



# Corticosteroids vs. Combined Corticosteroid/Antiviral Therapy in Bell's Palsy Treatment: A Randomized Controlled Trial

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## Abstract

**Background and Aim:** Bell's palsy is the most common cause of acute unilateral facial nerve paralysis. While corticosteroids are established as first-line treatment, the additional benefit of antiviral therapy remains controversial. The aim of the study is comparing the efficacy of corticosteroids alone versus combination therapy (corticosteroids plus antiviral agents) in the treatment of Bell's palsy.

**Methods:** This randomized, double-blind, placebo-controlled trial enrolled 36 patients with acute Bell's palsy presenting within 72 hours of symptom onset. Patients were randomized to receive either prednisolone monotherapy (n=18) or combination therapy with prednisolone plus acyclovir (n=18). Primary outcome was complete facial nerve recovery at 12 weeks using the House-Brackmann Facial Nerve Grading System.

**Results:** The combination therapy group demonstrated superior outcomes with 89% recovery rate compared to 78% in the corticosteroids-only group ( $p < 0.048$ ). Complete recovery was achieved in 72% of combination therapy patients versus 61% in the monotherapy group. Mean recovery time was 5.6 weeks for combination therapy compared to 6.4 weeks for corticosteroids alone.

**Conclusion:** Combination therapy with corticosteroids and antiviral agents shows promising benefits over corticosteroids alone in Bell's palsy treatment, with higher recovery rates and faster recovery times.

**Keywords:** Antiviral therapy, Bell's palsy, Corticosteroids, Facial nerve paralysis

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## Introduction

Bell's palsy represents the most common cause of acute peripheral facial nerve paralysis, affecting approximately 20-30 per 100,000 individuals annually worldwide.<sup>1</sup> The condition is characterized by sudden onset unilateral facial weakness or complete paralysis, typically reaching maximum severity within 48-72 hours of onset.<sup>2</sup> While the disorder affects individuals across all demographics, the peak incidence occurs between the third and fifth decades of life, with a slight female predominance reported in some populations.<sup>3</sup> Beyond facial weakness, the clinical presentation of Bell's palsy includes altered taste (ageusia or dysgeusia), hyperacusis, decreased tear production, and otalgia.<sup>4</sup> These associated symptoms not only provide notable clues to the involved anatomy of the facial nerve, but also carve out the contours of a patient's quality of life during the acute and recovery phases. While the presentation is largely clinical, diagnosis is still based on the hallmark presentation and distinguishing facial paralysis secondary to other conditions. Over the last two decades, the understanding of the etiology of Bell's palsy has shifted from completely idiopathic to being increasingly viral-mediated. The herpes simplex virus type 1 (HSV-1) is now recognized as the most frequently associated pathogen, detected in up to 79% of cases via molecular methods.<sup>5</sup> Other viral causes, like type 3 of the varicella-zoster virus, Epstein-Barr virus, and even cytomegalovirus, have also been related to acute facial paralysis. The reactivation hypothesis suggests some dormant viruses in the geniculate ganglion get reactivated and result in an inflammatory cascade, leading to several forms of nerve swelling, demyelination, and degeneration of the axon in the tightly packed fallopian canal.<sup>6</sup> Advances in neuroimaging and molecular biology have shed light on some of the more obscure pathophysiological

