

Bell's Palsy Treatment: Comparison of Famciclovir plus Prednisolone with Prednisolone Alone

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Abstract: Not many Indian studies have evaluated role of antiviral drug Famciclovir in treatment of Bell's palsy. Aim of this study was to analyze and compare clinical and electrophysiological recovery with Famciclovir plus prednisolone and prednisolone alone in treatment of Bell's palsy. 50 patients with clinical features compatible with Bell's palsy were included in the study. Detailed clinical, laboratory and electrophysiological evaluations of patients were done and patients were randomized into two groups. Group I received Famciclovir plus prednisolone while the Group II received 10 days of oral prednisolone alone. Outcome was assessed at 3 months with House-Brackmann scale and the patients were followed up to a period of three months. The mean age of patients was 35.0 years with M: F ratio of 64: 36. No significant differences exist between the groups in terms of age and gender. The rate of complete recovery was 68% in group I and 60% in the group II (p=0.04). The results of this study showed that the combined prednisolone and famciclovir therapy of patients with Bell's palsy is more effective than treatment with prednisolone alone.

Key words Bell's palsy treatment, Famciclovir, antiviral, combination therapy.

INTRODUCTION

Bell's palsy is the most common cause of acute onset unilateral peripheral facial weakness. The incidence of Bell's palsy is 20-30 cases for 100,000[1] and this constitutes 60-70% of all cases of unilateral peripheral facial palsy [2]. Gender of affection is almost same and may occur at any age, the median age is 40 years. The incidence is lower in children with no side preferences [3].

Many treatment options have been tried with varying results. About pathogenesis it is contemplated that Bell's palsy occurs as an inflammatory reaction to viral infection. Though expected to respond to antiviral, their role is still controversial [4-7]. Corticosteroids, is most widely used and time tested treatment option [7, 8]. Prednisone and acyclovir are also widely used, famciclovir in combination with steroids also tried. Famciclovir is a guanine analogue antiviral drug used for the treatment of various herpes virus infections; it is a prodrug form of penciclovir with improved oral bioavailability. However, their effectiveness has been controversial [5, 9, 10].

MATERIALS & METHODS

This prospective study was performed over 24 months from August 2015 to July 2017. Patients attending Outdoor Department of Neurology Department and referred from Medicine Outdoor Departments were included in the study. .

Informed consent was taken from all patients and approval of the Institutional Ethics Committee was obtained.

50 patients with clinical features compatible with Bell's palsy were included in the study. Detailed clinical, laboratory and electrophysiological evaluations of patients were done. Patients with any of the following conditions were excluded: paralysis of other cranial nerves, pregnancy, diabetes, and presence of acute otitis media or ipsilateral chronic otitis, recent head injury, psychiatric disease or any other condition where the use of corticosteroids was contraindicated.

Then, patients were subjected to NCS on Medelec Synergy Machine, Oxford, UK measuring facial motor latency, amplitude, and velocity.

The patients were divided into two groups of 25 patients in each, according to a computerized randomization table. Group I received Famciclovir 500 mg thrice a day for seven days plus prednisolone in a tapering dosage schedule (60 mg daily for initial 5 days, tapered by 10 mg daily over next 5 days). Group II received 10 days of oral prednisolone of similar schedule. Outcome was assessed at 3 months with House–Brackman scale and the patients were followed up to a period of three months.

The primary outcome was assessed using the House–Brackmann grading system for facial nerve function, which assigns patients to 1 of 6 categories. Grade 1 indicates normal function, while Grade 6 indicates no facial function. Intermediate severity grades were defined as slight (Grade 2), moderate (Grade 3), moderately severe (Grade 4) and severe (Grade 5) depending upon the loss of tone, magnitude of weakness, and presence of synkinesis, contracture or hemifacial spasm [11]. Based on the HouseBrackmann criteria, the response to treatment were graded as complete

recovery (grade 1), partial recovery (grade 2–5), and no response (grade 6). Final outcome was measured in terms of complete recovery of the facial nerve function (Grade 1 of House–Brackmann grading system) at 3 months.

