Professional fluoride varnish treatment for caries control: a systematic review of clinical trials


CRD summary
This review aimed to evaluate the effect of professional fluoride varnish treatments on caries prevention. The authors concluded that there is limited evidence that professional fluoride varnish treatment has a caries-preventive effect in permanent teeth in children and adolescents. Evidence in adults and children with primary dentition was inconclusive. The results were inconsistent across studies and this weakened the evidence.

Authors' objectives
To evaluate the effect of professional fluoride varnish treatments on caries prevention.

Searching
MEDLINE and the Cochrane Library were searched from 1966 to April 2003; the search terms were reported. The reference lists of retrieved articles were also checked for additional relevant studies. Studies published in English, Swedish, Danish, Norwegian, German, French, Italian and Spanish were eligible for inclusion. Abstracts were not included.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) and controlled clinical trials (CCTs) of at least 2 years’ duration were eligible for inclusion. At the stage of assessing full papers for inclusion, the authors introduced the exclusion criterion that studies utilising the split-mouth technique were not eligible for inclusion in the review.

Specific interventions included in the review
Studies of topical fluoride varnish applications, applied by professionals, were eligible for inclusion. The interventions in the included studies were Duraphat varnish (Colgate Oral Pharaceuticals) containing 2.25% fluoride, Fluor protector varnish (Vivadent) containing 0.1% fluoride, and Bifluoride varnish (Voco) containing 5.6% fluoride; they were used between once and four times per year. The control groups received Duraphat varnish, fluoride rinsing, APF-gel, placebo or no treatment.

Participants included in the review
Studies of patients of various ages were eligible for inclusion in the review. All of the included studies were conducted in children, aged between 3 and 14 years.

Outcomes assessed in the review
Studies that reported coronal caries increments in permanent and deciduous dentition as the outcome measures were eligible for inclusion. The primary outcome in the review was the prevented fraction. This was calculated as the difference in mean caries increment between the treatment group and control group, expressed as a percentage of the increment in the control group.

How were decisions on the relevance of primary studies made?
Two reviewers independently assessed studies for inclusion in the review.

Assessment of study quality
The studies were assigned a quality grade based on the following criteria: randomisation; diagnostic reliability described; baseline value described; explanation for attrition and attrition less than 10%; blinded outcome assessment;
representativeness of the population; and the consideration of bias and confounders. Each study was graded from A (high quality) to C (low quality) according to these predefined criteria. At least two reviewers independently assessed validity. Any disagreements were discussed by the entire project group until consensus was reached.

**Data extraction**
At least two reviewers independently extracted the data using a pilot-tested form. Any disagreements were discussed by the entire project group until consensus was reached. For each study, the coronal caries increment in permanent and deciduous dentition was extracted, while the prevented fraction for each treatment group and the number of tooth surfaces saved per year with the treatment were either extracted or calculated.

**Methods of synthesis**
How were the studies combined?
The studies were grouped by type of dentition (primary or permanent) and type of control (placebo or no treatment and other fluoride regimens). The mean prevented fraction across studies was calculated and presented, along with the range for each grouping. The level of evidence for each grouping was graded as strong, moderate, limited or inconclusive.

How were differences between studies investigated?
Heterogeneity was not formally assessed.

**Results of the review**
Twenty-four trials with a total of 12,371 participants were included in the review. There were 12 RCTs and 12 CCTs.

Primary dentition (3 trials).

One of the three studies that assessed fluoride varnish in the primary dentition of children was graded as moderate level of evidence, whilst the other two studies were graded as low level of evidence. Therefore, the evidence in this group was classed as inconclusive.

Young permanent dentition (21 trials).

The mean prevented fraction was 30% (range: 0 to 69) when professional fluoride varnish treatments were compared with placebo or no treatment (12 trials), and 17.8% (range: 0 to 52) when compared with other fluoride regimens (9 trials). The average number of saved permanent tooth surfaces was 0.4 (range: 0 to 1.6) per child per year in comparison with placebo or no treatment, and 0.3 (range: 0 to 1.6) in comparison with other fluoride regimens.

Six of the 12 trials with a placebo or no-treatment control group were graded as moderate level of evidence, while the other 6 trials were graded as low level of evidence. Therefore, the evidence in this group was classed as limited. Eight of the 9 trials with a fluoride control group were graded as moderate level of evidence, with the remaining trial graded as low level of evidence. There were conflicting findings amongst these studies and the majority demonstrated non significant results. Therefore, the evidence in this group was classed as inconclusive.

None of the included trials reported any serious adverse events.

**Authors’ conclusions**
There was limited evidence that professional fluoride varnish treatment has a caries-preventive effect in permanent teeth in children and adolescents. In adults and children with primary dentition the evidence was inconclusive. The evidence was also inconclusive for the efficacy of different fluoride varnishes and different frequencies of application.

**CRD commentary**
The review question was clear in terms of the study designs, intervention, participants and outcomes of interest. A limited number of relevant electronic databases were searched, although the search terms were reported. No attempts to
identify unpublished studies were made, thus increasing the potential for publication bias. Studies reported in eight languages were included, which reduces the potential for language bias. The study selection, data extraction and quality assessment processes were carried out in duplicate, thus reducing the potential for errors and reviewer bias. Study quality was assessed using appropriate criteria, and the overall level of evidence was graded and presented alongside the results.

Adequate details of the included studies were tabulated. The data were appropriately grouped, but were averaged across studies without a prior assessment of heterogeneity. Point estimates and 95% confidence intervals of treatment difference were not presented graphically, so it was not possible to assess the extent of differences in outcomes across the studies. The wide range of results observed across the studies suggests that averaging the values might not have been appropriate. The authors commented that some studies showed conflicting results, but did not discuss or explore potential reasons for such differences. Whilst this was a reasonably well-conducted systematic review, the limited evidence identified and the poor quality of the included studies have a detrimental effect on any attempts to draw firm conclusions about the effectiveness of professional fluoride varnish treatments. The authors' tentative conclusions are supported by the evidence presented.

**Implications of the review for practice and research**
Practice: The authors did not state any implications for practice.

Research: The authors stated that high-quality clinical research, incorporating modern concepts of clinical performance and evaluation, is required to assess the control of dental caries using professional fluoride varnish.

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