Prednisolone, but not valacyclovir, reduced time to complete recovery of facial-nerve function in Bell palsy


QUESTION
Does prednisolone or valacyclovir improve recovery of facial-nerve function in patients with Bell palsy?

METHODS
Design: Factorial, randomized, placebo-controlled trial (RCT).
Allocation: {Concealed}†.*
Blinding: Blinded (patients, study personnel, and data analysts).*
Follow-up period: 12 months.
Setting: 16 otorhinolaryngologic centers in Sweden and 1 in Finland.
Patients: 839 patients 18 to 75 years of age who were referred from primary or emergency care settings or who sought care directly within 72 hours of onset of acute, unilateral, peripheral facial palsy. Exclusion criteria included use of systemic antiviral medications in the past 2 weeks or steroid medication, or current or past conditions that could be affected by the study medication or could affect study completion (e.g., breastfeeding; potential for pregnancy; neurologic, serious heart, renal, hepatic, or psychiatric disease; diabetes; uncontrolled hypertension; gastric or duodenal ulcer; otitis; recent head injury; glaucoma; tuberculosis; and immunodeficiency).

Intervention: Prednisolone, 60 mg/d for 5 days, then reduced by 10 mg/d for 5 days, plus placebo (n = 213); valacyclovir, 1 g 3 times/d for 7 days, plus placebo (n = 207); prednisolone plus valacyclovir (n = 210); or both placebos (n = 209).

Outcomes: Included time to complete recovery of facial function (100 on Sunnybrook scale) and facial function at 12 months.
Patient follow-up: 89% (99% [median age 40 y, 59% men] in modified intention-to-treat analysis).

MAIN RESULTS
Complete facial recovery rates at 12 months are shown in the Table. Time to complete recovery was shorter in the prednisolone than in the no-prednisolone groups (hazard ratio [HR] 1.4, 95% CI 1.2 to 1.6); the valacyclovir and no-valacyclovir groups did not differ (HR 1.01, CI 0.9 to 1.2).
ConClusion

Prednisolone, but not valacyclovir, reduced time to complete recovery of facial-nerve function in patients with Bell palsy.

*See Glossary.
†Information provided by author.
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COMMENTARY

Bell palsy is an acute, unilateral, peripheral, facial nerve paralysis in which inflammation of the nerve and compression within the temporal bone are believed to play a role. Possible causes include autoimmune processes, demyelination, and infection, particularly herpes simplex virus. Complete recovery of facial-nerve function is seen in 70% to 85% of patients (1). In 2004, 2 Cochrane reviews were published: One pooled the results of 4 corticosteroid studies (2), and the other included 3 antiviral studies (3). Neither found sufficient evidence to support the treatments. A recent RCT that included more patients (n = 496) than the 2 reviews combined showed that prednisolone improved recovery at 3 (83%) and 9 months (94%); acyclovir did not (71% and 85%, respectively) (4).

The RCT by Engström and colleagues, which compared corticosteroids and antiviral therapy, is larger and used valacyclovir, which has higher bioavailability than acyclovir. Although complete recovery rates were slightly lower than in the smaller trial, they also found that prednisolone (plus placebo) was the only effective agent. The small differences in the results of the 2 studies can be attributed to differences in interventions, analytic methods, populations, and facial-nerve function grading systems. The smaller trial used the House-Brackmann scale to assess facial-nerve function, whereas Engström and colleagues used the Sunnybrook scale to increase sensitivity.

Engström and colleagues showed that corticosteroids are effective for Bell palsy, but antiviral therapy is not. This adds to growing evidence that prompt corticosteroid therapy is beneficial and antiviral therapy is not beneficial in the routine treatment of Bell palsy and provides an evidence base for practice patterns.

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REFERENCES