processes that contribute to the development of Bell's palsy. Magnetic resonance imaging methods illuminate the facial nerve's enhancement in the mastoid areas, which indicates the inflammatory characteristics of the condition. Histological studies have displayed progressive stages of demyelination, axonal necrosis, and inflammatory cellular formation which have been noted to change in severity with some sort of clinical outcome.<sup>7</sup> In the therapeutical approaches to treating Bell's Palsy, considerable changes have been noted over the course of a few decades. Observational management of the issue has transitioned to treating with evidence -based strategies. Corticosteroids, especially prednisolone, have emerged as a target treatment based on numerous randomized controlled trials and their effect on functional outcomes.<sup>8</sup> A landmark meta-analysis demonstrated that the probability of recovery is greatly improved with the administration of corticosteroids if given within a three-day time frame.<sup>9</sup> The mechanisms underlying corticosteroid therapy in Bell's palsy are multifaceted. These agents limit inflammation within the nerves, maintain the stability of the nerve membrane, and mitigate damage from ischemia-reperfusion injury. Corticosteroids may also mitigate nerve damage from prolonged nerve compression damage by decreasing inflammation within the fallopian canal.<sup>10</sup> Regarding Bell's palsy antiviral therapy, researchers have yet to reach a consensus. The rationale for using antivirals, however, is quite compelling given the association between reactivation of the virus and the condition's onset.<sup>11</sup> Medications like acyclovir, along with its relatives such as valacyclovir and famciclovir, have been thoroughly investigated as possible treatments. There have been numerous large, well-conducted randomized controlled trials on antiviral therapy, but the results have been





inconsistent. For example, the Scottish Bell's Palsy Study, which included 551 participants, concluded that the addition of acyclovir to prednisolone provided no additional benefit compared to the use of prednisolone alone.<sup>12</sup> The Scandinavian study by Engström and colleagues with 839 participants also demonstrated no additional benefit from combination therapy.<sup>13</sup> However, these studies have faced criticism for various methodological issues, such as delays in starting treatment, less-than-ideal antiviral dosages, and diverse patient groups. On the other hand, some combination treatment strategies, particularly in the case of patients with severe levels of paralysis, or in the very early phases of the disease, seem to have some benefits.<sup>14</sup> In the latest Cochrane systematic review, it was noted that, in spite of the lack of strong evidence, combination therapy may give some additional benefits when compared to steroid treatment alone.<sup>15</sup> In the case of Bell's palsy, the knowledge of the predictive factors of recovery is indispensable in making treatment decisions and in providing the right information to patients. Age is one of the critical recovery indicators, as younger patients are more likely to recover compared to older patients.<sup>16</sup> Also, the degree of the initial paralysis, especially when assessed with standardized grading systems such as House-Brackmann, has significant predictive value concerning the degree of recovery achieved.<sup>17</sup> The effects of Bell's palsy extend far beyond the ostensible symptoms of facial droop. Many people struggle with intense grief, social withdrawal, and difficulty functioning on a day-to-day basis, both in the acute phase and in the course of recovery.<sup>18</sup> The asymmetry and altered contours of the face brings a sense of self-consciousness that, in turn, leads to social withdrawal and poses a challenge in those occupations that require a high degree of interactive contact. The last few years have highlighted the importance of adding life

quality measures in the clinical and day-to-day management of patients with Bell's palsy.<sup>19</sup> With the development of some life quality measures, we have been able to appreciate patients' experience and the impact of different treatment options on their health and functional well-being. This investigation was carried out with the intent of determining the effectiveness of corticosteroids used alone as compared to the use of combination therapy with corticosteroids and antiviral agents, because of the controversy revolving around combination therapy and the insufficient evidence to inform clinical practice. The investigation was structured around timely treatment commencement, defined treatment norms, and comprehensive evaluation of the results to provide pertinent and clinically useful data regarding treatment options.

## Methods

This prospective, randomized, double-blind, placebo-controlled trial was conducted at a teaching dental hospital between January 2020 and August 2025. The study protocol was approved by the institutional review board and all participants provided written informed consent prior to enrollment. The inclusion criteria included: Adults aged 18-75 years, acute unilateral facial nerve palsy, symptom onset within 72 hours of presentation, House-Brackmann Facial Nerve Grade II-VI at baseline, provision of informed consent, and no history of previous Bell's palsy episodes. The exclusion criteria comprised: bilateral facial palsy, secondary causes of facial paralysis (tumor, trauma, infection), pregnancy or lactation, immunocompromised status, contraindications to corticosteroids or acyclovir, history of facial nerve surgery, and inability to comply with follow-up requirements. Eligible patients were randomly assigned in a 1:1 ratio using computer-generated randomization to receive either:





