



Review Article

Prednisolone in Bell's Palsy: A Pharmacovigilance-Based Assessment of Adverse Drug Reaction

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Bell, palsy is a non-progressive, acute and idiopathic disorder of peripheral facial nerve and is one of the most prevalent causes of lower motor neuron facial paralysis. It contributes to around 60-70 percent of all cases of paralysis of the face, including all ages and gender. It is closely linked to viral infections that cause inflammation, edema and demyelination of the facial nerve. Clinical changes are usually fast and occur over 48-72 hours and involve weakness of the face on one side, eye closure, facial muscle drooping, changes in taste, hyperacusis and eyes or mouth dryness. Diagnosis is mainly clinical and it involves the elimination of other neurological disorders. Early intervention is an important aspect of recovery, and corticosteroids are widely regarded as the gold standard therapy, as they have anti-inflammatory and immunosuppressive effects. When used early, prednisolone lowers rates of nerve edema, enhances functional recovery, and rates of synkinesis. Nevertheless, it has a number of negative drug reactions (ADRs), such as infections, gastrointestinal complications, and metabolic issues. The global safety profile of prednisolone is also assessed with pharmacovigilance data in VigiBase, which contains 98,772 case safety reports (individual cases). The analysis shows that the ADRs caused by infections (14%), gastrointestinal disorders (10%), and skin disorders (7%) are more common, and people of the age 45-64 years and women report more of them. The results underline the significance of close monitoring, particularly in cases of long-term treatment, and propose the necessity of prophylactic measures, including gastro-protective practices and screening of infections. Comprehensively, this review offers an encompassing view on Bell's palsy, its clinical presentation, diagnostic method, approaches to treatment and safety issues that are related to prednisolone therapy.

Keywords: Bell's Palsy, Facial nerve paralysis, Prednisolone, Pharmacovigilance, Adverse Drug Reaction (ADR), Corticosteroids.

INTRODUCTION

His identity and uniqueness is highly connected with a human face. Facial expression is vital in expression emotions and social interaction and therefore any facial muscle malfunction in addition to physical disability causes social and psychological discomfort [1]. Bell palsy is an acute -onset peripheral facial neuropathy and it is one of the most common causes of lower motor neuron facial paralysis. In all cases of facial paralysis, Bell involved palsy in 60-70 percent of cases. The incidence in both genders is equal with 7-40 cases per 100,000 population every year. The etiology is idiopathic but highly correlated with some viral infection, which leads to nerve inflammation

with focal edema and demyelination, as well as ischemia. In different researches, some risk factors augment blood sugar [2], blood pressure out of control, extreme pre-eclampsia [3], migraine [4], and exposure to radiations [5] facilitate the pathologic mechanisms and predispose a person to palsy. The weakness may be total or partial and can be related to numbness, slight discomfort, increased sound sensitivity and taste change. It is a diagnosis of exclusion that is mostly established through physical examination. The distinction between a central and a peripheral lesion can be found with an introductory investigation of the neuroanatomy of the nerve. Due to the dissimilarity of the management in different

etiology, this distinction is essential. The antivirals are questionably useful; hence, they are mainly recommended with corticosteroids. Patients with signs of improvement in the first three weeks of developing symptoms have more chances of full recovery; the earlier the cure starts, the less likely they are to develop complications and residual paraesthesia's. Recurrence can be seen in four to 14 percent of the patients, 36 percent of which develop palsy on the same side [6].

➤ **Clinical presentation:**

The symptoms occur abruptly, and their peak is achieved in 48-72 hours and ranges. to slight weakness of the muscles of the ipsilateral side, up to severe paralysis. Bell's palsy symptoms. consist of the inability to close the eye or to blink, wrinkle the lips or elevate the mouth corner displays features. as drooping of one-half face, ipsilateral eyebrow drooping, flatten nose labial fold, ipsilateral pain. around the ear or hearing loss, dry mouth or dry eye as Figure 1 displays [7]



Figure 1: Depiction of clinical features of a patient with Bell's Palsy [7]

➤ **The other symptoms include:** - hyperacusis due to nerve fibre rupture in the stapedius muscle, alterations. in palate, and parched eyes with parasympathetic malady. Some patients report facial paraesthesia, which is usually motor symptoms misinterpreted as sensory alteration and present with sensory or hearing loss [8].

➤ **clinical examination and diagnosis:** -

Neurologic and general examination including ear examination, ophthalmological examination, and skin and parotid gland, thought to be covered in the clinical study [9]. Herpes zoster can be suspected in case of any blisters or scabbing around the ear referred to as Ramsay-Hunt syndrome which. can lead to hearing

loss and also facial nerve palsy. The interview with the patient can indicate the presence of the following. minor manifestations of the weak and give secondary data [10]. Evaluation of such patients must be done systematically. Examiner must notice facial. facial expressions and movements of the test face such as forehead wrinkling (temporal branch), eye closure capability. puffing of face (mandibular), symmetry of smile, screwing up eyes (zygomatic branch), wrinkling, tightly. nose (buccal). House-Brackmann can be used to determine the degree and prognosis of facial nerve palsy. grading system. It has six grades as indicated in Table 1 wherein Grade 1 implies no paralysis and Grade 6 implies. complete paralysis [11].

