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Original Article

Comparison of Outcomes of Bell's Palsy Patients Treated with Steroid and Steroid with Antiviral Drug in a Tertiary Care Hospital

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Abstract

Background: Bell's palsy is the most common acute mononeuropathy associated with idiopathic unilateral facial weakness, characterized by facial asymmetry. Though steroids have effectiveness in managing Bell's palsy, the use of antiviral is still debatable. ***Objective:*** To compare the outcome of Bell's palsy with treatment by steroid versus combination of steroid and antiviral drugs. ***Methodology:*** A prospective analytical study was performed on 84 patients with acute Bell's palsy attending at Neurology outpatient department of Mymensingh Medical College Hospital from July 2014 to June 2016. The patients were divided into two groups purposively after initial assessment as per House-Brackmann grading system (HBS). Group-I patients were treated with oral prednisolone and oral valacyclovir and Group-II patients were treated with oral prednisolone only. Both groups received facial exercises as per demonstration and proper eye care throughout the study period. Follow-up was done after 2 weeks, 4 weeks and 3 months for collection of data about recovery according to reassessment. ***Results:*** The analysis revealed that recovery rates at all 3 follow-ups were higher in the combination group than that of the prednisolone-only group [29(67.44%) versus 18 (43.90%) at 2nd week follow-up, 35(81.39%) versus 25(60.97%) at 4th week follow-up and 40 (93.02%) versus 30(73.17%) at 3rd month follow-up]. Moreover, the expected recovery rate was higher in severe Bell's palsy patients in the combination group than in steroid-alone group (22, 88.0% complete recovery versus 13, 54.17% complete recovery at the end of 3 months of treatment) [p=0.034]. haemorrhagic shock, spinal cord damage, septic shock and crush syndrome. ***Conclusion:*** The study showed antiviral (valacyclovir) plus steroid (prednisolone) to be more effective than steroid (prednisolone) alone in the treatment of Bell's palsy. Moreover, outcome was more favorable in combination groups presenting with severe disease.lessen their severity.

Key Words: Bell's palsy, Combination treatment with antiviral and prednisolone, House-Brackmann grading

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Introduction:

Bell's palsy is the most common acute mononeuropathy associated with idiopathic unilateral facial weakness that occurs in 11.5-53.3 per 100,000 individuals a year across different populations.[1] Although the cause remains elusive, limited evidences suggest that the reactivation of dormant herpes viruses (herpes simplex virus-1, varicella-zoster virus) is known to be one of the causes of Bell's palsy.[2,3] For the treatment of Bell's palsy, the use of prednisolone is known to result in high recovery rates and fewer sequelae and there is no doubt that steroid treatment may prevent further damage and is beneficial in most cases.[4]

Although there is consensus that early use of prednisolone is an effective treatment, the use of antiviral agents has led to some researchers who are against the use of antiviral agents, to argue that there is no proof of additional benefit.[5,6]

However additional use of valacyclovir has been shown to be more effective than steroid treatment alone[7] and steroid antiviral treatment improves the recovery rate in patients with severe Bell's palsy.[8,9] These findings have led some to advocate for the use of antiviral agents along with steroids. A systematic review found that treatment with prednisolone reduced the chances of incomplete recovery but using an antiviral drug had an additional benefit.[10] Moderate quality evidence indicated that the combination of antivirals and corticosteroids reduced the sequelae of Bell's palsy compared with corticosteroids alone.[11]

A randomized prospective study found that a combination of an antiviral and a steroid was more effective in treating severe to complete Bell's palsy than a steroid alone.[8]

Following a literature review, we hypothesized that the additional effect of antiviral drugs would be different according to the severity of the palsy and that, in the case of severe to complete palsy, there would be a difference in recovery according to treatment methods. Therefore, we conducted a prospective analytical study to complete the recovery rate of Bell's palsy with the treatment by steroids versus a combination of steroid and antiviral drugs.

Methodology:

This prospective analytical study was carried out in Mymensingh, Bangladesh from July, 2014 to June, 2016 for a period of two years. Irrespective of age and gender, patients who had Bell's Palsy five (5) days of the attack were included.

