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Original Research Article

Treatment of Bell's Palsy: Comparing the Administration of a Single Dose Intravenous Methyl Prednisolone vs Oral Prednisolone: An Open Labeled, Randomized Controlled Trial

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Abstract

Aim: To compare the study of administration of single dose intravenous methyl prednisolone versus oral prednisolone in Bell's palsy. **Methods:** The open labeled, randomized controlled trial was conducted in the Department of Pharmacology, Darbhanga Medical College, Laheriasarai, Darbhanga, Bihar, India from July 2019 to May 2020. 100 patients were divided into two groups, according to a pre-generated computerized randomization table. Patients in group 1 received a single dose of 500 mg of IV infusion of methylprednisolone while those in group 2 received oral prednisolone in a tapering dosage schedule (60 mg daily for initial 5 days, tapered by 10 mg daily over next 5 days). All patients were followed for a minimum of 3 months after inclusion and the outcome analysis was done at 1-month and at 3 months. **Results:** After 1-month of treatment, 25 (50%) patients from group 1 and 20 (40%) from group 2 recovered completely; a total of 45 (45%) patients thus recovered completely. The patients treated with IV methylprednisolone and oral prednisolone, both, showed improvement in the symptoms. The results were however statistically non-significant when compared between the two groups. After 3 months of treatment, 40 (80%) patients from group 1 and 40 (80%) from group 2 recovered completely; a total of 80 (80%) patients recovered completely. No statistically significant differences were observed between the two treatment groups. **Conclusion:** Single dose of 500 mg of IV methylprednisolone may be an equally efficacious alternative to a 10-day course of oral prednisolone. Early institution of treatment should be attempted for optimum results.

Keywords: Bell's Palsy, Facial Nerve, Methylprednisolone

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Introduction

Bell's palsy is an acute peripheral unilateral facial weakness or paralysis with an as yet unknown cause. Bell's palsy accounts for almost three quarters of peripheral facial palsies and the annual incidence is about 30 patients per 100 000.

71% of untreated patients with Bell's palsy will completely recover and 84% will have complete or near normal recovery. The remainder will have persistent moderate to severe weakness, facial contracture, or synkinesis [1-3]. Because of its unclear etiology, there has been longstanding controversy about what treatment should be given, with potential alternatives including corticosteroids, antiviral drugs, acupuncture and physiotherapy. Inflammation of the facial nerve is the most probable cause of Bell's palsy. Therefore, corticosteroids are commonly used as treatment of Bell's palsy. A recent study shows significant short-term and long-term positive treatment effects of prednisolone in patients with Bell's palsy [4].

The eye should be protected from drying up with the use of eye drops or an eye patch. Surgery is generally not recommended. Often signs of improvement begin within 14 days, with complete recovery within six months. A few may not recover completely or have a recurrence of symptoms [1]. Bell's palsy is the most common cause of one-sided facial nerve paralysis (70%) [2, 5]. It occurs in 1 to 4 per 10,000 people per year[2]. About 1.5% of people are affected at some point in their life [6]. It most commonly occurs in people between ages 15 and 60. Males and females are affected equally. It is named after Scottish surgeon Charles Bell (1774–1842), who first described the connection of the facial nerve to the condition [1]. There is no specific test to diagnose Bell's palsy. Symptoms associated with the Bell's palsy help physician to determine the disease. Steroids have been shown to be effective at improving recovery in Bell's palsy while antivirals have not. In those who are unable to close their eyes, eye protective measures are required. Corticosteroids such as prednisone improve recovery at 6 months and are thus recommended [3]. Early treatment (within 3 days after the onset) is necessary for benefit with a 14% greater probability of recovery. Like most adrenocortical steroids, methylprednisolone is typically used for its anti-inflammatory effects. However, glucocorticoids have a wide range of effects, including changes to metabolism and immune responses. The list of medical conditions for which methylprednisolone is prescribed is rather long and is similar to other corticosteroids such as prednisolone. Common uses include arthritis therapy and short-term treatment of bronchial inflammation or acute bronchitis due to various respiratory diseases. It is used both in the treatment of acute periods and long-term management of autoimmune diseases, most notably systemic lupus erythematosus. It is also used as a treatment for multiple sclerosis. Another potential use of methylprednisolone is for vestibular neuritis [6]. The current study has been planned to compare the efficacy of a single dose of 500 mg of IV methylprednisolone with a 10 day oral prednisolone regime on recovery of patients with Bell's palsy.

