Critical Appraisal of the Cochrane Systematic Review on Water Fluoridation for the Prevention of Dental Caries

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Original study being reviewed: Water fluoridation for the prevention of dental caries. Iheozor-Ejiofor Z, Worthington HV, Walsh T, et al. Cochrane Database of Syst Rev 2015;6: CD010856.

Background
Dental caries is a chronic oral disease that continues to be highly prevalent in the United States and globally, and it remains a public health concern. Community water fluoridation, considered a key public health strategy for the prevention of dental caries, was initiated in the United States in 1945 and is currently practiced in approximately 25 countries.

Clinical question
What is the effect of water fluoridation (artificial or natural) on tooth decay prevention and on fluorosis of tooth enamel?

Summary and methods
A wide range of databases were searched from 1975 to February 2015 by two review authors, independently and in duplicate, who screened the titles and abstracts using a selection criteria and a validity assessment checklist.

Critical appraisal
The review process met the criteria of a well-conducted systematic review following established research requirements. The data for this review were extracted from prospective studies. The majority of the studies were conducted prior to 1975. The applicability of the results to current lifestyles is unclear because 71% of the studies examining tooth decay were conducted before fluoride toothpastes and other preventive measures were widely used in many US communities. The review for risk of bias showed 97% of the studies were at high risk for bias, which reduces the overall validity of the results.

Practical implications
Although findings from studies have demonstrated the effectiveness of fluoride at reducing the level of dental caries in adults and children, the studies in this review provided insufficient data to determine the effect that stopping water fluoridation programs would have on caries levels. More research is needed to understand the contribution of fluoride from sources other than water.

Int J Evid Based Pract Dent Hygienist 2016;2:33–36. doi: 10.11607/ebh.47

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Evidence summary

Background

Despite the improvement in the oral health of the American public, there are population groups that experience a disproportionate burden of dental decay, which on an individual level can have an impact on quality of life and productivity. In the United States, water fluoridation has been established as one of the greatest public health achievements and has been beneficial in reducing the prevalence of dental caries.[1]

In addition to community water fluoridation, other fluoride interventions have proven caries-protective benefits. There is strong evidence that the use of fluoridated toothpastes, gels, varnishes, and mouthrinses can be effective in controlling the progression of carious lesions.[2]

The prevalence of dental fluorosis is affected by changes in fluoride exposure from drinking water and is related not only to the timing of fluoride intake relative to the periods of tooth formation, but also to the cumulative duration of fluoride exposure.[3] Dental fluorosis can range from mild white patches on the teeth to severe mottling with brown staining that is considered to be an esthetic concern.

Clinical question

What is the effect of water fluoridation (artificial or natural) on tooth decay prevention and on fluorosis of tooth enamel?

Methods

This review is an update of the review by McDonagh et al[4] in 2000, with many of the studies conducted prior to the widespread use of fluoride toothpastes. The studies for this review were selected from a wide range of electronic databases (the Cochrane Oral Health Group's Trials Register, the Cochrane Central Register of Controlled Trials, EMBASE via OVID, Proquest, Web of Science Conference Proceedings, ZETOC Conference Proceedings, and other resources) using a search strategy developed for MEDLINE, which was revised depending on the database using keywords and MESH terms.

The study selection criteria included prospective studies with a concurrent control group that investigated water fluoridation for the prevention of dental caries and water fluoridation and dental fluorosis. The criteria included data selected before community water fluoridation was initiated. As a result, a significant amount of research on community water fluoridation was excluded. Inappropriate study design was the reason mentioned most often for the exclusion of articles.

The outcome measures included caries indices such as dmft and DMFT (decayed/missing/filled primary and permanent teeth) and proportion caries-free in both dentitions in the analyses. The prevalence of dental fluorosis was reported for the primary and permanent dentition as measured by the standard dental fluorosis indices used in epidemiology. Studies in another language were translated to English and included in the review. Possible sources of heterogeneity were explored, such as the differences in fluoridation technique, fluoride concentration, and outcome measurement indices and techniques. The studies were assessed by two authors independently and in duplicate using the inclusion criteria. Disagreements were discussed and a third review author was consulted when necessary.