Patients who were excluded: (i) patients with Bell's palsy attended after five (05) days of the attack; (ii) facial paralysis other than Bell's palsy with evidence of Ramsay Hunt Syndrome,[12] ontological cause (e.g. chronic suppurative otitis media, acute suppurative otitis media, post mastoidectomy) of facial paralysis, Bell's palsy patient with diabetes mellitus, and Melkersson Rosenthal Syndrome; (iii) history of previous Bell's palsy; and (iv) Bell's Palsy patient with pregnancy.

Considering inclusion and exclusion criteria, 99 cases were selected by purposive sampling and divided into two groups. Group I were prescribed both oral antiviral and oral steroid drugs, and the group II patients were prescribed with oral steroids only. The treatment protocol was: all patients (both Group I and group II) were prescribed oral prednisolone, 1 mg/kg/body weight (usually 40-60 mg daily) for 5 days with a tapering dose over the next 5 days. Moreover, Group 1 patients were also prescribed valacyclovir (500 mg 12-hourly) for 5 days. For follow-up, all patients were instructed to visit at out patients' department (OPD) at the end of the second week to review and reassess as per House-Brackmann Scale (HBS)[13] to monitor the improvement of facial weakness. Complete facial muscle recovery was defined as House- Brackmann grade I (HBS I), but weakness remains as per HBS IIor more, defined as incomplete recovery.

The data were analyzed by SPSS and a comparison of the efficacy of both regimens of therapy, Mann Whitney and Fischer's exact tests were used, and P values less than 0.05 were considered as significant.

Results:

The combination treatment group (prednisolone plus valacyclovir) comprised 43 patients and the steroid-only treatment group comprised 41 patients. The mean age in years ± standard deviation of the patients in both groups were: 32.42±15.19 in group I and 30.27±12.36 in group II. There was no significant intergroup difference in age, disease severity, or the period between onset and treatment. However, there was a significant difference in complete recovery between the 2 groups. (Table I)

Table I: Characteristics of the enrolled patients

Variables	Number (%) of the patients		P value
	Combination therapy (n=43)	Steroid only (n=41)	
Distribution of disease severity			
Mild to moderate (GR-II to GR-IV)	18 (41.86)	17 (41.46)	0.971
Severe (GR-V & GR-VI)	25 (58.14)	24 (58.54)	
Initiation of treatment			
Within 72 hours	29 (69.44)	20 (48.78)	0.083
>72 hours- 120 hours	14 (32.56)	21 (51.22)	
Recovery rate (%) at 3 months	40(93.02)	30(73.17)	0.015

At the end of 3 months, 40(93.02%) of the prednisolone plus valacyclovir group and 30(73.17%) of the prednisolone-only group had complete recovery (p = 0.015). (Table-II)

Table II: Comparison of the recovery rate of Bell's palsy patients in group I (treated with prednisolone and valcyclovir) and group II (treated with prednisolone only) at different times

Criteria	Time period	No. of patients (%) from treatment groups		P-value
		Valacyclovir Plus Prednisolone (n=43)	Prednisolone only (n=41)	
Accumulative recovery rate	2nd week	29 (67.44%)	18 (43.90%)	0.030
	4th week	35 (81.39%)	25 (60.97%)	0.038
	3rd month	40 (93.02%)	30 (73.17%)	0.015

Improvement of grading of palsy based on House-Brackmann Scale (HBS) after 3-months of treatment was also compared, which shows that initial average HBS of 4.42 came down to 1.12 in the patients treated with antiviral and steroid combination. Whereas, the initial average HBS of 4.41 came down to 1.51 in patients treated with steroid only. The difference between the two treatment groups was found significant (P- value < 0.05). (Table-III)

Table III: Improvement of grading of palsy based on House-Brackmann Score (HBS) from initial stage to follow up at 3-months of treatment

