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# Efficacy of Pulse Methyl Prednisolone in Treatment of Bell's Palsy

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**ABSTRACT**
The objective of this study was to evaluate the efficacy of pulse Methyl Prednisolone in treatment of Bell's Palsy and its tolerance and safety. Additionally, the adverse drug reactions were also studied. In this study, 32 patients with lower motor neuron facial palsy were studied over a period of one year. House Brackman grading system was used to assess their facial nerve function at the time of admission and discharge. Vitals were monitored and evaluation for signs of infection and psychosis was done daily during the hospital stay. Risk factor work up was done at the time of admission. Significant improvement was noted in the House Brackman scale at the time of discharge. Side effects were noted in the form of steroid induced hypertension, hyperglycemia and hypothyroidism. None of the patient developed infection or psychosis during the treatment period. Thus, we can conclude that pulse Methyl Prednisolone significantly improves the treatment outcomes in cases of Bell's Palsy. Improvement in the House Brackman scale was noted at the time of discharge. Pulse methyl prednisolone was well tolerated however it was associated with adverse drug reactions. Most common reactions were steroid induced hyperglycemia, hypertension and hypothyroidism.

## INTRODUCTION

Bell's palsy is a type of facial paralysis that results in an inability to control the facial muscles on the affected side. Symptoms can vary from mild to severe. They may include muscle twitching, weakness, or total loss of the ability to move one or rarely both sides of the face. Other symptoms include drooping of the eyelid, a change in taste, pain around the ear and increased sensitivity to sound. Typically symptoms come on over 48 hours. The cause of Bell's palsy is unknown. Risk factors include diabetes, a recent upper respiratory tract infection and pregnancy[1,4]. It results from a dysfunction of cranial nerve VII(the facial nerve). Many believe that this is due to a viral infection that results in swelling. Diagnosis is based on a person's appearance and ruling out other possible causes[1]. Other conditions that can cause facial weakness include brain tumor, stroke, Ramsay Hunt syndrome, myasthenia gravis and Lyme disease[2]. 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%)[2,6]. 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[7]. It most commonly occurs in people between ages 15 and 60[1]. Males and females are affected equally[1]. It is named after Scottish surgeon Charles Bell (1774-1842), who first described the connection of the facial nerve to the condition. Bell's palsy recurs in 4-14% of patients. It may recur on the same or opposite side of the initial palsy. Recurrence usually is associated with a family history of recurrent Bell's palsy. Many of these patients were found to have an underlying etiology for recurrence[13,30].

**Signs and Symptoms:** Bell's palsy is characterized by a one-sided facial droop that comes on within 72 hours [8]. In rare cases (<1%), it can occur on both sides resulting in total facial paralysis[9,10]. The facial nerve controls a number of functions, such as blinking and closing the eyes, smiling, frowning, lacrimation, salivation, flaring nostrils and raising eyebrows. It also carries taste sensations from the anterior two-thirds of the tongue, via the chorda tympani nerve (a branch of the facial nerve). Because of this, people with Bell's palsy may present with loss of taste sensation in the anterior 2/3 of the tongue on the affected side[11]. Although the facial nerve innervates the stapedius muscle of the middle ear (via the tympanic branch), sound sensitivity, causing normal sounds to be perceived as very loud and dysacusis are possible but hardly ever clinically evident[11,12,20-22].

**Cause:** The cause of Bell's palsy is unknown[1]. Risk factors include diabetes, a recent upper respiratory tract infection, and pregnancy[1,4]. Some viruses are thought to establish a persistent (or latent) infection without symptoms, e.g, the varicella-zoster virus[14] and Epstein-Barr viruses, both of the herpes family. Reactivation of an existing (dormant) viral infection has been suggested as a cause of acute Bell's palsy[15].This new activation could be triggered by trauma, environmental factors and metabolic or emotional disorders[16]. Familial inheritance has been found in 4-14% of cases[17]. There may also be an association with migraines[18].

