5,000 ppm F dentifrice for caries prevention in adolescents

Abstracted from

Nordström A, Birkhed D.

Preventive effect of high-fluoride dentifrice (5,000 ppm) in caries-active adolescents: a 2-year clinical trial. *Caries Res.* 2010; **44**: 323–331

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Question: In caries-active adolescents how effective is a 5,000 ppm F dentifrice compared with a 1,450 ppm F dentifrice in preventing caries?

Design Randomised controlled trial

Intervention Volunteers aged 14–16 years with DMFS ≥ 5 were recruited, those with orthodontic appliances were excluded. Participants were assigned dentifrices for unsupervised toothbrushing. The test group received Duraphat 5,000 ppm F (Colgate-Palmolive AB, Danderyd, Sweden) and the control group Pepsodent Superfluor 1,450 ppm F (Lever Fabergé, Stockholm, Sweden), both as NaF. Toothbrushes and dentifrices were delivered to their home addresses by post, every third month. Participants and their parents were instructed to keep the 5,000 ppm dentifrice in a safe place away from small children. Evaluations were carried out at two years and a compliance questionnaire was administered.

Outcome measure The outcome variables were caries incidence and progression of proximal and occlusal caries.

Results 28% of participants were considered to have had poor compliance as assessed by questionnaire. Those using 5,000 ppm F toothpaste had significantly lower caries progression compared to those using 1,450 ppm F toothpaste with a prevented fraction of 40%, with those with poorer compliance showing a slightly higher prevented fraction (42%).

Conclusions The 5,000 ppm toothpaste therefore appears to be an important vehicle for the treatment and prevention of caries in patients with a high caries risk. The data may indicate that 5,000 ppm toothpaste has a greater impact on individuals who do not use toothpaste regularly or do not brush twice a day.

Commentary

This well designed study looked at the clearly focussed question of whether dentifrice containing 5000 ppm fluoride is more effective than a dentifrice containing 1450ppm fluoride in caries-active adolescents. The study is important and increasingly relevant to the delivery of preventative dentistry. Recent commentary in the EBD¹ highlighted the effectiveness and relative cost-benefit of high concentration fluoride toothpaste when compared to fluoride varnish for an older age group within care homes. The recently published SDCEP guidance (www.sdcep.org.uk/index.aspx?o=2858) recommends the prescribing of 2800ppm toothpaste for children over ten years who are at higher caries risk.

The participants were randomised into two different groups. The authors chose an unusual, simplified randomisation method. Instead of using conventional randomisation methods, (eg using randomisation tables or computer generated randomisation) the participants were numbered and placed into groups based on whether they were an even or odd number. This method of allocation (alternate allocation) is not ideal. According to the Cochrane handbook (www.cochrane-handbook.org/) if future assignments can be anticipated, either by predicting them or by knowing them, then selection bias can arise. This selection bias may occur as the person recruiting trial participants may know the next intervention and may be influenced in the recruitment (<http://www-users.york.ac.uk/~mb55/msc/trials/howrand.htm>). This is the reason random allocation is recommended over alternate allocation.²

CASP, the Critical Appraisal Skills Programme³ recommends that researchers consider the balance of the groups at entry to the trial. Nordstrom gives clear information on ages of the participants, but unfortunately does not include other demographic information. Socioeconomic variables can influence caries.⁴ Within Nordström's study if there was disparity between the two groups socioeconomically, this confounding variable may have influenced caries. It is important within any study involving a clinical intervention to ensure that groups are evenly matched socioeconomically. In this case, matched socioeconomic groups would have increased the likelihood that caries risk was similar in both groups.

The authors note the study was single blinded, ie the person examining for caries was not aware of the type of toothpaste the participant was using. The authors advise that it was not possible for the manufacturer to provide the toothpaste in a form where the participant was unaware of the type of paste used. Knowledge of treatment allocation may have affected compliance and retention of trial participants, eg it might be that participants who were aware they were

on a higher dosage of fluoride toothpaste may have changed their brushing habits (eg they may have reduced the amount of toothpaste they used).⁵ To ensure participants were blinded one approach may have been to request a commercial pharmacy to re-package the toothpaste into coded tubes.

Keeping in line with CONSORT guidance (www.consort-statement.org), the authors provided a clear diagram with information on participant enrolment, intervention allocation, follow up and data analysis. The flow diagram shows that participants in all groups were followed up and data collected in the same way.

Although the authors provided written information within the results on participant drop outs, loss to follow-up, exclusion from analysis etc, in keeping with CONSORT it would have been useful to include this information on the flow diagram.

Within the study the radiographic examiner was calibrated by a radiology specialist. In addition intra-examiner reproducibility was checked by reanalysing 10% of radiographs. The reader is advised however that this intra-examiner reproducibility was only performed for the radiographs and not for the examinations.

Using scoring systems based on dentinal cavitation is problematic.⁶ The authors have overcome this by using a detailed scoring system for enamel and dentine caries.

The results are presented as preventive fraction, ie the difference in mean caries incidence between the two different toothpastes expressed as a percentage of the incidence and progression in the lower dose toothpaste.

Caries incidence and progression are displayed with means plus/minus SD. It might have aided clarity for the reader to have this

information provided as confidence intervals, which are more easily understood.

The difficulty within any clinical trial is determining, within the intervention period, the compliance of the participants. To overcome this problem the researchers developed a questionnaire to ask participants how often they brushed their teeth, and this information was used to analyse the effect of low compliance, high compliance and pooled compliance on caries rates within both groups.

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Practice points

- This study adds to the evidence that higher fluoride toothpastes are more effective at reducing dental decay than lower fluoride toothpastes.

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