HBS grade status	No. of patients (%) at different grades by HBS initially and at follow up in two treatment groups						p-value
	Anti-viral & steroid (n-43)			Steroid only (n-41)			
	Initial	At 3 months		Initial	At 3 months		
Grades (GR-I to GR-VI) of HBS to show improvement	GR-II 2 (4.65)	GR-I 2 (100.00)	GR-II 0 (0.00)	GR-II 2 (4.88)	GR-I 2 (100.00)	GR-II 0 (0.00)	0.032
	GR-III 5 (11.63)	GR-I 5 (100.00)	GR-II 0 (0.00)	GR-III 5 (12.20)	GR-I 5 (100.00)	GR-II 0 (0.00)	
	GR-IV 11 (25.58)	GR-I 11 (100.00)	≥GR-II 0 (0.00)	GR-IV 10 (24.39)	GR-I 10 (100.00)	≥GR-II 0 (0.00)	
	GR-V 23 (53.49)	GR-I 22 (95.65)	≥GR-II 1 (4.35)	GR-V 22 (53.66)	GR-I 13 (59.09)	≥GR-II 9 (40.91)	
	GR-VI 2 (4.65)	GR-I 0 (0.00)	≥GR-II 2 (100.00)	GR-VI 2 (4.88)	GR-I 0 (0.00)	≥GR-II 2 (100.00)	
Average HBS in Groups	4.42	1.12		4.41	1.51		

A comparison of outcomes between two groups of severe Bell's palsy was also analyzed; a significant difference in complete recovery was seen between the two groups in patients presented with severe Bell's palsy (P value <0.05). (Table-IV)

Table IV: Comparison of outcomes between two groups of severe Bell's palsy patients

Treatment group with severe disease	No. (%) of patients showing outcome at Month 3		*P-value*
	Complete recovery	Incomplete recovery	
Anti -viral & steroid (Group -I) (n=25)	22 (88.00)	3 (12.00)	0.034
Steroid only (Group -II) (n=24)	13 (54.17)	11 (45.83)	

Discussion:

In this study, in the patients treated with anti-viral (valacyclovir) and steroid (prednisolone), the recovery rate was 93.02 %, whereas, in the steroid (prednisolone) only group, it was found to be 73.17 % (p-value = 0.015), revealing the efficacy of combination therapy in the treatment of Bell's palsy.

In many clinical trials, including Hato et al,[7] Lee et al,[8] Karthika et al,[14] Shahidullah et al,[15] Kang et al,[16] Yeo et al,[17] Khajeh et al,[18] the combination therapy of steroids and the antiviral drug was compared with steroids alone in the treatment of Bell's palsy. All of these studies show an increased recovery rate of Bell's palsy with antiviral and steroid combination therapy in comparison with steroid treatment alone.

In the randomized control therapy study by Karthika et al,[14] 50 patients were treated with acyclovir (2000 mg/day) plus methylprednisolone (1 mg/kg/day) and 50 patients with methyl-prednisolone alone (1 mg/kg/day). The recovery rate was significantly higher in the steroid and antiviral-treated group (86% versus 82%) with a P value of 0.038, which is consistent with this study.

Another study done in Karachi, Pakistan by Talib et al[19] showed Bell's Palsy treatment with combined antiviral (acyclovir) and prednisolone is found superior in the

recovery rate to prednisolone alone, which is also consistent with this study.

In this study, the initial average House-Brackmann Score (HBS) (Baseline HBS) was 4.42 in Group I and 4.41 in Group II patients. Three months after treatment, the average HBS score came down to 1.12 and 1.51 in Group I patients and Group II patients respectively indicating improvement in average HBS scoring better in the combined group than the prednisolone alone group. A small effect of adding antiviral agents was seen in treating patients with severe Bell's palsy.[20]

In this study patients, who presented with severe disease (initial HBS V and VI), the complete recovery rate after three months of treatment was 88.00% in the antiviral and steroid treatment group, and 54.17% in steroid only group (P value 0.034). Kim et al study found that combination therapy with steroids and antiviral agents resulted in significantly (p= 0.02) higher favourable recovery rates than steroids alone in severe Bell's palsy patients,[21] which is consistent with this study.

Thus, steroid antiviral combination treatment has more chance of complete recovery than that of steroid-only treatment in patients with severe Bell's palsy, which was consistent with other study findings.[7,8,16,22] Shahidullah et al[15] have shown 10-fold chance of complete recovery in patients present with severe Bell's palsy if antiviral drugs are added with steroid treatment.

In conclusion, steroid plus antiviral (valacyclovir) treatment is more effective in treating Bell's palsy than steroid treatment only. So, clinicians should consider combination therapy with steroid and antiviral of choice in individuals presenting with Bell's palsy within 5 days of onset.

Conflict of interest: None declared.

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