Results

Of the 155 studies (162 publications) that met the inclusion criteria for the review, only 107 studies provided sufficient data for quantitative synthesis. A total of 20 prospective observational studies provided data on caries outcomes, disparities in caries, or both. One of the studies assessed dental caries outcomes of the same 12-year-old children who lived in fluoridated and nonfluoridated areas over 4 years. Data extracted from 92 studies reported findings on either fluorosis severity or fluorosis of esthetic concern at a population level. A total of 112 studies were excluded from the search, most frequently due to inappropriate study design as a result of the absence of data, unsuitable control groups, or absence of a concurrent control group. Three prospective observational studies met the inclusion criteria for disparities in caries but did not provide data suitable for analysis. The majority of studies (71%) were conducted prior to 1975 and the widespread introduction of the use of fluoride toothpaste.

The assessment of heterogeneity was not conducted due to the limited data and lack of clarity in reporting within the caries studies. The Cochrane risk of bias assessment tool was adapted for use with the prospective studies in this review and assessed domains that included sampling, confounding, blinding of outcome assessment, completeness of outcome data, risk of selective outcome, and risk of other potential sources of bias. For this review, important confounders were identified for the primary (dental caries) and secondary (dental fluorosis) outcomes, such as sugar consumption/dietary habits, status (SES), ethnicity, and use of other fluoride sources. The results showed data that over 97% of the 155 studies were at a high risk of bias, which reduces applicability of the evidence to current lifestyles.

The results from the caries severity data indicate that the initiation of water fluoridation results in mean differences (reductions) in dmft of 1.81 (95% confidence interval [CI] = 1.31 to 2.31) and in DMFT of 1.16 (95% CI = 0.72 to 1.61). This translates to a

35% reduction in dmft and a 26% reduction in DMFT compared with the median control group mean values. There were also increases in the percentage of caries-free children: 15% (95% CI = 11% to 19%) in primary dentition and 14% (95% CI = 5% to 23%) in permanent dentition.

There is insufficient information to determine whether initiation of a water fluoridation program results in a change in disparities in caries across SES levels. There is also insufficient information to determine the effect on caries levels of stopping water fluoridation programs. No studies that aimed to determine the effectiveness of water fluoridation in preventing caries in adults met the review's inclusion criteria. With regard to dental fluorosis, it was estimated that for a fluoride level of 0.7 ppm the percentage of participants with fluorosis of esthetic concern (defined as moderate to severe) was approximately 12% (95% CI = 8% to 17%). This increases to 40% (95% CI = 35% to 44%) when considering fluorosis of any level (detected under highly controlled clinical conditions). When controlling for study effect, the odds of dental fluorosis increased by a factor of 3.13 for each one-unit increase of fluoride exposure (1 ppm F).

There were several weaknesses of the review data and within the included studies. Over 97% of the studies were at high risk of bias and there was substantial between-study variation. The confidence in the size of the effect estimates is limited due to the observational design of the studies, in addition to the high risk of bias within the studies and the application of the evidence to individual lifestyles. There was limited reporting of adverse effects other than dental fluorosis in the included studies.

Conclusions

The authors concluded that there is insufficient information to determine the effect on caries levels of stopping water fluoridation programs. The evidence in this review is limited due to high risk of bias within the studies as well as substantial between-study variation. However, a significant association was detected between dental fluorosis (of esthetic concern for all levels of fluorosis) and fluoride level. The authors noted that more research is needed to understand the contribution of fluoride from sources other than water. The exclusion/inclusion criteria used to determine which studies to include in further analysis may be less appropriate for community interventions such as water fluoridation.

