summary

Chlorhexidine varnishes provide little benefit for children at low risk for caries

Fennis-le YL, Verdonschot EH, Burgersdijk RCW, König KG, van't Hof MA. Effect of 6-monthly applications of chlorhexidine varnish on incidence of occlusal caries in permanent molars: a 3-year study. J Dent 1998; 26:233–238

Objective To assess the effect of a chlorhexidine varnish on occlusal caries incidence when applied every 6 months into the fissures of erupting and freshly erupted permanent molars.

Design A double-blind randomised controlled trial.

Intervention Three hundred and thirty-two children aged 5/6 and 11/12 years, attending a Child Dental Health Centre were randomly assigned to a control and an experimental group. Criteria for inclusion were that all first permanent molars in 5/6-year-olds and all second permanent molars in 11/12-year-olds either had recently erupted, were erupting, or would erupt within 6 months every 6 months over a maximum of 3 years. The test group occlusal surfaces of molars had a 40% chlorhexidine varnish application, the control group had placebo varnish.

Commentary

This randomized controlled trial (RCT) evaluated the effect of 6-monthly applications of a 40% chlorhexidine diacetate varnish over 3 years, on dental caries incidence in the pits and fissures of first and secondary permanent molars. The control group received a sandarac-based varnish, an agent that was later discovered to have some antimicrobial activity.

Chlorhexidine varnish did not prevent dental caries in low-caries risk children compared with the "placebo". However, in 25 children (15%) with ≥ 10 mutans streptococci (MS) per ml of saliva at baseline, the varnish reduced the incidence of new carious lesions by 36% compared with the control group.

In evaluating the findings of RCTs, the CONSORT (Consolidated Standards for Reporting Trials) standards,¹ which were adopted in 1999 by the British Dental Journal,² and the Jadad *et al.* quality scale of RCTs³ provide useful guidelines. The design and conduct of a clinical trial impact on the strength of its finding.⁴ Low-quality RCTs, produce inflated treatment benefit in

comparison with good-quality RCTs.⁴ This study does not conform to all the CONSORT guidelines as it was published before this requirement but using the Jadad scale³ this RCT would receive a score of '1' for randomization, '1' for double blinding, and '1' for description of withdrawals and dropouts giving it an acceptable score of 3 out of 5 (a score of under 3 would indicate poor quality).

This study finds that children with low-caries risk in the Netherlands did not benefit from professional applications of a 40% chlorhexidine varnish. However, in children with a severe 'dental infection', chlorhexidine was effective.

Unfortunately, there are no accurate, simple, and cheap tests that can help dentists to identify patients with high MS levels. The currently marketed saliva tests for MS in some countries are at best crude. New developments may result in developing more accurate tests that can provide dentists with an immediate analysis of caries risk of a patient. In the meantime, dentists should use clinical, social-economic, behavioural and other markers of

Outcome measures Counts of dmfs/DMFS and mutans streptococci in saliva were recorded at baseline and end.

Results During a mean follow-up time of 2.5 years, there was no significant occlusal caries reduction using ANOVA in the 312 children completing the study. After stratification into low and high caries risk groups, a statistically significant caries-reducing effect on occlusal caries in permanent molars was found in children with $\ge 10^6$ mutans streptococci/ml saliva (P < 0.05).

Conclusion Six-monthly application of chlorhexidine varnish has no caries-reducing effect on occlusal caries in recently erupted permanent molars in a population with low caries prevalence.

Address for reprints: YL Fennis-le, Dept of Cariology and Endodontology, TRIKON: Faculty of Medicine and Dentistry, University of Nijmegen, P.O. Box 9101, NL-6500 HB Nijmegen, The Netherlands.

> dental caries activity as well as their "clinical judgment" to identify patients who would benefit from chlorhexidine varnishes and other anti-microbial interventions. For children with lowcaries risk, chlorhexidine varnishes do not seem to provide an additional benefit.

- Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin R, Rennie D *et al.* Improving the quality of reporting of randomized controlled trials. The CONSORT statement. JAMA 1996; 276:637–639.
- Needleman I. CONSORT. Consolidated Standards of Reporting Trials. Br Dent J 1999; 186:207.
- Jadad A, Moore A, Carroll D, Jenkinson C, Reynolds DJM, Gavaghan DJ *et al.* Assessing the quality of reports of randomized clinical trials: is blinding necessary. Control Clin Trials 1996; 17:1–12.
- Moher D, Pham B, Jones A, Cook D, Jadad A, Moher M *et al.* Does quality of reports of randomised trials affect estimates of interventions efficacy reported in metaanalyses? Lancet 1998; 352:609–606.

Amid Ismail

School of Dentistry, University of Michigan Ann Arbor, USA