Material and methods

An open labeled, randomized controlled trial was conducted in the Department of Pharmacology, Darbhanga Medical College, Laheriasarai, Darbhanga, Bihar, India from July 2019 to May 2020, after taking the approval of the protocol review committee and institutional ethics committee. The technique, risks, benefits, results and associated complications of the procedure were discussed with all patients. Total 100 adult patients with unilateral acute facial palsy of no identifiable cause, within 1-week of onset were included in this study. Patients with pregnancy, diabetes, severe hypertension, renal or hepatic disease, gastric or duodenal ulcer, 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 were excluded from study. The patients were divided into two groups,

according to a pre-generated computerized randomization table. Patients in group 1 received a single dose of 500 mg of IV infusion of methylprednisolone while those in group 2 received oral prednisolone in a tapering dosage schedule (60 mg daily for initial 5 days, tapered by 10 mg daily over next 5 days). All patients were followed for a minimum of 3 months after inclusion, and the outcome analysis was done at 1-month and at 3 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 hemi facial spasm [7]. Assessment of the patients was carried out on the basis of grade of palsy as well as early (≤3 days) versus late (between 4 and 7 days) initiation of treatment regimes. 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

The results were expressed as percentage and mean ± standard deviation. The Chi-square Fisher exact test, wherever applicable, was used to compare the dichotomous variables. The Chi-square for trend analysis was used to compare categorical variables. The unpaired t-test was used to compare continuous variables. $P < 0.05$ was considered as significant. All the analyses were carried out using SPSS version 21.0 and presented in tables.

Table 1: Demographic profile of the patients

Parameter	IV MPS	Oral prednisolone	Both group
Mean age (years)	38.20±12.12	41.10±10.25	39.26±10.17
Gender			
Male	36	24	60
Female	14	26	40
Total	50	50	100

100 patients were enrolled in the study. Demographic distribution was comparable between two groups [Table 1].

Table 2: Based on Affected side

Affected side	IV MPS	Oral prednisolone	Both group
Right	36	37	73
Left	14	13	27
Total	50	50	100

Table 3: Duration of illness

Variables	IV MPS	Oral prednisolone	Both group
Duration of illness			
Mean (days)	4.75±3.10	4.35±2.98	4.44±2.84
Within 3 days	40	35	75
After 3 days	10	15	25
Grade of palsy (mean)	4.50±1.35	4.22±1.22	4.28±1.26

IV=Intravenous, MPS=Methyprednisone, *n*=Number of patients

Table 4: Outcome assessment (complete recovery to grade 1) at 1-month and 3 months between the two groups in different grades

Grades/ Follow-up	Group 1=50	Group 2=50	OR (95% CI)	
Grade 2 and 3	n=12	n=14		
1-month	12 (100)	14(100)	NA	
3 months	12(100)	14 (100)	NA	
Grade 4	n=22	n=20		
1-month	10 (45.46)	4 (20)	3.25 (0.79-13.82)	0.07
3 months	19 (86.37)	17 (85)	1.22 (0.25-7.71)	0.77
Grade 5	n=10	n=12		
1-month	3 (30)	2 (16.67)	4.22(41-41.23)	0.15
3 months	7 (70)	9(75)	1.42 (0.17-8.99)	0.71
Grade 6	n=6	n=4		
1-month	0 (0.0)	0 (0.0)	NA	
3 months	2 (33.33)	0 (0.0)	NA	