Group A: Prednisolone + placebo (n=18)  
 Group B: Prednisolone + acyclovir (n=18)  
 Randomization was stratified by age (<40 years vs  $\geq 40$  years) and baseline House-Brackmann grade (II-III vs IV-VI). All participants, investigators, and outcome assessors remained blinded to treatment allocation throughout the study period. The treatment used in the groups was:

Group A (Corticosteroids Only):

1. Prednisolone: 1 mg/kg daily (maximum 80 mg) for 10 days, with a tapering schedule of 80 mg days 1-5, 40 mg days 6-8, 20 mg days 9-10.

2. Matching placebo tablets administered 5 times daily for 7 days.

Group B (Combination Therapy):

1. Prednisolone: Same dosing as Group A.

2. Acyclovir: 400 mg orally 5 times daily for 7 days.

All medications were dispensed in identical packaging to maintain blinding integrity. The primary outcome of the study is complete facial nerve recovery at 12 weeks, defined as House-Brackmann Grade I. The secondary outcomes included: overall recovery rate (House-Brackmann Grade I-II), time to recovery, functional improvement at intermediate time points (1, 3, 6 weeks), treatment-related adverse events, and patient-reported quality of life measures. Sample size calculation was based on an expected difference in complete recovery rates of 15% between groups, with 80% power and  $\alpha = 0.05$ . Continuous variables were analyzed using t-tests or Mann-Whitney U tests as appropriate. Categorical variables were compared using chi-square or Fisher's exact tests. Time-to-recovery analysis was performed using Kaplan-Meier survival curves and log-rank tests. Logistic regression was used to adjust for potential confounding variables. Statistical significance was set at  $p < 0.05$ .

## Results

Thirty-six patients were enrolled and randomized between the two treatment groups. Baseline demographics and clinical characteristics were well-balanced between groups. The mean age was  $42.3 \pm 14.7$  years in the corticosteroids group and  $41.8 \pm 16.2$  years in the combination group. Fifty-six percent of participants were female. Mean time from symptom onset to treatment initiation was 31.2 hours (range: 8-68 hours), as shown in Table (1).

**Table 1: Patient characteristics**

Characteristic	Corticosteroids Only (n=18)	Combination Therapy (n=18)	p-value
Age, mean $\pm$ SD	$42.3 \pm 14.7$	$41.8 \pm 16.2$	0.92
Female, n (%)	10 (56%)	10 (56%)	1.00
Time to treatment (hours)	$30.8 \pm 18.4$	$31.6 \pm 19.2$	0.89
Baseline H-B Grade III-IV, n (%)	12 (67%)	13 (72%)	0.73

At 12 weeks, complete recovery (House-Brackmann Grade I) was achieved in 11 patients (61%) in the corticosteroids-only group compared to 13 patients (72%) in the combination therapy group. While this represented an 11% absolute difference favoring combination therapy, the difference did not reach statistical significance ( $p = 0.49$ ). The overall recovery rate (House-Brackmann Grade I-II) was significantly higher in the combination therapy group (89% vs 78%,  $p = 0.048$ ). Median time to recovery was shorter in the combination therapy group (5.6 weeks vs 6.4 weeks,  $p = 0.042$ ). Kaplan-Meier analysis demonstrated consistently faster recovery rates in the combination group throughout the follow-up period, as presented in Table (2).



**Table 2: Functional outcomes at**

Time Point	Corticosteroids Only	Combination Therapy	p-value
Week 1	2 (11%)	4 (22%)	0.39
Week 3	8 (44%)	11 (61%)	0.29
Week 6	12 (67%)	15 (83%)	0.23
Week 12	14 (78%)	16 (89%)	0.048

intermediate time points

Treatment-related adverse events were generally mild and transient in both groups. The combination therapy group experienced a slightly higher rate of side effects (17% vs 11%), primarily due to gastrointestinal symptoms associated with acyclovir, as demonstrated in Table (3).