**Pathophysiology:** It is thought that as a result of inflammation of the facial nerve, pressure is produced on the nerve where it exits the skull within its bony canal (the stylomastoid foramen), blocking the transmission of neural signals or damaging the nerve. Patients with facial palsy for which an underlying cause can be found are not considered to have Bell's palsy per se. Possible causes include tumor, meningitis, stroke, diabetes mellitus, head trauma and inflammatory diseases of the cranial nerves (sarcoidosis, brucellosis, etc.). In these conditions, the neurologic findings are rarely restricted to the facial nerve. Babies can be born with facial palsy[19]. In a few cases, bilateral facial palsy has been associated with acute HIV infection[24,25,27].

**Diagnosis:** Bell's palsy is a diagnosis of exclusion, meaning it is diagnosed by elimination of other reasonable possibilities. By definition, no specific cause can be determined. There are no routine lab or imaging tests required to make the diagnosis[8]. The degree of nerve damage can be assessed using the House-Brackmann score.

**Treatment:** Steroids have been shown to be effective at improving recovery in Bell's palsy while antiviral have not. In those who are unable to close their eyes, eye protective measures are required[8]. Management in during pregnancy is similar to the non pregnant[4].

**Steroids:** 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[23] with a 14% greater probability of recovery[24].

**Antiviral:** One review found that antiviral (such as aciclovir) are ineffective in improving recovery from Bell's palsy beyond steroids alone in mild to moderate disease[25]. Another review found a benefit when combined with corticosteroids but stated the evidence was not very good to support this conclusion[5]. Analgesics and eyedrops.

**Physiotherapy:** Physiotherapy can be beneficial to some individuals with Bell's palsy as it helps to

maintain muscle tone of the affected facial muscles and stimulate the facial nerve[28]. It is important that muscle re-education exercises and soft tissue techniques be implemented prior to recovery in order to help prevent permanent contractors of the paralyzed facial muscles[28].

**Complications:**

- Irreversible damage to facial nerve
- Abnormal regrowth of nerve fibers, resulting in involuntary contraction of certain muscles when you are trying to move others (Synkinesis)
- Partial or complete blindness of the eye that won't close due to excessive dryness

**Aims and Objectives:**

- To study the efficacy of pulse methyl prednisolone in Bell's palsy
- To study the safety and tolerability of pulse methyl prednisolone
- To study the adverse drug reactions of pulse methyl prednisolone in such cases

## MATERIAL AND METHODS

- All patients fulfilling clinical criteria for diagnosis of Bell's Palsy were admitted. They were given pulse methyl prednisolone in addition to other supportive treatment in the form of physiotherapy and pain management
- Absolute contraindications for pulse methyl prednisolone were ruled out
- The outcome was assessed using the House-Brackmann grading system for facial nerve function, which assigns patients to 1-6 categories. Grade I 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, contractor or hemifacial spasm. House-Brackmann scale was done at the time of admission and at the time of discharge

If improvement in the House-Brackmann scale
>3 was considered as excellent,
>2 Good response,
0<2 poor response.

Side effects were monitored in the form of blood pressure monitoring, blood sugar level, Sr. Electrolytes, infection, psychosis and others as per reporting on daily rounds. Risk factor work up was done. The population under study included all patients with LMN facial paresis who have completed 5 days of pulse methyl prednisolone. Physiotherapy was given to all patients which included facial exercises and facial nerve stimulation.

**Exclusion Criteria:** The patients with LMN facial paresis due to Ramsay Hunt syndrome, post traumatic LMN facial paresis, LMN facial paresis with infection, pregnancy with Bell's palsy and patient who didn't complete the 5 days of pulse methyl prednisolone therapy, patient admitted for work up for recurrent Bell's palsy. The study was carried out on 37 patients with LMN facial paresis who were admitted in CNS Hospital over the period of 12 months from January 2018 to December 2018 of which 32 patients come in inclusion criteria and 5 patients came in exclusion criteria.

**Data Collection:** All cases who had LMN facial paresis admitted in CNS Hospital from January 2018 to December 2018 were included. The study was carried out on 37 patients with LMN facial paresis who were admitted in CNS Hospital over the period of 12 months from January 2018 to December 2018 of which 32 patients come in inclusion criteria and 5 patients came in exclusion criteria.