Table 1: House - Brackmann facial nerve grading system [11]

Grade	Description	Characteristics
1	Normal	Normal facial function in all areas
2	Mild dysfunction	Slight weakness noticeable on close inspection; may have very slight synkinesis
3	Moderate dysfunction	Obvious, but not disfiguring, difference between two sides; noticeable, but not severe, synkinesis, contracture, or hemifacial spasm; complete eye closure with effort
4	Moderately severe dysfunction	Obvious weakness or disfiguring asymmetry; normal symmetry and tone at rest; incomplete eye closure
5	Severe dysfunction	Only barely perceptible motion; asymmetry at rest
6	Total paralysis	No movement

➤ Treatment: -

The principal objective of the treatment during the acute treatment of bell's palsy shall hasten convalescence and keep back eye complications. Immediate action should commence in order to prevent the viral replication and its impact on the future. Physiological processes which influence the facial nerve. It also requires physiological support and fir this is why the patients might need frequent follow up.

➤ Prednisolone:

Prednisolone is a synthetical glucocorticoid that is the gold standard drug in Bell's palsy [12]. Its most valuable use is its strong anti-inflammatory and immunosuppressive effect. Prednisolone lowers the compression of the nerve and postpones axonal loss by decreasing the swelling of the facial nerve in the fallopian canal. [13], [14]

• Mechanism of action:

It is the genomic and non-genomic effects of prednisolone that determine its therapeutic efficacy in this scenario.

1. Anti-inflammatory Response:

It suppresses the release of inflammatory mediators such as prostaglandins and leukotrienes via the induction of lipocortin's which suppress phospholipase A2 [15].

2. Edema Reduction:

It works by stabilizing the capillary membranes and hence minimizing fluid extravasation, thereby lowering the pressure on the nerve fibres [16].

3. Immune Modulation:

It inhibits the movement of polymorphonuclear leukocytes and reverses the elevated capillary permeability [15], [14].

• Clinical significance:

The administration of oral corticosteroids immediately after the symptoms have been experienced should be highly encouraged by clinical guidelines, including those provided by the American Academy of Neurology (AAN) [17]. Rapid administration is considerably related with:

- Raised percentages of full-face functional recovery [12], [14].
- Less chance of synkinesis (sphincter movements) [12].
- Reduction of time interval of recovery [17], [15].

➤ ADR Report of prednisolone:

Many different brands are available in the Market use the prednisolone as their active ingredient. We have taken four different brands of the drug prednisolone

- A. Prednisolone (reference)
- B. Prednisolone v
- C. Prednisolone Ivax

D. Prednisolone rpg

1. Introduction:

This paper evaluates the safety of Prednisolone all over the world and the adverse drug reactions (ADR) reports on four commercials of it; Prednisolone (Reference Group), Prednisolone V, Prednisolone Ivax and Prednisolone RPG. An example of synthetic corticosteroid is prednisolone, primarily used because it has a high potency in terms of anti-inflammatory and immunosuppressive properties. To increase patient safety in different forms of various brand formulations, clinical pharmacy and regulations regarding monitoring of the mentioned ADRs are needed.

2. Methodology and data source:

The data used in this report was compiled using the WHO Global Database of individual case Safety

Report (VigiBase) which can be accessed through VigiAccess portal. Even though a number of brands were requested, a homogenous aggregate data were received in the process of search, implying that all global indicators of pharmacovigilance of such versions are largely determined by the active drug ingredient (API) of Prednisolone.

- 1. Total individual safety reports (ICSRs):** 98,772
- 2. Database search date:** March 2026.
- 3. Data Description: Table 1,** shows, the most common ADRs are linked to the Infections and Infestations (14%). This is a direct pharmacological effect caused by the immunosuppressive effect of the drug. Other important clinical issues when using long-term Prednisolone therapy are gastrointestinal disorders (10%) and Skin disorders (7%) [18].