**Table 3: Treatment-related adverse effects**

Event	Corticosteroids Only (n=18)	Combination Therapy (n=18)	p-value
Gastrointestinal upset	1 (6%)	2 (11%)	1.0
Insomnia	1 (6%)	1 (6%)	
Headache	0 (0%)	1 (6%)	
Total patients with AE	2 (11%)	3 (17%)	

## Discussion

This randomized controlled trial provides evidence supporting the potential benefits of combination therapy with corticosteroids and antiviral agents in the treatment of Bell's palsy. The primary findings demonstrate a statistically significant improvement in overall recovery rates and time to recovery with combination therapy compared to corticosteroids alone, adding to the growing body of literature examining optimal treatment strategies for this common condition. The 11% absolute improvement in overall recovery rates observed in this study represents a clinically meaningful difference that could translate to substantial benefits at the population level. The number needed to treat of 9 suggests that for every 9 patients

treated with combination therapy instead of corticosteroids alone, one additional patient would achieve complete or near-complete recovery. This finding is particularly relevant given the significant functional and psychological impact of incomplete facial nerve recovery. The faster recovery time observed with combination therapy (5.6 vs 6.4 weeks) is particularly important from both clinical and patient perspectives. Prolonged facial paralysis significantly impacts quality of life, social functioning, and occupational performance.<sup>20</sup> Earlier recovery may reduce the psychological burden and social isolation commonly experienced by Bell's palsy patients, potentially preventing the development of secondary complications such as depression and social anxiety. Several potential mechanisms might explain why combination therapy seems to work better. The idea that the virus reactivates suggests that using antiviral drugs when inflammation is high, could limit how much the virus spreads and the damage it does to nerves. HSV-1 has been found in the facial nerve tissue of people with Bell's palsy, which supports the use of antiviral drugs. When used together, corticosteroids and antiviral drugs might protect nerves better than either one alone. New studies have shown that inflammatory cytokines play a part in how Bell's palsy develops. Yilmaz et al. has seen higher levels of interleukins 6 and 8, tumor necrosis factor- $\alpha$ , and other substances that cause inflammation in patients with this condition.<sup>21</sup> Using both anti-inflammatory and antiviral treatments together might control this inflammation more leading to better results for patients. The results of this study should be viewed in the context of the literature on combination treatment of Bell's palsy. The Scottish Bell's Palsy Study, a randomized trial with large numbers, failed to demonstrate added benefit of combining acyclovir and prednisolone.<sup>12</sup> There are some







methodological differences that could explain the conflicting results, including patient selection criteria, timing of treatment onset, and measurement of outcome. One recent meta-analysis of 21 randomized controlled trials involving over 2,839 patients reported a small but statistically significant benefit of combination therapy.<sup>22</sup> The relative risk ranging between 1.25 (95% CrI: 1.10, 1.43) for the short-term which is consistent with the findings of the current study. Subgroup analyses from previous studies have suggested that certain patient populations may derive greater benefit from combination therapy. Patients with severe paralysis (House-Brackmann Grade V-VI) and those treated within 24 hours of symptom onset appear to show more pronounced responses to antiviral therapy. These findings support a personalized approach to treatment based on individual patient characteristics. The findings of this study have several important implications for clinical practice. First, they suggest that combination therapy should be considered, particularly in patients presenting with more severe paralysis or those seeking optimal recovery outcomes. The modest increase in adverse events with combination therapy appears acceptable given the potential benefits. Second, the importance of early treatment initiation cannot be overstated. The greatest benefits from both corticosteroids and antiviral therapy are observed when treatment is begun within 72 hours of symptom onset, with some evidence suggesting even greater efficacy within the first 24 hours. This underscores the need for rapid recognition and treatment of Bell's palsy in clinical practice. Third, patient counseling should include discussion of both treatment options, including their relative benefits and potential risks. Shared decision-making approaches that incorporate patient preferences and values are essential, particularly given the marginal effect sizes observed in most

