Treatments for spit tobacco use: a quantitative systematic review


CRD summary
This review assessed interventions for spit tobacco (ST) use. The authors concluded that behavioural interventions are effective in reducing the use of ST, bupropion sustained-release probably effective, and nicotine replacement therapy may be effective. This was a well-conducted review and the authors' conclusions are likely to be reliable.

Authors' objectives
To assess the efficacy and safety of pharmacological and behavioural interventions for the treatment of spit tobacco (ST) use.

Searching
Searches were conducted in MEDLINE (1966 to September 2001), EMBASE (1988 to September 2001), CINAHL (1982 to September 2001), HealthSTAR (1975 to September 2001), ERIC (1967 to September 2001), PsycINFO (1984 to September 2001), NTIS (1964 to September 2001), Dissertation Abstracts Online (1861 to September, 2001), the Cochrane Controlled Trials Register (1991 to Issue 2, 2001), DARE (1995 to Issue 2, 2001) and Current Contents (1998 to week 40, 2001); the search terms were stated and no language limitations were applied. In addition, reference lists of identified studies, reviews, conference proceedings and the authors' personal files were checked. Experts in the field were contacted for details of unpublished RCTs, and researchers in tobacco and ST tobacco use were also contacted.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were included if allocation was performed using a random sequence. The included studies were randomised at the organisational level, or at the level of the individual.

Specific interventions included in the review
Studies of any pharmacological or behavioural intervention were eligible for inclusion. Behavioural interventions could be directed at individuals or groups of people. The included studies used nicotine replacement therapy (NRT; patch or gum), non-NRT such as bupropion sustained-release (SR), and behavioural interventions based on a variety of underlying theories including self-help materials and counselling plus telephone support; further details were given in the report. Conterventions included behavioural interventions in pharmacological studies, and nicotine gum offered in one behavioural study. Pharmacological interventions were compared with placebo. The interventions, where stated, lasted between 4 weeks and 2 years.

Participants included in the review
Studies of ST users were eligible for inclusion. In the review, ST was defined as any tobacco product that is placed in the mouth and not burned. The included behavioural studies recruited participants from dental practices, college campuses, high schools and worksites.

Outcomes assessed in the review
The review assessed point prevalence abstinence and continuous abstinence. The former (point prevalence) was defined as no use of any type of ST or tobacco at least 7 days before the assessment or between study visits (whichever was the longer). The latter (continuous) was defined as not using any type of ST or tobacco since the tobacco quit day. All of the included pharmacological studies confirmed tobacco abstinence using biochemical testing. Most of the behavioural studies assessed tobacco abstinence using self-report; a minority (25%) of behavioural studies confirmed tobacco abstinence using biochemical testing. The included studies assessed the outcomes between 4 weeks and 2 years.

How were decisions on the relevance of primary studies made?
Two reviewers independently selected the studies. There was full agreement on study selection.

**Assessment of study quality**

Studies were assessed on the basis of the following: allocation concealment; blinding of the participants, investigators and outcome assessors; comparability between treatment groups at baseline; equal treatment of groups; completeness of follow-up; analysis conducted on an intention-to-treat basis; and the use of a placebo or active intervention control group. Two reviewers independently assessed validity using a standardised form. Any disagreements were resolved by consensus.

**Data extraction**

Two reviewers independently extracted and coded the data using a standardised form. Any disagreements were resolved by consensus. Data on the number of participants abstinent from ST use were extracted from individual studies and used to derive odds ratios (ORs) and 95% confidence intervals (CIs).

**Methods of synthesis**

**How were the studies combined?**

The studies were combined using a random-effects meta-analysis. Pooled ORs and 95% CI were calculated separately for NRT, bupropion and behavioural interventions. Data from studies reporting adverse effects were presented in a narrative.

**How were differences between studies investigated?**

Statistical heterogeneity was assessed using the chi-squared statistic. Data from pharmacological RCTs of NRT were pooled separately from non-NRT studies; data pertaining to patch and gum use were also presented separately. Statistically significant heterogeneity among behavioural studies was explored by analysing studies that used an oral examination separately from those studies that did not use an oral examination.

