A comparison of measures used to assess effectiveness of the transdermal nicotine patch at 1 year

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Authors' objectives
To compare the outcome measures of abstinence among studies reporting 12-month outcomes of the nicotine transdermal patch using difference measures of effectiveness.

Searching
The articles were identified by a search of MEDLINE, and from article and book reference lists. The dates covered by the search and search strategy were not stated.

Study selection
Study designs of evaluations included in the review
Placebo-controlled trials having at least two treatment groups with participants allocated by randomisation, and reporting 1-year validated abstinence rates, were included.

Specific interventions included in the review
Transdermal nicotine patches of 16 or 24 hours' duration versus concomitant therapy. The latter comprised the following: brief advice in general practice; cognitive-behavioural therapy; weekly brief counselling sessions with a nurse; physical exam and smoking cessation advice by physician, with follow-up by nurse and booklet; or behavioural support from a specialised clinic with self-help materials.

Participants included in the review
Participants in smoking cessation programmes were included.

Outcomes assessed in the review
The abstinence rates for the nicotine transdermal patch were assessed at 12 months using three measures: point prevalence, and continuous and prolonged abstinence. Self-reported abstinence was confirmed predominantly by expired carbon monoxide, and less often by salivary cotinine.

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

Assessment of study quality
The author does not state that they assessed quality.

Data extraction
The author does not state how the data were extracted for the review, or how many of the reviewers performed the data extraction.

Methods of synthesis
How were the studies combined?
The author compared the results on each of the three outcome measures and discussed these in a narrative review.

How were differences between studies investigated?
There were no statistical tests for differences between the studies. However, the author noted that a comparison of the
12-month outcomes was difficult because of different criteria for abstinence, the length of use of the patches, very
different concomitant therapies, the motivation of the study participants, and the number of follow-up visits.

Results of the review
Ten randomised controlled trials with 3,806 participants met the inclusion criteria. Six studies (1,011 participants)
measured point prevalence, 4 studies (2,500 participants) measured prolonged abstinence, and 3 studies (2,591
participants) measured continuous abstinence.

Compared with placebo, all studies using continuous or prolonged abstinence as the outcome measure showed a
significant effect of the active patch, which in most studies was more than double.

Those studies using point prevalence measures did not show an effect for the active patch at 1 year.

Authors' conclusions
The active patch usually produced at least double the rate of success, which was revealed when the outcome was
presented in terms of continuous or prolonged abstinence at 1 year. The success rates varied greatly across the studies,
and may have been influenced by the nature and intensity of adjuvant smoking cessation counselling.

CRD commentary
The author stated the research question and the inclusion and exclusion criteria. However, the literature search was
limited to one database, which may have missed publications published outside of the USA. The study was also
limited by language restrictions and there was no mention of searches for unpublished data. The study was also
limited by language restrictions and there was no mention of searches for unpublished data. The author further stated
that future research is needed to evaluate all studies reporting 1-year abstinence, even though this was supposed to be
the objective of the current review.

The author did not report who selected the articles for inclusion, and there was no quality assessment of the included
studies. The individual studies were combined statistically, but this process was not reported. In addition, there were
no tests for heterogeneity even though the authors highlighted several areas where the study differences were judged to
be large.

This review should be viewed with caution because of the lack of detail and possibility of bias in the conduct of the
review.

Implications of the review for practice and research
The author states that a further meta-analysis, which includes all studies reporting 1-year abstinence, needs to be
conducted.

Bibliographic details
Richmond R L. A comparison of measures used to assess effectiveness of the transdermal nicotine patch at 1 year.
Addictive Behaviors 1997; 22(6): 753-757

PubMedID
9426792

Indexing Status
Subject indexing assigned by NLM

MeSH
Administration, Cutaneous; Humans; Nicotine /administration & dosage; Nicotinic Agonists /administration & dosage;
Time Factors; Tobacco Use Disorder /drug therapy
AccessionNumber
11998003353

Date bibliographic record published
31/12/1999

Date abstract record published
31/12/1999

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.