Meta-analysis of the efficacy of a single dose of phenylephrine 10 mg compared with placebo in adults with acute nasal congestion due to the common cold

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CRD summary
This review assessed the efficacy of oral phenylephrine 10 mg as a nasal decongestant. The authors concluded that the evidence supports the effectiveness of a single dose of phenylephrine as a decongestant in adults with a common cold. There was insufficient information to judge whether the results were reliable, therefore this conclusion should be treated with caution.

Authors' objectives
To assess the efficacy of oral phenylephrine 10 mg as a nasal decongestant.

Searching
The studies were obtained from two previous reviews and from a MEDLINE search (1966 to January 2007); the search terms were reported.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Studies that compared a single 10-mg dose of orally-administered phenylephrine (as the single active ingredient) with placebo were eligible for inclusion. All of the included studies provided identical capsules or tablets containing either the active ingredient or placebo.

Participants included in the review
Studies of patients with acute nasal congestion due to the common cold were eligible for inclusion. No studies conducted in children were included.

Outcomes assessed in the review
Studies assessing nasal airway resistance (NAR) and providing enough data to allow reanalysis or meta-analysis were eligible for inclusion. Where reported, all studies used the same procedures to determine NAR.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

The authors extracted or calculated the change from baseline in NAR, and the natural logarithm of the ratio of the post-baseline value to the baseline value (ln ratio NAR) at each post-baseline assessment time (ranging from 15 to 240 minutes after dosing). In the reanalysis of the study results, a clinically meaningful result was defined as statistical significance at 30 and 60 minutes after dosing and a reduction of at least 20% from baseline in NAR with
Methods of synthesis
How were the studies combined?
The results of all the studies were tabulated and compared in the text of the review. In addition, the results of RCTs that used the same crossover study design and method of outcome measurement were pooled using meta-analysis. Both random-effects and fixed-effect models were used.

How were differences between studies investigated?
Heterogeneity between the studies in the meta-analysis was investigated statistically at each post-dosage time point using a treatment-by-study interaction in an analysis of covariance.

Results of the review
Eight RCTs (163 participants), including 7 crossover trials (113 participants) and 1 parallel study (50 participants), were included.

Phenylephrine had a significantly greater effect on NAR than placebo in 4 studies, and no significantly different effect in 4 studies.

In the meta-analyses (7 RCTs, 113 participants, except at 180- and 240-minute time points which included 5 RCTs, 82 participants), significantly greater effects of phenylephrine over placebo were found at 30, 60 and 90 minutes after dosing using the random-effects model, and at 30, 45, 60, 90, 120 and 180 minutes after dosing using the fixed-effect model. Significant heterogeneity (p<0.10) was detected at all time points.

No adverse events were reported in 7 studies. One study reported comparable adverse events in the phenylephrine and placebo groups.

Authors' conclusions
The evidence supports the effectiveness of a single dose of phenylephrine 10 mg as a decongestant in adults with acute nasal congestion associated with the common cold.

CRD commentary
The review addressed a clear question with defined inclusion criteria. The limited search for primary studies may mean that relevant studies were missed. Publication bias was not assessed, whereas the potential for language bias could not be assessed as the authors did not state whether any language restrictions were applied. They also did not report whether they took measures to reduce reviewer error and bias in the study selection and data extraction processes. The methodological quality of the included studies was not reported, however, the included studies were all double-blind placebo-controlled trials.

The study results appear to have been analysed and combined using appropriate techniques, and heterogeneity was investigated statistically. However, few individual study details were presented which makes it impossible to assess whether the decision to pool the studies was appropriate, especially given that there was statistical heterogeneity between the studies and an even split between those in support of and those not supporting the efficacy of phenylephrine. In summary, owing to a lack of information about individual studies, it is not possible to judge whether the results of the review are reliable and, therefore, the authors’ conclusion should be treated with caution.

Implications of the review for practice and research
The authors did not state any implications for practice or further research.
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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.