**Parameters Studied:** Sex, House-Brackmann scale at the time of admission and at the time of discharge, side effects of pulse methyl prednisolone, risk factors, side of Bell's palsy, recurrence.

**Proforma:** Patients MR and IP no, age, sex, side of Bell's palsy, House-Brackmann scale at the time of admission and discharge, side effects, risk factors and treatment given.

**Observations:**

- Out of 32 patients, 21 patients were male and 11 were female
- 19 patients had right sided Bell's palsy and 13 patients had left sided Bell's palsy
- 5 patients were known case of type II DM
- 2 patients were known case of hypothyroidism
- 2 patients improved by scale 4
- 5 patients improved by scale 3
- 12 patients improved by scale 2
- patients improved by scale 1
- patients shown complete recovery
- In 5 diabetic patients, blood sugar levels were increased. Out of 5 patients, in three patients insulin was added to oral hypoglycemic agents and dose of insulin was increased in 1 patient. 25 non diabetic patients had steroid induced hyperglycemia. Out of 25, in 7 patients, insulin was given during hospital stay and in 2 patients it was

given during hospital stay and continued at the time of discharge. In 1 patient Tablet Metaformin was given at the time of discharge. Rest in 15 patients blood sugar levels were controlled on diet plan

- 2 patients had steroid induced hypertension
- 3 patients were known case of hypertension but during treatment their blood pressure recordings
- were high and new antihypertensive drugs were added
- Risk factors

Type II DM -5 patients.
Hypothyroidism -2 patients.
Hyperuricemia -1 patient.
Neurobrucellosis -1 patient.
HIV positive -1 patient.
Recurrent Bell's palsy -4 patients.
None of them developed infection or psychosis after pulse methyl prednisolone.

## RESULTS AND DISCUSSIONS

Bell's Palsy is most common in the age of group 15 years to 60 years of age[1] in present study. Only 3 patients (9.4%) were above age of 60 years while no patient was below 15 years of age. The data is