**Results of the review**

Fourteen RCTs met the inclusion criteria, but ten were included in the analysis (n=4,010). Four studies were omitted from the meta-analysis of behavioural studies because of insufficient data, lack of a control group, outcomes assessed at less than 6 months, and the lack of adjustment for intraclass correlations.

The losses to follow-up were greater than 20% in two of the 6 pharmacological RCTs. Among the 8 behavioural RCTs, three reported follow-up in more than 80% of the patients, six analysed data on an intention-to-treat basis, and one reported allocation concealment.

**Pharmacological interventions (6 RCTs).**

Bupropion SR significantly increased point prevalence tobacco abstinence at 12 weeks compared with control; the OR was 2.1 (95% CI: 1.0, 4.2), based on 138 patients in 2 RCTs. No statistically significant heterogeneity was detected (P=0.86).

NRT with patch or gum significantly increased point prevalence tobacco abstinence at 6 months compared with control; the OR was 1.3 (95% CI: 1.0, 1.6), based on 1,120 patients in 4 RCTs. No statistically significant heterogeneity was detected (P=0.9).

**Behavioural interventions (4 RCTs).**

Behavioural therapy significantly increased point prevalence tobacco abstinence at 6 months or more compared with control; the OR was 1.7 (95% CI: 1.1, 2.9), based on 2,795 patients in 4 RCTs. Statistically significant heterogeneity was detected (P<0.01).

A sub-group analysis found that abstinence rates were highest for interventions that included feedback on mucosal
changes detected at an oral examination; the OR was 2.9 (95% CI: 1.9, 4.5), based on 993 patients in 2 RCTs. No statistically significant heterogeneity was detected (P=0.74).

No significant difference was found in studies that did not include an oral examination; the OR was 1.2 (95% CI: 0.9, 1.6), based on 1,802 patients in 2 RCTs. No statistically significant heterogeneity was detected (P=0.16).

Adverse effects.

All significant adverse effects reported were for NRT. One RCT found that a nicotine patch increased skin reactions and nausea compared with control, but found no difference in withdrawals due to adverse effects. One study reported two cases of headache and gastrointestinal distress with nicotine gum.

**Authors' conclusions**

Behavioural interventions are effective in reducing the use of ST, bupropion SR is probably effective, and NRT may be effective. The addition of feedback of findings from an oral examination to behavioural interventions appears to increase the effectiveness of the programmes.

**CRD commentary**

The review question was clear in terms of the study design, intervention, participants and outcomes. Many relevant sources were searched and the search terms were stated. Attempts were made to minimise language and publication bias. Two reviewers independently selected the studies and extracted the data, which reduces the potential for bias and errors. Validity was assessed using established criteria and the results of this assessment were reported.

Adequate details of each included study were given. The data were appropriately grouped by type of intervention and combined in a meta-analysis, with an assessment of statistical heterogeneity. In general, the reasons why some studies were excluded from the meta-analysis were appropriate and details of these studies were provided. Where significant heterogeneity was found, potential causes were explored. The authors discussed the evidence in relation to study quality and discussed some of the limitations of the review. The authors' conclusions are likely to be reliable.

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

Practice: The authors stated that until further research finds other results, evidence-based strategies for cigarette smoking should be used for ST users. They also stated that patients should be asked about ST use, and the individual's stage of change should be assessed to enable interventions to be tailored to the appropriate stage. Interventions should incorporate behavioural therapy with feedback from an oral examination and provide pharmacological therapy, and should follow up patients.

Research: The authors stated that further RCTs that use adequate methods of randomisation, confirm outcomes biochemically and follow up all patients over at least 6 months, are required. They also stated that research is required to identify the effects of individual components of behavioural interventions and the effect of interventions on different types of ST use, and to assess the effects of interventions in adolescents.

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