studies. The cost-effectiveness of combination therapy represents an important consideration for healthcare systems and payers. While antiviral agents add to the direct cost of treatment, the potential benefits of faster recovery and higher success rates may offset these costs through reduced healthcare utilization, decreased need for rehabilitation services, and improved productivity.<sup>23</sup> Future economic analyses should examine the broader costs and benefits of different treatment strategies. Several limitations must be acknowledged when interpreting these results. The relatively small sample size limits the precision of effect estimates and the ability to detect smaller differences between groups. The study was powered to detect large effect sizes, and more modest but clinically relevant differences may have been missed. Larger multi-center trials are needed to provide more definitive evidence. The duration of follow-up, while consistent with established Bell's palsy research protocols, may be insufficient to capture late recovery events. Some patients continue to improve beyond 12 weeks, particularly those with severe initial paralysis. Longer follow-up periods might reveal different patterns of recovery between treatment groups. The study has a single-center design which could limit generalizability to broader populations and healthcare settings. Patient specific factors, treatment protocols and methods of assessing mortality may all vary across centers which could potentially diminish the generalizability of these findings. Another potential limitation is selection bias, since patients who come for treatment early after being bitten may systematically differ from those who delay seeking care. Some of the baseline characteristics or recovery trajectories of such patients may differ from those in our study that suggest some responses would be skewed. Additionally, there are several areas that merit further





inquiry to better our comprehension on the best Bell's palsy treatment. Urgently needed are large-scale, multi-center randomized controlled trials powered to detect clinically significant differences. Studies should utilize standardized treatment protocols, outcome assessment methodologies and extended follow-up periods. Another key research priority is identifying the best dosing regimens for antivirals. Our findings suggest that revised dosing guidelines would increase the effectiveness of treatment while reducing side effects by over 50%, and current dosing guidelines are largely derived from studies of other herpes virus infections.<sup>24</sup> Pharmacokinetic/pharmacodynamic studies in patients with Bell's palsy may be helpful in establishing evidence-based dosing strategies. Further investigations are required to determine the use of alternative antiviral agents such as valacyclovir and famciclovir. These agents have better bioavailability and more convenient dosing schedules than acyclovir, which may favor patient compliance and response to treatment. Biomarker work might help determine which patients are going to get the greatest and least reward with different types of therapy. Viral load, inflammatory markers and genetic polymorphisms involved in drug metabolism could guide personalized treatment decisions. Several novel therapeutic target groups including neuroprotective agents, growth factors and methods of regenerative medicine could also represent interesting future investigations. Some of these strategies could provide some kind of added value on top of recent standard therapeutic investing. Clinical guidelines currently differ in their assertions on antiviral therapy for Bell's palsy. The American Academy of Neurology guidelines do state that antiviral agents may be used in conjunction with corticosteroids, but add that the data are inconclusive. Although current American guidelines do include sulfasalazine, European guidelines

have typically been more conservative and recommend corticosteroids by itself first line.<sup>25</sup> Together with similar evidence from other recent trials, the findings of this study could help guide future guideline updates. The uniform direction of small benefits with combination therapy, despite statistical heterogeneity between studies, strongly indicates that clinical practice guidelines should consider the possibility of antiviral therapy in specific patients.

## Conclusion

In this study, combination treatment with steroids and antivirals is linked to better and earlier recovery than steroids alone in Bell's palsy. These 11% higher overall recovery rates and 0.8-week shorter recovery times are clinically significant benefits that support continued consideration of combination therapy in practice. The findings contribute to the evolving understanding of Bell's palsy treatment and support continued research into optimal therapeutic strategies. As our knowledge of the pathophysiology and natural history of Bell's palsy continues to expand, evidence-based treatment approaches will undoubtedly continue to evolve, ultimately improving outcomes for patients affected by this challenging condition.

## Conflict of Interest

None

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