Effect of a chlorhexidine mouthrinse on plaque, gingival inflammation and staining in gingivitis patients: a systematic review

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CRD summary
The authors concluded that, in patients with gingivitis, chlorhexidine mouthwash, together with oral hygiene, versus placebo or control mouthwash, significantly reduced plaque and gingivitis, but significantly increased staining. The review combined very different trials, and had limitations in the search; some of the pooled results should be interpreted cautiously.

Authors' objectives
To evaluate the effects of chlorhexidine mouthwash on plaque, gingival inflammation and staining in patients with gingivitis.

Searching
PubMed, EMBASE, and Cochrane Central Register of Controlled Trials (CENTRAL) were searched, in April 2011, for published articles, in English. The search strategy for PubMed was presented. The reference lists of selected articles were screened for further studies.

Study selection
Eligible for inclusion were randomised controlled trials comparing chlorhexidine mouthwash (alone or as an addition to therapy) with placebo rinse, control rinse, or regular oral hygiene, in healthy adults (at least 18 years old) with gingivitis. Trials had to last at least four weeks. The outcomes of interest were the mean scores for plaque, gingivitis, and bleeding (primary outcomes), and for tooth staining (adverse effect; secondary outcome). Trials of patients with periodontitis, prosthodontics, orthodontics, or implants were excluded.

The included trials were highly variable in their design, duration, and rinsing regimen. None of them assessed chlorhexidine mouthwash used alone. Patient characteristics varied, including their use of dentifrice. Half the trials mentioned industry funding. The specific outcome measures for plaque, gingivitis, bleeding, and staining, and other details were reported.

Two reviewers independently selected the trials. Disagreements were resolved by discussion, or with the involvement of a third reviewer.

Assessment of study quality
Trial quality was assessed using 17 criteria combined from several established tools. The criteria covered internal, external, and statistical validity. Seven criteria estimated the risk of bias, covering random allocation, comparable groups, blinding, appropriate comparison condition, loss to follow-up, and defined eligibility criteria. Allocation concealment was not initially assessed. Trials were classed as low, moderate, or high risk of bias.

Two reviewers assessed the quality of the included trials.

Data extraction
Mean values and standard deviations (or standard errors) were extracted for the outcomes of interest. Where necessary, missing data were imputed, using established methods, and trial authors were contacted for additional data.

The data were extracted by two reviewers.

Methods of synthesis
Where possible, weighted mean differences and 95% confidence intervals were calculated, using random-effects meta-analysis. A fixed-effect model was used in cases where there were fewer than four trials. Statistical heterogeneity was assessed using $\chi^2$ and $I^2$; up to 40% was considered to be unimportant.
Subgroup analyses were conducted analysing only trials assessed to be at low risk of bias. Publication bias was assessed in funnel plots, in cases where there were at least five trials.

**Results of the review**

Thirty trials were included in the review (range 20 to 597 participants, where reported). The risk of bias was estimated to be low in nine trials (when allocation concealment was added, three trials remained low risk), moderate in 10 trials, and high in 11 trials; the full results were reported.

Meta-analysis was possible for 13 trials that compared the effects of chlorhexidine mouthwash as an addition to oral hygiene, with placebo rinse, control rinse, or regular oral hygiene.

The results were statistically significant in favour of chlorhexidine mouthwash for the Silness-Loe Plaque Index (WMD -0.39, 95% CI -0.70 to -0.08; four trials; I²=91%), Quigley-Hein Plaque Index (WMD -0.67, 95% CI -0.82 to -0.52; eight trials; I²=84%), Gingival Index (WMD -0.32, 95% CI -0.42 to -0.23; seven trials; I²=65%), bleeding aspect of the Gingival Index (WMD -0.08, 95% CI -0.10 to -0.05; eight trials; I²=78%), Papillary Bleeding Index (WMD -0.21, 95% CI -0.37 to -0.04; two trials; I²=0), and bleeding on marginal probing (WMD -0.16, 95% CI -0.26 to -0.07; two trials; I²=18%). Chlorhexidine mouthwash resulted in significantly more tooth staining (WMD 0.91, 95% CI 0.12 to 1.70; four trials; I²=99%).

When the weighted mean differences of trials assessed to be at a low risk of bias were analysed, chlorhexidine mouthwash reduced plaque by 33% and gingivitis by 26%, compared with control. There was evidence of publication bias in the analysis for Gingival Index. Further results were reported.

**Authors' conclusions**

In patients with gingivitis, chlorhexidine mouthwash together with oral hygiene versus placebo or control mouthwash significantly reduced plaque and gingivitis scores, but significantly increased the staining score.

**CRD commentary**

The review question was clear, and the inclusion criteria were adequately specified. Relevant sources were searched, but language and publication restrictions could mean that relevant trials were missed. The review process contained appropriate steps to minimise error and bias. The included trials were assessed for quality using relevant criteria, and these results were presented clearly, and were used in analysing the results of the review. Appropriate synthesis methods were used, and substantial statistical heterogeneity was evident in several analyses.

The authors drew attention to various limitations to their review, including the interpretation of risk of bias, limitations in the search, and a very specific population. These, with the moderate to high variation in many of the analyses, mean that some of the pooled results should be interpreted cautiously.

**Implications of the review for practice and research**

**Practice:** The authors did not state any implications for practice.

**Research:** The authors stated that research was needed to evaluate the effects of chlorhexidine mouthwash alone. Modifications to the mouthwash were needed to reduce the side-effect of tooth staining, while retaining its anti-plaque and anti-gingivitis effects. Trials should report their allocation concealment methods.

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