Statistical analysis of the data was performed in Microsoft Excel format and analyzed using SPSS for Windows and Data was expressed in mean, percentage, and standard deviation. Pearson's correlation coefficient was used for comparing clinical data with Electro physiological parameters. P-value less than 0.05 were considered significant.

RESULTS

Demographic characteristics of patients are shown in Table 1 and Table 2. Among the 50 patients with Bell’s palsy in this study, 25 patients were treated with famciclovir plus prednisolone and 25 patients with prednisolone alone. There were no noteworthy differences in case of age and gender between the two groups ($p > 0.05$).

Table-1: Age at presentation

Age at presentation	Number of cases	Percent of total cases
0-10	00	00
11-20	02	04
21-30	17	34
31-40	16	32
41-50	07	14
51-60	07	14
61-70	01	02

Table-2: Gender distribution

Gender	Number of cases	Percent of total cases
Male	32	64
Female	18	36

Table-3: Treatment results. Recovery pattern at 3 month

Recovery extent	Famciclovir plus prednisolone (Group I)		Prednisolone alone (Group II)	
	No. of cases	Percent of total cases	No. of cases	Percent of total cases
Complete	17	68	15	60
Partial	08	32	06	24
No response	0.0	0.0	02	08

After 3-month of treatment, 17 (68%) patients from group 1 and 15 (60%) from group 2 recovered completely; a total of 32 (64%) patients thus recovered completely. The patients treated Famciclovir plus prednisolone and oral prednisolone alone, both, showed improvement in the symptoms. Statistically significant differences were observed between the two treatment groups with better improvement in combined group with p value 0.04.

DISCUSSION

Consensus is evolving on how to treat Bell’s palsy. Rate of complete recovery in our study was 68% in patients who received Famciclovir plus prednisolone and in those who received prednisolone alone it was 60% ($p = 0.04$). Many studies have shown higher performance and greater improvement rate of combination therapy of prednisolone and acyclovir compared with

prednisolone alone (12-15). One study also demonstrated that patients with Bell's palsy who were treated with prednisolone and Famciclovir performed better [16].

Comparison of acyclovir and famciclovir in the treatment of Bell's palsy is not clear. Ho Joo King *et al* in 2016 compared recovery outcomes in patients with Bell's palsy treated with acyclovir and famciclovir. Patients were given prednisolone plus either acyclovir ($n = 457$) or famciclovir ($n = 245$). House-Brackmann scale was used for assessment, according to initial severity of disease and underlying disease. The overall recovery rate tended to be higher in the famciclovir than in the acyclovir group. The rate of recovery in patients with initially severe facial palsy (grades V and VI) was significantly higher in the famciclovir than in the acyclovir group ($p = 0.01$), whereas the rates of recovery in patients with initially moderate palsy (grade III-IV) were similar in the two groups. Treatment with steroid plus famciclovir was more effective than treatment with steroid plus acyclovir in patients with severe facial palsy. They suggested that famciclovir may be the antiviral agent of choice in the treatment of patients with severe facial palsy [17].

Hato *et al.* reported that the recovery rate in patients treated with valacyclovir and prednisolone was higher than for patients treated with prednisolone alone [18]. Giving prednisolone and famciclovir together was more effective than prednisolone alone in the treatment of Bell's palsy in a study and a significant number of patients improved by adding famciclovir [19]. Adding an antiviral to the treatment of Bell's palsy looks prudent because of HSV involvement in facial nerve inflammation. Antiviruses can eradicate the virus while corticosteroid reduced nerve swelling.

Studies have shown that the effect of corticosteroids in the treatment of Bell's palsy is clear though role of antivirals is having only weak evidence [20, 21].

In some cases of Bell's palsy, probably combination therapy with famciclovir is more effective than prednisolone alone and results in more complete recovery of facial weakness

CONCLUSION

In some cases of Bell's palsy, combination therapy like famciclovir and prednisolone is more effective than prednisolone alone and can result in more complete recovery of facial weakness.

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