Critical appraisal

To evaluate the quality of this systematic review, the AMSTAR[5] criteria for assessing systematic reviews were applied. The AMSTAR assessment demonstrated that this review met the criteria and was well conducted, as all of the key factors were addressed. The meta-analysis provides an update and a current systematic review that reflects any emerging contemporary evidence and follows the objectives established in the McDonagh et al 2000 review.[4] The method used to identify reports for this review followed a predetermined inclusion-exclusion criteria for all research publications relevant to the review objective.

The articles that met the inclusion criteria were retrieved from the electronic database and other sources and assessed by two review authors independently and in duplicate. Data extraction was conducted using specifically designed data-extraction forms. If there was any disagreement regarding a study not meeting the inclusion criteria, a third review author was consulted to gain consensus. The authors of this review disclosed any conflict of interest.

To obtain the articles for this review, a comprehensive literature search was conducted from seven electronic databases, with no restrictions on the language of the publication, as well as CENTRAL and other databases for ongoing trials. The result of one unpublished study was included in the analysis. A hand search was also conducted as part of the Cochrane worldwide handsearching programme. Any excluded articles were recorded and the reason for their exclusion was reported. The PRISMA flow diagram provided the search, screening results, and selection of included studies. The characteristics of the included studies were provided in summary tables that included the research design and participant details such as gender, SES, disease status, duration of the intervention, and other reported diseases.

To evaluate the effects of water fluoridation (artificial or natural) on the prevention of dental caries, only prospective observational studies were selected. Due to the nature of the research question, randomized controlled trials were not feasible. As a result, random sequence generation or allocation concealment was not discussed, as these were not relevant to the prospective study design.

The results and quality of evidence for each outcome were presented in the summary of findings table, applying the Grading of Recommendations Assessment, Development, and Evaluation

(GRADE)[6] criteria as stated in the review protocol. However, as the primary and secondary outcomes of this review are based on public health interventions, which are often rated as low quality, the authors reached a consensus not to use the GRADE[6] terminology, but to discuss the findings in terms of the authors' confidence in the results. Therefore, the authors concluded that the confidence in the size of the effect estimates is limited by the observational nature of the study designs.

In this review statistical pooling of the data was conducted and standard deviations were imputed when necessary. The pooled estimates demonstrated an increase in the proportion of caries-free children in the areas with water fluoridation (0.15 for primary teeth and 0.14 for permanent teeth). The proportion caries-free analysis calculated the difference between the fluoridated and control groups. The fluorosis data were calculated to present the log odds, which were shown as probabilities for interpretation. The evidence is limited due to high risk of bias within the studies and substantial between-study variation.

An assessment of the risk of bias of all studies was recorded using the Cochrane risk of bias assessment tool adapted for nonrandomized controlled studies. Tabulation and a description of the risk of bias domains were provided for each trial, along with a judgment of low, high, or unclear risk of bias. All of the studies were assessed to be at high risk of bias confounding. The review author's judgment about each risk of bias item for each included study is summarized graphically.

In support of the evidence from this meta-analysis are the results of a study that tested the association between water fluoridation schemes and selected health outcomes, which showed strong evidence of lower prevalence of dental caries among children living in fluoridated areas and no strong evidence of an association between fluoridation and adverse health outcomes.[7] An update to the recommendations on water fluoridation was conducted by the Community Preventive Services Task Force. An examination of over 150 articles provided results that showed strong evidence of the effectiveness of water fluoridation in reducing dental caries across all age groups.[8]

Fluoridation of community drinking water is recognized among the top 10 greatest public health achievements in the world in the last century.[1] For practitioners it is important to be knowledgeable about community water fluoridation levels and their patients' tap water consumption. This information is essential when recommending an oral health intervention, as the number of fluoride sources have increased. These factors as well as a patient's oral hygiene habits and diet are assessed to determine the patient's risk for dental disease. The evidence demonstrates that residents of communities with water fluoridation exhibit a decrease in dental decay compared with residents of nonfluoridated communities, without adverse effects, and that water fluoridation is a safe, cost-effective population-based preventive measure.

Acknowledgments

The author reports no conflicts of interest related to this article.

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