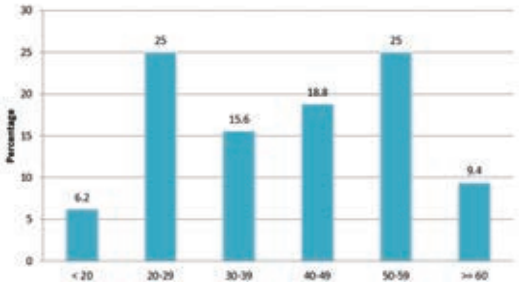


Fig. 1: Age distribution

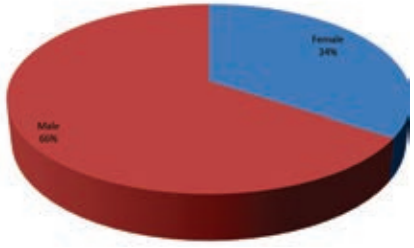


Fig. 2: Sex distribution

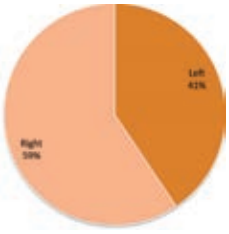


Fig. 3: Side of Bell's Palsy

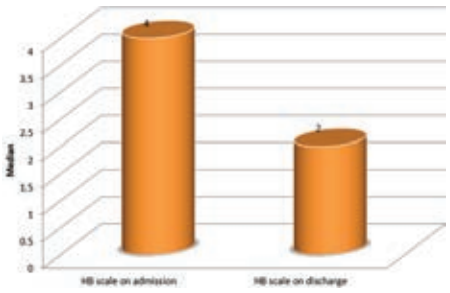


Fig. 4: Reduction in House-Brackmann scale

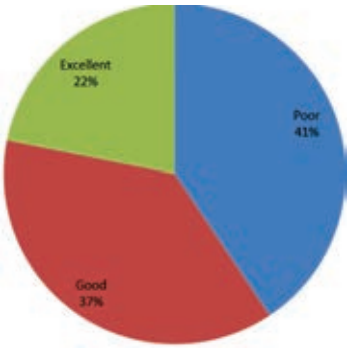


Fig. 5: House-Brackmann grading system

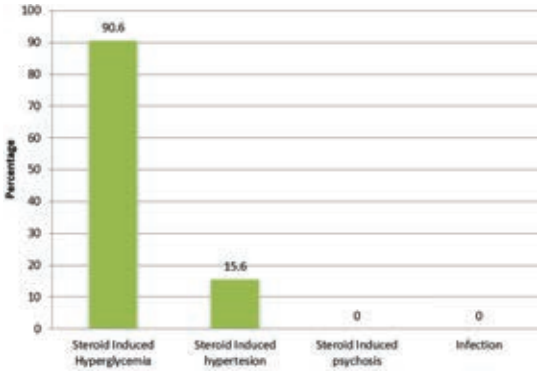


Fig. 6:Distribution of side effects

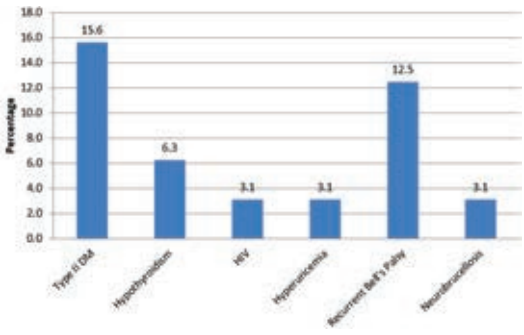


Fig. 7: Distribution of risk factors

mentioned in table No. 1 and it correlates well with the study conducted by NINDS. February 5, 2016[1]. There is no sex predilection in Bell's palsy and it is equally

**Table 1: Age distribution**

| Age | Frequency | Percentage |
|---|---|---|
| < 20 | 2 | 6.2 |
| 20-29 | 8 | 25.0 |
| 30-39 | 5 | 15.6 |
| 40-49 | 6 | 18.8 |
| 50-59 | 8 | 25.0 |
| >= 60 | 3 | 9.4 |
| Total | 32 | 100.0 |

**Table 2: Sex distribution**

| Sex | Frequency | Percentage |
|---|---|---|
| Female | 11 | 34.4 |
| Male | 21 | 65.6 |
| Total | 32 | 100.0 |

Z = 2.63, p = 0.008

**Table 3: Age and sex distribution**

| | Sex | | |
|---|---|---|---|
| Age | Female | Male | Total |
| < 20 | 0 | 2 | 2 |
| 20-29 | 4 | 4 | 8 |
| 30-39 | 2 | 3 | 5 |
| 40-49 | 3 | 3 | 6 |
| 50-59 | 2 | 6 | 8 |
| >= 60 | 0 | 3 | 3 |
| Total | 11 | 21 | 32 |

**Table 4: Side of Bell's Palsy**

| Side | Frequency | Percentage |
|---|---|---|
| Left | 13 | 40.6 |
| Right | 19 | 59.4 |
| Total | 32 | 100.0 |

Z = 1.53, p = 0.13

**Table 5: Reduction in House-Brackmann scale**

| House-Brackmann scale | Median | Mann-Whitney U- statistic value | p-value |
|---|---|---|---|
| HB scale on admission | 4 | 30.5 | <0.0001 |
| HB scale on discharge | 2 | | |

Mann-Whitney Test applied

**Table 6: House-Brackmann grading system**

| Scale | Frequency | Percentage |
|---|---|---|
| Poor | 13 | 40.6 |
| Good | 12 | 37.5 |
| Excellent | 7 | 21.9 |
| Total | 32 | 100.0 |

**Table 7: Distribution of Side effects**

| Side effects | Frequency | Percentage |
|---|---|---|
| Steroid Induced Hyperglycemia | 29 | 90.6 |
| Steroid Induced hypertension | 5 | 15.6 |
| Steroid Induced psychosis | 0 | 0.0 |
| Infection | 0 | 0.0 |

