Critical Review Form
Meta-analysis

Corticosteroids for Bell's palsy (idiopathic facial paralysis)
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Objective: **"To determine the effectiveness and safety of corticosteroid therapy in people with Bell's palsy." (p. 2)**

Methods: **Three authors searched the Cochrane Neuromuscular Disease Group Trials Specialized Register, MEDLINE, EMBASE, and LILACS using Bell's palsy and its synonyms as search terms. They also reviewed bibliographies and contacted study authors for additional references. Irrespective of time since symptoms began, the Cochrane authors included all randomized or quasi-randomized studies using corticosteroid or ACTH hormone therapy. They extracted trial data to conduct an intention-to-treat analysis generating risk-ratios by a fixed effects model for the primary outcome of incomplete facial motor function at six-months or more after randomization.**

Two Cochrane authors extracted data and assessed methodological quality of each trial on several domains: randomization method, blinding, potential to conduct an ITT analysis, and number of losses to follow-up. Two *a priori* subgroup analyses were planned:

1) **Patients with treatment less than 48-hours after symptom onset;**
2) **Patients with complete facial paralysis.**

Guide	Question	Comments
I	***Are the results valid?***	
1.	Did the review explicitly address a sensible question?	Yes. Does the use of corticosteroid therapy improve outcomes in patients with Bell's palsy?
2.	Was the search for relevant studies details and exhaustive?	Yes, the Cochrane investigators searched the Cochrane Neuromuscular Disease Group in addition to three electronic databases and a hand-search of relevant bibliographies. In addition, they also contacted original study investigators.
3.	Were the primary studies of high methodological quality?	Yes. "None of the trials was considered a poor quality trial". (p. 5 – see Fig 1, p.6)
4.	Were the assessments of the included studies reproducible?	Uncertain. "Disagreement was resolved by discussion." (p. 3). The Cochrane authors do not report how often disagreements occurred.

II.	*What are the results?*	
1.	What are the overall results of the study?	• Eight trials totaling 1569 participants were identified, only one of which included children. • The corticosteroid used in each trial was different: - cortisone acetate 200 mg in divided doses x3 d then 100 mg QD x 3-days then 50 mg QD x 2-days (Taverner 1954) - Prednisone 410 mg in descending doses over 10 days (May 1976) - Prednisone 1 gm IV daily x3 days, then 0.5 mg IV daily x3 days (Lagalla 2002) - Methyl-prednisone 1 mg/kg/daily for 10 days with subsequent 3- to 5-day taper (Unuvarr 1999) - Prednisolone 25 mg twice daily for 10 days (Sullivan 2007) - Prednisolone 60 mg QD x5 d, then ↓ 10mg/day for 10 days The primary outcome was incomplete facial paralysis recovery at 6-months • Seven trials with 1507 participants demonstrated a significant improvement in facial paralysis recovery in the steroid group with moderate heterogeneity (Fig 2, p. 7): RR 0.71 (95% CI 0.61- 0.83) NNT 10 (95% CI 7 – 18) I^2 = 55%. • Heterogeneity is likely due to variable inclusion of patients > 48° after symptom onset. **Cosmetic disfigurement** at six months (secondary outcome) • Five trials of 668 participants demonstrating no effect (see Fig 3, p.8) RR 0.97 (95% CI 0.44 – 2.15) with I^2 = 0%. **Motor synkinesis or autonomic dysfunction** • Two trials with 901 participants demonstrated significant reduction with steroids: RR 0.60 (95% CI 0.44 – 0.81) NNT 12 (95% CI 6 – 25) with I^2 = 0%. • Most studies did not report adverse effects and those that did failed to detect significant effects in steroid group. • Subjects with complete facial paralysis had no benefit (RR 0.98, 95% CI 0.45 – 2.11). • Patients receiving steroids less than 48-hours after symptom onset had less incomplete recovering at 6-months: RR 0.51 (95% CI 0.32 – 0.80) NNT 11 (95%, CI 7 – 32), I^2 = 70%.
2.	How precise are the results?	See 95% CI above.

3.	Were the results similar from study to study?	No, there was significant heterogeneity (I^2 > 25%) noted for several of the meta-analyses so a random-effects model ought to have been utilized.
III.	***Will the results help me in caring for my patients?***	
1.	How can I best interpret the results to apply them to the care of my patients?	Corticosteroids within 72-hours of symptom onset reduce rates of incomplete facial paralysis resolution and motor synkinesis without apparent adverse effects.
2.	Were all patient important outcomes considered?	No. How was facial paralysis severity graded? Was it consistent from trial-to-trial? Are the scales used (House-Brackmann, Sunnybrook, Yanagihara) related to patient-oriented evidence that matters? What about corneal ulcerations or dry eye symptoms? What is the optimal dose, duration, and type of steroid for Bell's palsy?
3.	Are the benefits worth the costs and potential risks?	Probably. Steroids are cheap, readily available, safely used for a wide variety of inflammatory pathology (asthma, migraines, sore throat, etc). Future cost benefit analyses will need to assess the morbidity of incomplete facial recovery against the inconvenience of an ED evaluation for Bell's palsy with the expense/side effect profile of a short-course of steroids.

Limitations

1) **Failure to conduct random-effects analysis when significant heterogeneity noted.**

2) **Overly optimistic interpretation of findings for some outcomes.**

3) **Failure to elaborate on the "holes" left by the existing literature or to contemplate cost-benefit for steroids in Bell's palsy.**

Bottom Line

In adults with Bell's palsy less than 72-hours after symptom onset, steroids improve the likelihood of complete facial recovery (NNT 10 but I^2 = 55%) and reduce rates of motor synkinesis/autonomic dysfunction at six months (NNT 12, I^2 0%) with significant adverse effects. Future trials will need to assess the optimal timing, steroid, dosing, and duration to achieve benefit. In the meantime there is no apparent reason not to use a single corticosteroid for 10 – 14 days in adult Bell's palsy patients presenting within three days in onset.