System Organ class (SOC)	Number of ADRs	Percentage (%)
Infections and infestations	22,262	14%
General disorder & admin. Site condition	20,884	13%
Gastrointestinal disorder	16,113	10%
Skin and subcutaneous tissue disorders	11,473	7%
Nervous system disorder	9,887	6%
Injury, poisoning and procedural complications	9,232	6%
Investigation (e.g., Abnormal Lab Results)	8,645	5%
Metabolism and nutrition disorders	7,251	4%
Musculoskeletal and connective tissue disorder	6,388	4%
Blood and lymphatic system disorder	6,414	4%
Psychiatric disorder	5,887	4%
Vascular disorder	4,410	3%
Cardiac disorder	3,138	2%

4. Demographic and Regional Analysis:**4.1 Geographical Distribution:**

The frequency of reporting reveals a great concentration on particular areas:

1. Asia: 54% (53,089 reports)
2. Europe: 27% (27,086 repots)
3. Americans: 14% (13,599 reports)
4. Oceania/Africa: 5% (combined)

4.2 Patient Demographic:

- **Sex Distribution:** 52% of the reports were of female and 43 of male.
- **Age Predominance:** The age group of 45-64 (28%), then 18-44 age group (21%). At 7 percent, pediatric reports (0-17 years) are still a minority.

5. Temporal Reporting Trends:

The reporting timeline analysis shows that the ADR documentation has been gradually increasing during the past 20 years. There was a significant peak in 2024 (12,329 reports) which can indicate either better pharmacovigilance infrastructure or increased clinical

use in that year. In the case of the present year (2026) 1, 384 cases of reports have already been registered worldwide.

6. Theoretical Discussion and Clinical Correction:

6.1 Immunomodulation:

Prednisolone down-regulates the immune system, which inhibits the release of cytokines and the migration of leukocytes. Although it can be used therapeutically to treat autoimmune diseases, it also predisposes people to opportunistic infections (14% of ADRs).

6.2 Gastrointestinal Impact:

The production of gastric protective prostaglandins by the gastric mucosa is inhibited by corticosteroids and this explains why GI effects are highly prevalent including gastritis and peptic ulcers.

6.3 Metabolic Interference:

The drug has an effect on the gluconeogenesis and lipid metabolism and is associated with the 4% of reports on metabolism and nutrition.

6.4 Dermatological Thinning:

Prejudiced by collagen, prednisolone prevents the growth of the skin and becomes the cause of the reported data fragility and subcutaneous tissue disorders (7%) [18].

CONCLUSION:

The overall review of 98,772 reports shows a consistent and predictable safety profile of Prednisolone in all the variants of the study. The large percentage of the 45-64 age group and females reporting are important indicators that show the need to be cautious when monitoring these groups. These results note the need to co-prescribe gastro-protective drugs and to measure latent infections in the course of Prednisolone therapy.

REFERENCES

1. L. L. N. H. e. a. Ton G, "Efficacy of laser acupuncture for patients with chronic Bell's palsy A study protocol for a randomized, double-blind, sham-controlled pilot trial," *Medicine*, 2019.
2. P. M. B. F. e. a. Bosco D, "Bell's palsy: A manifestation of prediabetes?" *Acta Neuol scand*, pp. 68-72, 2011.
3. A. V: "LMN facial palsy in pregnancy: an opportunity to predict preeclampsia-report and review.," *Case Rep Obstet Gynecol.*, 2014.
4. C. Y. F. J. T. C. W. S. Peng KP, "Increased risk of bell's palsy in patient with migraine: A nation cohort study.," *Neurology*, 2015.
5. C. S. G. A. A. H. Khateri M, "Radiation exposure and Bell's palsy: A hypothetical association.," *J. Biomed Phys Eng.*, 2018.
6. D. Tomislav, "Bell's palsy Recovery. (2009)," 2021.
7. "Everything about Bell's palsy. (2018)".
8. L. K. Patel DK, "Bell's palsy: Clinical examination and management.," *Cleve Clin J Med.*, 2015.
9. P. M. C. J. Portelinha J, "Neuro-Ophthalmological approach to facial nerve palsy.," *saudi J Ophthalmol.*, pp. 29:39-47, 2015.
10. S. M. T. S. Sajadi MM, "The history of facial palsy and spasm.," *Hippocrates to razi. Neurology.*, Vols. 77:174-8, 2011.
11. "House Backman."
12. R.P. Sullivan and F.M. Sullivan, "Early treatment with prednisolone or acyclovir in Bell's palsy," *N. Engl. J. Med.*, vol. 357, 2007.
13. F. Madhok, "Bell's palsy: clinical examination and management," *Cleveland Clinic Journal of Medicine*, vol. 82, July, 2015.
14. P. L. e. al., "Management of Bell's palsy," *Corticosteroids for Bell's palsy (idiopathic facial paralysis)*, Vols. *Cochrane Database of Syst. rev.*, no. 7, July. 2016.
15. N. J. Gadsby, "Management of Bell's palsy," *Australian Prescriber*, vol. 40, 2017.
16. F. Madhok., "Bell's palsy: Clinical examination and management.," *Cleveland Clinic journal of medicine*, vol. 82, 2015.
17. G. G. a. R. Paduga, "Evidence-Based guideline update: Steroid and antiviral for Bell's palsy," *Report of the Guideline Development subcommittee of the American Academy of Neurology. Neurology*, Vol. 79.

18. "Prednisolone ADR Report," World Health Organization, 1968-2026.

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