Corticosteroid treatment for idiopathic facial nerve paralysis: a meta-analysis

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Authors' objectives
To evaluate facial recovery in patients with complete idiopathic facial nerve paralysis (IFNP) by comparing the outcomes for those treated with corticosteroid therapy and those treated with placebo or no treatment.

Searching
MEDLINE was searched from 1966 to January 1998 for English language publications, using the following MeSH and free-text terms: 'facial paralysis', 'Bell's Palsy', 'idiopathic facial nerve paralysis', combined with 'drug therapy' and 'therapy'. The search results were then combined with 'corticosteroids', 'adrenal cortex hormones', 'synthetic glucocorticoids', 'prednisolone', 'prednisone' and 'steroids'. The term 'therapeutic use' was applied in some cases to the drug terms. Additional articles were found by examining Current Contents and the bibliographies of relevant articles and book chapters.

Study selection
Study designs of evaluations included in the review
Prospective trials with concurrent controls were considered. Follow-up of at least 4 months, or to complete recovery, was an inclusion criterion.

Specific interventions included in the review
Corticosteroid treatment with a total prednisone equivalent dose of 400 mg or greater, compared with placebo or no treatment. Treatment for IFNP had to have started within 7 days of onset of paralysis. Multiple interventions other than corticosteroids were excluded.

Participants included in the review
Patients with complete IFNP, also known as Bell's palsy. Only studies where IFNP was diagnosed with the exclusion of other causes of facial paralysis, and that the diagnosis was unilateral, nonrecurrent IFNP, were included.

Outcomes assessed in the review
Clinically complete or incomplete facial motor recovery. Complete paralysis was defined as House-Brackmann grade 6, or otherwise defined by the trial as total or complete paralysis. Cure was defined as complete or total recovery of facial paralysis or House-Brackmann grade 1.

How were decisions on the relevance of primary studies made?
Three independent reviewers performed the study selection based on eight a priori inclusion and exclusion criteria.

Assessment of study quality
A quality index was calculated for trials meeting the inclusion criteria, using an 8-point assessment scale adapted from Chalmers method for assessing RCTs (see Other Publications of Related Interest). Quality scores were averaged to give a final quality assessment score. A quality index ranging from 0 to 1 was calculated for each study based on the percentage of total points earned. This index was used as a general assessment of the quality of the trial design. Three independent reviewers performed the quality assessment.

Data extraction
Three independent reviewers performed the data extraction using a standardised form to record inclusion criteria, treatment rendered, epidemiological characteristics, treatment and control numbers, and, if available, outcome data.

Effect magnitude and significance were evaluated by calculating the rate difference (RD) with 95% confidence
intervals (CIs) for each individual trial.

**Methods of synthesis**

How were the studies combined?
The pooled RD and 99% CIs were calculated using a random-effects model.

How were differences between studies investigated?
Heterogeneity was assessed using the Q statistic.

**Results of the review**

Three prospective RCTs with 230 participants were included in the review. However, the heterogeneity assessment indicated that one trial with the smallest sample size (n=24) was an outlier, and this was therefore excluded from the analysis.

The quality assessment scores for each individual study ranged from 33 to 73%, with a mean of 59%.

Complete recovery rates ranged from 27 to 100% for treatment groups and 24 to 85% for control groups. The pooled RD demonstrated a 17% (99% CI: 0.01, 0.32, p=0.005) improvement in clinically complete recovery for the treatment group using the random-effects model.

A sensitivity analysis including the third small sample size trial, i.e. the outlier, gave a RD of 12% (99% CI: -0.07, +0.31, p=0.11), which was not statistically significant. Analysis of 6 excluded studies (1 prospective and 5 retrospective) gave recovery rates ranging from 49 to 97% for the treatment group and 23 to 64% for the control group.

Analysis of the three trials demonstrated statistically-significant heterogeneity (p=0.06). Heterogeneity assessment indicated that one trial with the smallest sample size was an outlier, and this was therefore excluded from the analysis (RD -0.19, 95% CI: -0.58, 0.20). The resulting heterogeneity for the 2 remaining trials was minimal (p=0.20).

**Authors' conclusions**
The authors state that corticosteroid treatment provides a clinically and statistically-significant improvement in recovery of function by 17% in complete IFNP.

**CRD commentary**

This was a very well-conducted review. The authors clearly stated their research question and the inclusion and exclusion criteria were very thorough. The literature search was good and the authors limited the search to English language publications. It is unlikely that additional studies were missed.

The authors reported who, and how many of the authors, performed the study selection, quality assessment and data extraction. A formal assessment of quality was carried out using a recognised assessment scale, and the results were used in the analysis of the included studies.

The review assessed possibilities of heterogeneity and used appropriate methods for pooling the data, although only two studies were eligible for the analysis. The included data was presented in tables and text, and there was an extensive discussion about the differences between the included studies and the possible effects they may have had on the outcome of the review. The authors' conclusions appear to follow from the results.

**Implications of the review for practice and research**

Practice: The authors state that patients with complete IFNP should be treated with a minimum of 400 mg of prednisone, or an equivalent dose of corticosteroid, started within 7 days of onset of facial weakness.

Research: The authors did not state any implications for further research.
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Other publications of related interest

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MeSH
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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.