The effectiveness of the nicotine patch for smoking cessation: a meta-analysis
Fiore M C, Smith S S, Jorenby D E, Baker T B

Authors' objectives
To estimate the overall efficacy and optimal use of the nicotine patch for treating tobacco dependence.

Searching
MEDLINE was searched to September 1993. Psychological Abstracts were searched as were unpublished studies referred to in applications submitted to the US Food and Drug Administration.

Study selection
Study designs of evaluations included in the review
Double blind randomised placebo controlled trials (RCTs) of at least four weeks duration, using biochemical confirmation of abstinence, and subjects not selected on the basis of specific diseases.

Specific interventions included in the review
Nicotine patches (16 hour versus 24 hour).

Participants included in the review
Men and women, were not selected on the basis of specific diseases.

Outcomes assessed in the review
Abstinence rates at the end of the treatment and at 6 months, based on biochemical confirmation.

How were decisions on the relevance of primary studies made?
Data were independently rated by two assessors, with consensus decisions for any disagreements.

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

Data extraction
Two raters independently recorded the end of treatment and 6-month abstinence rates overall and by patch type (16 hour versus 24 hour), patch treatment duration (8 weeks versus >8 weeks), dosage reduction (weaning), counselling format (individual versus group) and intensity of behavioural counselling. All abstinence rates were based on intention-to-treat.

Methods of synthesis
How were the studies combined?
Meta-analysis (Mantel-Haenszel) to estimate a common odds ratio for each of the comparisons made. Each trial was weighted by its sample size when computing pooled abstinence rates from individual trials.

How were differences between studies investigated?
The Breslow-Day test for homogeneity of the common odds ratio was computed. Where statistically significant heterogeneity was detected, outlier odds ratios were deleted until homogeneity criteria were satisfied. Sub-categories of studies were discussed according to 16 hour versus 24 hour patch, duration of treatment, weaning, format and intensity of counselling.
**Results of the review**

Seventeen RCTs were included.

The active patch was superior to the placebo patch regardless of patch type, patch treatment duration, weaning, counselling format or counselling intensity. Overall abstinence rates for the active patch were 27% (95% confidence intervals (CIs) 25.4, 28.8) versus 13% (CI: 11.8, 14.5) for placebo at the end of treatment and 22% (CI: 19.7, 23.9) versus 9% (CI: 7.8, 11.0) for placebo at 6 months. The combined odds ratios for efficacy of active patch versus placebo patch were 2.6 (CI: 2.2, 3.0) at the end of treatment and 3.0 (CI: 2.4, 3.7) at 6 months.

The results of studies were compared with respect to a number of characteristics:

- Studies using 16 hour patches had higher efficacy than 24 hour patches.
- Studies with treatment extending beyond 8 weeks did not show increased efficacy at the end of treatment.
- Studies weaning patients off the nicotine patch at the end of treatment had the same effect as those with no weaning.
- Studies with individual counselling showed no difference from those with group counselling.

**Cost information**

Average retail cost of $4 per patch would result in an 8-week course totalling $224 and a 12-week course costing $336. Given the projected sales figures of $300 million in 1993, limiting treatment to 8 weeks may result in a saving of $100 million.

**Authors' conclusions**

The nicotine patch is an effective aid to quitting smoking across different patch-use strategies. Active patch subjects were more than twice as likely to quit smoking as individuals wearing a placebo patch. This effect was present at both high and low intensities of counselling.

**CRD commentary**

The review methods were rigorous, however the search terms were not defined clearly. Effectiveness was evaluated at the end of treatment and at 6 months' follow-up. Different results may be obtained with a longer follow-up period.

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

The nicotine patch is an effective aid in smoking cessation and could be used with or without patient counselling.

**Bibliographic details**


**PubMedID**

8201739

**Other publications of related interest**


**Indexing Status**
Subject indexing assigned by NLM

MeSH
Administration, Topical; Adult; Confidence Intervals; Counseling; Drug Administration Schedule; Humans; Nicotine /administration & dosage /therapeutic use; Odds Ratio; Randomized Controlled Trials as Topic; Smoking Cessation /methods; Tobacco Use Disorder /drug therapy; Treatment Outcome

AccessionNumber
11994008088

Date bibliographic record published
02/03/1995

Date abstract record published
02/03/1995

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.