

Fluoride gel effective at reducing caries in children

Abstracted from

Marinho VC, Worthington HV, Walsh T, Chong LY.

Fluoride gels for preventing dental caries in children and adolescents.

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Address for correspondence: Luisa Fernandez Mauleffinch, Managing Editor, Cochrane Oral Health Group, School of Dentistry, The University of Manchester, JR Moore Building, Oxford Road, Manchester, M13 9PL, UK.

E-mail: luisa.fernandez@manchester.ac.uk

Question: Are fluoride gels safe and effective at preventing caries?

Data sources Cochrane Oral Health Group Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL), Medline, Embase, CINAHL, LILACS, ProQuest Dissertations and Theses, the Web of Science Conference Proceedings, ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform.

Study selection Randomised or quasi-randomised controlled trials comparing topically applied fluoride gel with placebo or no treatment in children up to 16 years were considered. Studies had to be at least one year in duration with a frequency of application of at least once a year with blind outcome assessment. The main outcome was caries increment measured by the change in decayed, missing and filled tooth surfaces in both permanent and primary teeth (D(M)FS and d(e/m)fs).

Data extraction and synthesis At least two reviewers extracted data and assessed risk of bias. The primary measure of effect was the prevented fraction (PF). Where data could be pooled random-effects meta-analyses were conducted. Potential sources of heterogeneity were examined in random-effects meta-regression analyses.

Results Twenty-eight trials involving 9140 children and adolescents were included. Most of the studies (20) were at high risk of bias, with eight at unclear risk of bias. Twenty-five trials (8479 participants) provided data for meta-analysis on permanent teeth, with a D(M)FS pooled prevented fraction (PF) estimate of 28% (95% CI; 19-36%; $P < 0.0001$; with substantial heterogeneity ($P < 0.0001$; $I^2 = 82\%$); moderate quality evidence). Subgroup and metaregression analyses suggested no significant association between estimates of D(M)FS prevented fractions and the prespecified trial characteristics. However, the effect of fluoride gel varied according to the type of control group used, with D(M)FS PF on average being 17% (95% CI 3% to 31%; $P = 0.018$) higher in non-placebo-controlled trials (the reduction in caries was 38% (95% CI 24% to 52%; $P < 0.0001$, 2808 participants) for the ten trials with no treatment as control group, and 21% (95% CI 15% to 28%; $P < 0.0001$, 5671 participants) for the 15 placebo-controlled trials.

A funnel plot of the 25 trials in the D(M)FS PF meta-analysis indicated a relationship between prevented fraction and study precision, with an apparent lack of small studies with statistically significant large effects.

For primary teeth the d(e/m)fs pooled prevented fraction estimate for the three trials (1254 participants) = 20% (95%CI; 1% - 38%; $P = 0.04$; with no heterogeneity ($P = 0.54$; $I^2 = 0\%$); low quality evidence).

There was limited reporting of adverse events. Only two trials reported information on acute toxicity signs and symptoms during the application of the gel (risk difference 0.01, 95% CI -0.01 to 0.02; $P = 0.36$; with no heterogeneity ($P = 36$; $I^2 = 0\%$); 490 participants; very low quality evidence). None of the trials reported information on tooth staining, mucosal irritation or allergic reaction.

Conclusions The conclusions of this updated review remain the same as those when it was first published. There is moderate quality evidence of a large caries-inhibiting effect of fluoride gel in the permanent dentition. Information concerning the caries-preventive effect of fluoride gel on the primary dentition, which also shows a large effect, is based on low quality evidence from only three placebo-controlled trials. There is little information on adverse effects or on acceptability of treatment. Future trials should include assessment of potential adverse effects.

Commentary

Dental caries remains a significant public health problem, with untreated caries in permanent teeth being the most prevalent condition noted in the 2010 Global Burden of Disease study.¹ Around 35% of the global population, or 2.4 billion people, are affected, with the World Health Organisation estimating that it is the fourth most expensive chronic disease to treat.² Consequently, the prevention of caries in children and adolescents is considered a priority for dental services. Topical fluoride is available in a number of formats eg toothpastes (dentifrices), mouthrinses, gels and varnishes and widely used in caries prevention programmes and widely recommended in evidence-based guidelines.³⁻⁴

This current review is an update of the Cochrane review of fluoride gels for preventing caries in children and adolescents that was first published in 2002 and is one of a series of Cochrane reviews on topical fluoride interventions.⁵⁻¹⁴

The review has been conducted using the usual robust Cochrane methodology and it is worth noting that one of the inclusion criteria is that studies were required to have used blind outcome assessment. This update adds just three new trials to the review; a majority (12) were conducted in the 1960s, seven in the 1970s, five in the 1980s,

This paper is based on a Cochrane Review published in the Cochrane Library 2015, issue 6 (see www.thecochranelibrary.com for information). Cochrane Reviews are regularly updated as new evidence emerges and in response to feedback, and the Cochrane Library should be consulted for the most recent version of the review.

one in the 1990s with another three trials conducted in the late 1990s and early 2000s. A range of fluoride concentrations (2425 ppm F to 12,500 ppm F) were used in the studies with application being carried out by professionals (operator applied) in seventeen studies.

Overall the review demonstrates an average 28% reduction in decayed missing and filled surfaces in the permanent teeth with the confidence interval suggesting that the true effect could lie somewhere between 19-36%. The authors highlight that a smaller reduction of 21% was seen in trials that used a placebo gel compared with those trials where the control group received no treatment, which demonstrated a 38% reduction. Fewer trials were conducted on primary teeth, with the available evidence suggesting a 20% reduction in decayed, missing and filled tooth surfaces. There was little information in the included studies on adverse effects. There was not sufficient information available to assess the impact of initial level of caries severity, background exposure to fluoride, mode of use frequency of use or fluoride concentration.

One potential concern about the findings is linked to the age of the included studies with many having been published prior to the widespread availability of fluoride toothpaste. In their discussion the review authors' note that the data from the three studies conducted in the Netherlands and published in the 2000s demonstrated similar effects to those of the overall pooled sample.

In conclusion, this review provides moderate quality evidence that fluoride gels provide a 28% reduction in decayed missing and filled teeth. While this represents an important level of caries reduction, these gels are typically applied in trays with application times varying from 2-10 minutes and anecdotally many patients find this unpleasant, (I certainly did when receiving fluoride gel treatment as a child), and nausea, vomiting, headache and abdominal pain have been reported. As a result there has been an increasing in use in fluoride varnish, which has been shown to have a larger caries reduction (43%) and is easier to apply.⁵

Derek Richards

*Centre for Evidence-based Dentistry, Dental Health Services
Research Unit, Dundee University, Scotland, UK*

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