A meta-analysis of clinical studies on the caries-inhibiting effect of fluoride gel treatment

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Authors' objectives
To calculate the caries-inhibiting effect of clinical fluoride gel treatment in children aged 6 to 15 years, and to explore factors potentially modifying this effect.

Searching
MEDLINE was searched from 1965 to 1995 for papers published in English or German, using the following keywords: 'fluoride', 'gel' and '(dental) cavities'.

Study selection
Study designs of evaluations included in the review
Randomised clinical trials on study populations representative of the general population. The studies compared fluoride gel treatment versus no treatment or placebo treatment.

Specific interventions included in the review
Fluoride gel application. A variety of gel types were used, including 1.1% acidulated phosphate fluoride (APF), 1.23% APF, 1.1% sodium fluoride (NaF), 0.4% stannous fluoride (SnF2), 0.78% monofluorophosphate (MFP), and 0.4% amino fluoride (AmF). The gel was administered using a tray or brush, by professionals, 'self supervised' or self. The application frequency ranged from 1 to 360 applications per year.

Participants included in the review
The participants were children aged 6 to 15 years at the start of the study. The prevalence of decayed, missing and filled surfaces (DMFS) ranged from 0.7 to 10.1.

Outcomes assessed in the review
The outcome assessed was preventative fraction (PF), which measures the reduction in the incidence of caries with fluoride gel treatment relative to the incidence in the control group.

How were decisions on the relevance of primary studies made?
The studies for consideration were evaluated independently by two examiners.

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

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

Methods of synthesis
How were the studies combined?
Ninety-five per cent confidence intervals (CIs) were calculated for the PF values on the basis of the binomial distribution. The PF was obtained by calculating the difference between the incidence of DMFS in the control and experimental groups, and dividing by the incidence of DMFS in the control group. The overall 95% CIs were assessed by weighting the individual PFs for reciprocal error variance. A multiple regression (weighted according to the reciprocal standard error) was performed to detect those factors influencing the caries-inhibiting effect of fluoride gel application (effect modifiers).
How were differences between studies investigated?
The authors do not state how differences between the studies were investigated.

Results of the review
Seventeen studies (19 data sets) comprising 8,263 participants were included.

A funnel plot to investigate publication bias showed an almost complete funnel-shaped plot. However, the lower left corner of the funnel lacked publications, indicating that some studies with small sample sizes showing small effects are probably missing.

The overall PF of the fluoride gel treatment studies indicated that the reduction of caries incidence by fluoride gel treatment was 22% (95% CI: 18, 25) relative to the incidence group. Multiple regression analysis showed no significant influence of the variables 'baseline caries prevalence', 'general fluoride regimen', 'application method' (tray/brush) and 'application frequency' on the PFs. A strong correlation was found between 'application method' and 'application frequency', implying that the effect of these variables should not be examined separately.

The number-needed-to-treat, based on the average 22% PF (95% CI: 18, 25), was 18 in a population with a caries incidence of 0.25 DMFS per year, and 3 in a population with a caries incidence of 1.5 DMFS per year (the treatment duration was 1 year).

Cost information
Yes. The authors presented cost-effectiveness calculations for the fluoride gel treatment situation in the Netherlands, where the twice-a-year application of fluoride gel is still often routine action in dental offices. They calculated that the effort required to prevent 1 DMFS by fluoride gel treatment costs DFL 4,455 and DFL 795 for children in the high- and low-socio-economic status groups, respectively. This means that the cost-to-effect relationship of fluoride gel application in this child population is unfavourable, even in the low-socio-economic status group.

Authors' conclusions
The included trials showed a 22% overall caries-inhibiting effect resulting from fluoride gel treatment.

A funnel plot indicated that studies with small sample sizes and small effects were probably missing. The effect of this publication bias on the overall PF will be marginal, because the weight of such unpublished low-power studies is only small.

The variables 'baseline caries prevalence', 'general fluoride regimen', 'application method' and 'application frequency' did not significantly affect the caries-inhibiting effect of fluoride gel treatment.

From the current standpoint of cost-effectiveness, the additional effect of fluoride gel treatment in current low populations of children with even moderate caries incidence must be questioned.

CRD commentary
The review focused on a well-defined question.

The search was very narrow and could have been extended to include other databases, such as EMBASE, and an attempt to identify unpublished material by contacting experts in the field. The inclusion and exclusion criteria were reported. These criteria were appropriate, with the exception that studies in which more than two thirds of the participants dropped out were excluded. Studies with high drop-out rates should be included so that the reasons for drop-out can be explored. The validity of the included studies was not assessed. Details of the individual studies were presented, although it would have been useful to have included drop-out rates. Studies were combined without being tested for heterogeneity first.

The authors' conclusions follow from the results.
Implications of the review for practice and research
The authors state that future clinical studies should focus on the additional caries-inhibiting effect of professionally and self-applied fluoride gel treatment using trays, in a population which is representative of the present low caries-active child population generally using fluoride toothpaste. The effectiveness of fluoride gel treatment has to be evaluated according to application frequencies. In addition, the caries risk status of the participants has to be compared with the effectiveness of other preventive methods, including cost-to-effect relations.

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