summary

Chlorhexidine varnish use in high-caries-risk adolescents is questioned

Forge AH, Paterson M, Pine CM, Pitts NB, Nugent ZJ. A randomised controlled trial of the caries preventing efficacy of a chlorhexidine-containing varnish in high-caries-risk adolescents. *Caries Res* 2000; 34:432–439

Objective To assess the efficacy of a two-stage chlorhexidine varnish preparation (Chlorozin) in reducing caries in high-risk adolescents.

Design Randomised controlled trial in a community setting.

Intervention Children were randomised in four groups: active Chlorozin varnish, placebo Chlorozin varnish, positive control and an observational control. All groups except the observational group received comprehensive caries care advice, regular oral hygiene advice and demonstrations. Children were screened annually by a clinician who was blind to allocation groups.

Outcome measures DMFS increment at 3 years and *mutans* streptococci levels using CariesScreen (Knowell Therapeutics, Toronto, Ontario, Canada).

Results A temporary reduction in *mutans* streptococci was seen but there was no significant difference in the 3-year caries increment compared with the placebo varnish group (see Table 1).

Table 1 Results of chlorhexidine varnish use after 3 years

	Observational control	Positive control	Active varnish	Placebo varnish
n at start	324	324	268	324
Drop outs (n)	76	81	46	50
Mean DMFS increment (clinical and bite-wing radiographs)	10.68	10.91	11.03	10.24

Conclusions The study does not support the use of Chlorozin in the regimen evaluated for caries prevention in high-risk adolescents.

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Commentary

Balance, care and relevance are words that come to mind on reading the results of this trial, which compared four groups in a double-blind design with clear description of the study sample, treatments and placebos, examiner calibration and blinding, and outcome measures. Ethics of the study were cleared beforehand; the potential ethics dilemma was withholding of benefit in the placebo and observational groups, which was overcome by treatment of any caries that developed with closer than usual scrutiny.

Selection of 11 to 13-year-old children into the high-risk category was if whole stimulated saliva *mutans* streptococci numbers were approximately 250 000 cfu/ml; their mean DMFS score was 18% higher than the national average, which the authors say confirms the high risk.

The trial results showed that the groups were comparable at the beginning of the trial and 3 years later, that the mean caries increments between the groups did not differ significantly

and that reductions in *mutans* streptococci numbers were temporary. The main conclusion that the varnish did not prevent caries is supported by the data.

This is an important study that is a model for dental researchers, in my opinion; the authors must be congratulated on a logistically difficult study. The investigation has asked clear questions and the trial has been done in a community setting so that relevance is assured for the population that would normally receive the varnish. The design of the study has allowed proper statistical evaluation. My belief is that earlier studies of similar varnishes would not stand up to the rigour of the statistical analysis used in the current investigation.

The mean caries increments in the study groups over 3 years were pretty high, ranging between 10.24 and 11.03 DMFS with clinical observation and bite-wing radiographs that indicate the children studied could indeed be in a high-risk group. Classification of children into caries risk categories is difficult, however

and, in my opinion, the best way to do it is still not known. A semiquantitative salivary *mutans* streptococci test is used by many clinicians and researchers — I have used it myself in the past, and it was used in the current study — but I now doubt the value of organism counts, as I do for dietary assessments of an individual. In African populations we have not found strong associations between *mutans* streptococci counts and caries. Some method is needed to measure the resistance of an individual to caries. What I look forward to is finding out the caries increments in the low caries group not included in the publication.

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