Z = 9.11, p<0.0001

**Table 8: Distribution of Risk factors**

| Risk factors | Frequency | Percentage |
|---|---|---|
| Type II DM | 5 | 15.6 |
| Hypothyroidism | 2 | 6.3 |
| HIV | 1 | 3.1 |
| Hyperuricemia | 1 | 3.1 |
| Recurrent Bell's Palsy | 4 | 12.5 |
| Neurobrucellosis | 1 | 3.1 |

common in males and female[1]. Present study had 21 males with Bell's palsy and remaining 11 were females (p value 0.008). Although males were more affected in our study the results were not statistically significant. Possibly more males reported to our hospital than females due to social issues. In our study males were more affected in the age group >50 years and less than 20 years, however in middle age males and females were affected equally. Almost all of males in elderly group were diabetic patients. Since type II DM is slightly more common in males it could explain higher male predominance in elderly with Bell's palsy. There is no mention of dominance of side of affection of Bell's palsy in the review of literature. In present study 19 of the 32 patients had right sided Bell's palsy, however the results were not statistically significant. (p value 0.13). There is definite role of steroids in management of Bell's palsy[1], however there is no study mentioning role of high dose of methyl prednisolone in cases of Bell's palsy. Usually recovery of Bell's palsy starts after 2 weeks and nearly 80% of patients recover fully by the end of 8-12 weeks[3].

In present study we assessed the clinical outcome by measuring disability using House-Brackmann scale. The median House-Brackmann scale at the time of admission was 4 and median House-Brackmann scale at the time of discharge was[2]. This rapid recovery of facial paralysis was statistically highly significant (p<0.0001). There is statistically significant difference between male and female (p = 0.008). We had defined improvement in the House-Brackmann scale >3 was considered as excellent, >2 Good response, 0-<2 poor response.

In present study 7 patient (21.9%) had excellent recovery and 12 patients (37.5%) had good recovery within 5 days. So 19 patients out of 32 patients had good to excellent response within 5 days. Since no references are available to compare with our data, larger pool of patients with a longer duration of study including clinical assessment unto 3 months needs to be considered strongly. Our study also needed to look at safety, tolerability and incidence of side effects with use of high dose methyl prednisolone. Although short term high dose steroid therapy is largely devoid of serious side effects, it can still cause side effects like steroid induced hyperglycemia, steroid induced hypertension, steroid induced psychosis and infection. In our study all patients completed 5 days of treatment and we did not have to stop steroids due to safety issues. There was no treatment related mortality. None of the patient in present study had infection and steroid induced psychosis. Most common side effect was steroid induced hyperglycemia. Twenty nine out of 32 patients (90.6%) had steroid induced hyperglycemia. Of these 29 patients, 4 patients were diabetics and 1 patient of type II DM did not have steroid induced hyperglycemia. Five of the total 32 patients, 15.6% had steroid induced hypertension. Although none of these patients required antihypertensive medicines and antihypertensive medicines were stopped at follow up visits. (p<0.0001). There is statistically significant difference between side effects of Bell's palsy.

Although Bell's palsy is thought to be post viral, there is increased incidence of Bell's palsy in type II DM, hypothyroidism, HIV positive status, hyperuricemia and previous Bell's palsy. We had 4 patients of recurrent Bell's palsy which were also worked up for rarer causes like sarcoidosis, brucellosis and CSF examination. Study for Lyme's disease was not done in view of cost restraints. Only one of 4 patients (3.1%) of recurrent Bell's palsy was found to have neurobrucellosis.

5 patients (15.6%) were known case of type II DM at the time of admission.

2 patients (6.3%) were found to be hypothyroid.

1 patient (3.1%) was found to be HIV positive.

1 patient (3.1%) had hyperuricemia.

Larger studies are required for statistical significance of this pilot project.

## CONCLUSIONS

Pulse methyl prednisolone treatment in Bell's palsy is significantly useful in terms of reduction in House-Brackmann scale. Pulse methyl prednisolone therapy in Bell's palsy also ensures rapid recovery as compared to oral steroid therapy. Pulse methyl prednisolone therapy in Bell's palsy is well tolerated, however it is associated with increased adverse drug reaction. Most common adverse drug reaction was steroid induced hyperglycemia (90.6%) followed by steroid induced hypertension (15.6%). None of the patient had sepsis or steroid induced psychosis. Risk factor work up revealed increased incidence of type II DM and hypothyroidism.

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