

THERAPEUTICS

Early treatment with prednisolone, but not acyclovir, promoted complete recovery of facial-nerve function in Bell palsy

Sullivan FM, Swan IR, Donnan PT, et al. Early treatment with prednisolone or acyclovir in Bell's palsy. *N Engl J Med*. 2007; 357:1598-607.

Clinical impact ratings: Emergency Med ★★★★★☆ GIM/FP/GP ★★★★★★ Neurology ★★★★★★ Oncology ★★☆☆☆☆

QUESTION

In patients with Bell palsy, does early treatment with prednisolone or acyclovir improve the chance of complete recovery of facial-nerve function?

METHODS

Design: 2 × 2 factorial, randomized, placebo-controlled trial.

Allocation: Concealed.*

Blinding: Blinded (clinicians, patients, data collectors, and outcome assessors).*

Follow-up period: Up to 9 months.

Setting: 17 hospitals in Scotland, United Kingdom.

Patients: 551 patients ≥ 16 years of age (mean age 44 y, 51% men) with unilateral facial-nerve weakness of no identifiable cause who were referred by their primary care physician or the emergency department within 72 hours of onset of symptoms. Exclusion criteria included pregnancy, uncontrolled diabetes, peptic ulcer disease, herpes zoster, and multiple sclerosis. 54% of patients started treatment within 24 hours of onset of symptoms. Mean score on the 6-grade House–Brackmann scale was 3.6 (higher grade indicates worse facial paralysis).

Intervention: Prednisolone, 25 mg twice daily, plus placebo for acyclovir (*n* = 138); acyclovir, 400 mg 5 times daily, plus placebo for prednisolone (*n* = 138); prednisolone plus acyclovir (*n* = 134); or both placebos (*n* = 141). Study drugs were taken for 10 days.

Outcomes: Complete recovery (grade 1 on the House–Brackmann scale for facial-nerve function), health-related quality of life, facial appearance, and pain.

Patient follow-up: 90% (intention-to-treat analysis).

MAIN RESULTS

At 3 and 9 months, complete recovery rates were higher in the prednisolone groups than in the no-prednisolone groups but did not differ between the acyclovir groups and the no-acyclovir groups (Table). Compared with the group that received neither drug (complete recovery rates of 65% at 3 mo and 85% at 9 mo), complete recovery rates were increased in the group that received prednisolone alone but not in the groups that received acyclovir alone or both drugs. The

addition of acyclovir to prednisolone did not increase the chance of complete recovery compared with prednisolone alone. At 3 months, health-related quality of life, facial appearance, and pain improved to a similar extent in all groups.

CONCLUSION

In patients with Bell palsy, early treatment with prednisolone, but not acyclovir, improved the chance of complete recovery of facial-nerve function.

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For correspondence: Dr. F.M. Sullivan, University of Dundee, Dundee, Scotland, UK. E-mail f.m.sullivan@chs.dundee.ac.uk.

*See Glossary.

Early treatment with prednisolone or acyclovir for Bell palsy†

Follow-up	Complete recovery rates‡		RBI (95% CI)	NNT (CI)
	Prednisolone	No prednisolone		
3 mo	83%	64%	27% (15 to 37)	6 (5 to 11)
9 mo	94%	82%	15% (8 to 18)	9 (7 to 15)
	Acylovir	No acyclovir	RBR (CI)	NNH
	3 mo	71%	76%	3.8% (–7 to 17)
9 mo	85%	91%	5.6% (–1 to 16)	Not significant

†Abbreviations defined in Glossary. RBI, RBR, NNT, NNH, and CI calculated from odds ratios in article, adjusted for age, sex, baseline score, receipt of the other study drug, and time to start of treatment.

‡Grade 1 on the 6-category House–Brackmann scale for facial-nerve function.

COMMENTARY

Inflammatory, viral, and ischemic causes have been postulated for Bell palsy (1), and steroids and antiviral agents are commonly recommended. The most recent Cochrane reviews of these drugs for Bell palsy concluded that neither treatment has been proven to improve recovery (2, 3).

The study by Sullivan and colleagues is the first properly designed and sufficiently powered trial to show that steroids, given within 3 days of onset, improve outcome in Bell palsy. It did not show any benefit of acyclovir, in contrast to a recent randomized trial of valacyclovir and prednisolone that suggested that antiviral treatment is effective (4). However, the results of the latter study need to be interpreted with caution because of several methodological flaws, including lack of assessor blinding and low follow-up rate. The evidence for treatment with antiviral agents remains poor.

Most patients with Bell palsy recover completely; however, Sullivan and colleagues showed that, without treatment, 35% of patients at 3 months and 15% at 9 months had persistent facial weakness. Prednisolone therapy will lead to 1 additional person with complete recovery at 9 months for every 9 patients treated, but some patients

will still be left with incomplete recovery, facial pain, and possible psychological distress. It is important to warn older patients and those with hypertension, impaired taste, pain other than in the ear, and complete facial weakness—all factors that carry poor prognosis (1)—that they may not recover completely, even with steroid treatment.

Previous studies tested intravenous steroids and much higher doses of oral steroids for Bell palsy. Sullivan and colleagues showed that 10 days of prednisolone, 25 mg twice daily, is sufficient and not associated with serious side effects. Based on these results, our patients with Bell palsy should be treated with steroids but not antiviral agents.

Wieslaw Oczkowski, MD
McMaster University
Hamilton, Ontario, Canada

References

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