Results

After 1-month of treatment, 25 (50%) patients from group 1 and 20 (40%) from group 2 recovered completely; a total of 45 (45%) patients thus recovered completely. The patients treated with IV methylprednisolone and oral prednisolone, both, showed improvement in the symptoms. The results were however statistically non-significant when compared between the two groups. After 3 months of treatment, 40 (80%) patients from group 1 and 40 (80%) from group 2 recovered completely; a total of 80 (80%) patients recovered completely. No statistically significant differences were observed between the two treatment groups. Subgroup. Analysis According to grade of palsy after, 1-month, patients with facial palsy (Grade 2 and 3) showed early and complete recovery.

All patients of Grade 2 and 3 recovered completely while only 45.46% and 40% patients in Grade 4 and Grade 5, respectively, showed complete recovery. No meaningful recovery was observed in patients with Grade 6 Bell's palsy. After 3 months, trends of recovery almost converged in terms of the difference in the two groups.

In Grade 6, only 2 (33.33%) patients from group 1 showed complete recovery [Table 2]. According to the initiation of treatment the patients were also analyzed according to early (≤3 days) versus late (between 5 and 7 days) initiation of treatment based upon their time of arrival for the treatment. In the methylprednisolone group, at 1-month, 60 patients (early group) and 50% patients (late group) had complete recovery. At 3 months, 88% and 75% patients in the two respective groups had complete recovery. In oral prednisolone group, at 1-month, 40% patients (early group) and 34% patients (late group) had complete recovery, while at 3 months 86% and 74% patients, respectively, had complete recovery. A trend toward better recovery with early institution of treatment (IV or oral) was observed where IV methylprednisolone was found to be better than oral prednisolone, but the difference was not statistically significant. Adverse events none of the patients in either treatment groups reported any adverse event during the study period.

Discussion

This study evaluated the efficacy of a single dose IV methylprednisolone versus oral prednisolone. We observed that a single dose administration of IV methylprednisolone was as effective as 10 days treatment with oral prednisolone in patients with acute Bell's palsy. Treatment options for patients of Bell's palsy are

aimed to facilitate functional recovery. Treatment options include corticosteroids and antiviral drugs, alone or in combination. Even without treatment, a large number of patients (approximately 80%) recover completely within 4 months and approximately 20% of patients may not recover completely [8, 9]. We noted that approximately 86% patients recovered completely at 3 months of treatment with either IV methylprednisolone or oral prednisolone. Intravenous methylprednisolone resulted in non-significantly better functional recovery rate especially at 1-month when assessed against oral prednisolone and in terms of early institution of treatment (≤3 days). Combined treatment with a corticosteroid and an antiviral agent has been shown to be more effective in treating severe to complete Bell's palsy than corticosteroid treatment alone [10]. Physiotherapy appears to be effective only in the more severe Bell's palsy, whereas less severe Bell's palsy might result in complete spontaneous recovery, regardless of physiotherapy [11]. We showed that grade of Bell's palsy (severity) is the most important prognostic determinant for recovery. Our results are similar to those reported by Sullivan et al. who found that patients with facial palsy of lower grades had a better outcome [12]. Grade 6 patients infrequently had complete recovery. In patients with Bell's palsy, early treatment with prednisolone significantly improves the chances of complete recovery at 3 and 12 months. Consistent with these findings; our results also suggested that treatment of Bell's palsy should be commenced promptly. In majority number of patients, facial nerve spontaneously and completely recovers. The limitation of our study was the non-inclusion of a control group owing to an ethical concern of depriving patients of a recommended form of treatment [13,14]. The study was targeted to look for short-term recovery patterns; an extension to 6 months would have provided more details of patients with incomplete recovery or those in the process of recuperation. A 5-day regimen of IV methylprednisolone, for severe Bell's palsy, also needs to be investigated.

Conclusion

Single dose of 500 mg of IV methylprednisolone may be an equally efficacious alternative to a 10-day course of oral prednisolone. Early institution of treatment should be attempted for optimum results.

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