

CRITICAL SUMMARIES

Limited evidence suggests fluoride mouthrinse may reduce dental caries in children and adolescents

A critical summary of Marinho VCC, Chong LY, Worthington HV, Walsh T. Fluoride mouthrinses for preventing dental caries in children and adolescents. *Cochrane Database Syst Rev*.2016;7:CD002284.

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Systematic review conclusion. Within the limitations of the evidence in this systematic review (SR), the authors concluded that supervised regular use of a fluoride mouthrinse may result in large reductions in caries in the permanent teeth of children and adolescents, particularly in a school setting but also possibly in other settings such as at home, but with the caries-preventive effect being less clear.

Critical summary assessment. This SR of 37 randomized or quasi-randomized controlled trials with high or unclear risk of bias reports moderate quality evidence that a fluoride mouthrinse may reduce caries increment in the permanent teeth of children and adolescents.

Evidence quality rating. Limited.

Clinical question. In children and adolescents, does fluoride mouthrinse prevent dental caries compared with a placebo or no treatment?

Review methods. The reviewers searched 9 databases with no restriction on language or date of publication up through April 22, 2016. They searched for ongoing trials in 2 trial registries, searched the reference lists of the retrieved articles for relevant studies, contacted authors for additional information when indicated, and incorporated unpublished trials from a manufacturer in the search. They included randomized, quasi-randomized, and cluster-randomized (except when only 1 cluster was assigned to each study group) controlled trials conducted with follow-up that were at least 1 year or 1 school year in duration in which blinded outcome assessment was stated or indicated comparing fluoride mouthrinse with placebo or no treatment in children

or adolescents 16 years or younger. They excluded studies that did not report blinded outcome assessment or when it was unlikely to have been used. They also excluded split-mouth studies, as contamination of fluoride becomes unavoidable, and studies in which investigators selected for specific oral or general health conditions. The reviewers excluded studies with other caries-preventive agents or procedures, such as sealants. At least 2 reviewers independently selected the studies, extracted data, and assessed risk of bias. The SR authors used accepted methods and standards for assessing risk of bias, and a third reviewer resolved any disagreements.¹ Risk of bias was assessed in 8 domains: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, balance of baseline characteristics, and from contamination

or co-intervention. The main outcome assessed was the change in caries increment in decayed, missing, and filled surfaces (DMFS) in permanent teeth or primary teeth, which was reported as a prevented fraction (PF), and or changes in caries increment in the permanent or primary teeth themselves (decayed, missing, and filled teeth [DMFT]). Dental caries were defined as clinical and radiographic lesions recorded at the dentin level of diagnosis. The primary objective was to assess the effectiveness and safety of fluoride mouthrinse in preventing dental caries in children and adolescents. The secondary objective was to assess whether the effect of the fluoride mouthrinse was affected by initial level of caries severity; background exposure to fluoride in water, salt, toothpastes, or other fluoride sources other than those in the study; or the fluoride concentration (parts per million of fluoride [ppm F]) or frequency of use (times

per year). The reviewers conducted the meta-analyses using the random-effects model to pool the data when possible. They conducted the SR and assessed the quality of the evidence according to accepted methods and standards.^{2,3}

Main results. A total of 37 trials involving 15,813 children and adolescents, aged 6-14 years, were included. Nearly all of the trials were conducted in schools on the supervised use of fluoride mouthrinse except for 2 studies that were conducted in a home-based setting. Most of the participants received sodium fluoride rinses to rinse for 1 to 2 minutes on either a 230 ppm F daily or a 900 ppm F weekly or every 2 weeks. Twenty-eight studies were at high risk of bias, with 9 studies at unclear risk of bias. The PF was defined as the difference in mean caries increments between treatment and control groups expressed as a percentage of the mean increment in the control group. PF values

between 1% and 10% were considered mostly a small effect; 10% to 20%, mostly a moderate effect; and over 20%, mostly a large or substantial effect. A meta-analysis of 35 trials (15,305 participants) with data on permanent tooth surfaces showed the DMFS pooled PF was 27% (95% confidence interval [CI], 23%-30%; $P < .0001$; $I^2 = 42\%$), which suggested a large effect. A meta-analysis of 13 trials (5,105 participants) with data for the permanent teeth (rather than tooth surfaces) showed the DMFT pooled PF was 23% (95% CI, 18%-29%; $P < .0001$; $I^2 = 54\%$), which suggested a moderate to large effect. The evidence in both meta-analyses were of moderate quality.³ Investigators found no significant association between estimates of DMFS PFs and baseline caries severity, background exposure to fluorides, rinsing frequency, or fluoride concentration in the meta-regression analyses. A funnel plot of the 35 studies in the

DMFS pooled PF meta-analysis did not show evidence of publication bias.

Conclusions. Within the limitations of the available evidence, the SR authors concluded, with moderate certainty of the size of the effect, that supervised use of a fluoride mouthrinse is associated with a large reduction in caries increment tooth decay in the permanent teeth of children and adolescents. Most of the results were from studies performed in school-based settings, but they may be applicable to other supervised or unsupervised settings, although the size of the effect may be less clear.

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COMMENTARY

Importance and context. Dental caries is the most prevalent chronic disease, with untreated caries in permanent teeth affecting 35% of the global population, including 60% to 90% of school-aged children and most adults.⁴⁻⁶ Children in lower socioeconomic groups often have more caries. If left untreated, dental caries may progress to the destruction of tooth structure and even lead to tooth pain; it is the fourth most expensive chronic disease to treat as reported by the World Health Organization.⁷ Besides toothpaste, fluoride may be applied to teeth in a mouthrinse as an extra preventive measure to promote remineralization of early carious lesions and inhibit demineralization of tooth structure.⁸ A fluoride mouthrinse is not recommended for children younger than 6 years. For those children 6 years or older, the supervised use of a fluoride mouthrinse has been frequently used in school-based programs to prevent caries. Prevention of dental caries in children and adolescents is considered more cost-effective than its treatment.⁹ This SR updates the 2003 Cochrane review of the use of a fluoride mouthrinse for preventing dental caries in children and adolescents.¹⁰

Strengths and weaknesses of the systematic review. The SR had a focused clinical question and clearly described the inclusion and exclusion criteria and assessed the risk of bias and quality of the evidence using accepted methods and standards.¹⁻³ The SR authors had an extensive detailed search strategy in each database, and they searched with no restriction on language or date of publication. The SR authors did not include any hand searching in relevant journals, although they did incorporate a list of records as provided from 1 manufacturer for unpublished trials. The authors contacted study investigators for missing data and to clarify if inclusion criteria were met. This updated review included 1 new RCT that was carried out in Sweden in the early 2000s that also reported a large effect of using a fluoride mouthrinse in participants with a lifetime use of fluoride toothpaste. The SR had detailed tables of the characteristics of the included studies, and at least 2 reviewers performed the study selection and data extraction. However, the authors did not assess the interrater reliability or the agreement among the reviewers such as with κ statistics.¹¹ With study investigators having different protocols on how

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