present study did not find any beneficial effect in treating the patients with Acyclovir alone. Even though the study sample is small this observation concurs with the observation made by De Diego, et all in the study comparing prednisolone vs acyclovir. They found that patients treated with prednisolone had better complete recovery rates, 93.6% vs 77.7%.

Time is taken for recovery
Analyzing the time taken for improvement in the various groups, the recovery in the control group started by 6-8 weeks while in the treatment group improvement started between early by 2-4 weeks. Taverner et al in his study, reported a trend for steroid-treated patients to recover faster than the control patients, but the differences were not significant.

Role of early treatment in bells palsy.
Williamson IG et al and May MM et al have suggested that steroids work best in patients with Bell’s palsy if started early. Shafshak however deferesthis observation in his study. Analyzing the outcome of patients in group C, (by CMAP ratio) those who were treated, five out of thirteen, had good recovery.

Complications due to treatment.
Three studies discussed steroid side effects. Side effects occurred in 1% to 4% of treated patients. These side effects, in descending order of frequency, are dyspepsia, loss of blood sugar control, recurrent duodenal ulcers, mood swings, and acute psychosis. The present study observed treatment-related complications in four patients. Two patients who developed dyspepsia were more than 65 years old. The patient who had melena after therapy was also an alcoholic. One 47-year-old patient treated with steroids and acyclovir developed vomiting. This observation indicates that steroid-related complications are more among older people and persons who are having other risk conditions. Otherwise treatment of Bells palsy with steroids is effective and safe.

CONCLUSION
Steroids are safe and are probably effective in the management of bells palsy which improves the rate of recovery. Acyclovir in combination with prednisolone is safe and has a definite role in improving facial functional outcomes in patients with Bell’s palsy than using the drugalone. Early treatment in cases with incomplete paralysis hastens the recovery and it has no effect on cases with the severe deficit.

REFERENCES
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