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[Intervention Review]

Interventions for treating oral leukoplakia

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ABSTRACT

Background

Oral leukoplakia is a relatively common oral lesion that in a small but significant proportion of cases changes into cancer. Since most leukoplakias are asymptomatic, the primary objective of treatment should be to prevent such malignant transformation.

Objectives

To assess effectiveness, safety and acceptability of treatments for leukoplakia.

Search methods

The following databases were searched for relevant trials: Cochrane Oral Health Group's Trials Register (to April 2006), CENTRAL (*The Cochrane Library* 2006, Issue 1), MEDLINE (from 1966 to December 2005), and EMBASE (from 1980 to December 2005). Handsearching was performed for the main oral medicine journals. References of included studies and reviews were checked. Oral medicine experts were contacted through an European mailing list (EURORALMED).

Selection criteria

Randomised controlled trials (RCTs), enrolling patients with a diagnosis of oral leukoplakia, were included. Any surgical or medical (topical and systemic) treatment was included. The primary outcome considered was malignant transformation of leukoplakia. Other outcomes considered were clinical resolution, histological modification and frequency of adverse effects.

Data collection and analysis

Data were collected using a specific extraction form. Malignant transformation of leukoplakia, demonstrated by histopathological examination, was the main outcome considered. Secondary outcomes included clinical resolution of the lesion and variation in dysplasia severity. The validity of included studies was assessed by two review authors, on the basis of the method of allocation concealment, blindness of the study and loss of participants. Data were analysed by calculating risk ratio. When valid and relevant data were collected, a meta-analysis of the data was undertaken.

Main results

The possible effectiveness of surgical interventions, including laser therapy and cryotherapy, has never been studied by means of a RCT with a no treatment/placebo arm. Twenty-five eligible RCTs of non-surgical interventions were identified: 11 were excluded for different reasons, five were ongoing studies, leaving nine studies to be included in the review (501 patients). Two studies resulted at low risk of bias, six at moderate risk of bias and one at high risk of bias. Vitamin A and retinoids were tested by five RCTs, two studies investigated beta carotene or carotenoids, the other drugs tested were bleomycin (one study), mixed tea (one study) and ketorolac (one study). One study tested two treatments. Malignant transformation was recorded in just two studies: none of the treatments tested showed a benefit when compared with the placebo. Treatment with beta carotene, lycopene and vitamin A or retinoids, was associated with significant rates of

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clinical resolution, compared with placebo or absence of treatment. Whenever reported, a high rate of relapse was a common finding. Side effects of variable severity were often described; however, interventions were well accepted by patients, since drop-out rates were similar between treatment and control groups.

Authors' conclusions

To date there is no evidence of effective treatment in preventing malignant transformation of leukoplakia. Treatments may be effective in the resolution of lesion, however relapses and adverse effects are common.

PLAIN LANGUAGE SUMMARY

Interventions for treating oral leukoplakia

No evidence from trials to show how to prevent leukoplakia in the mouth becoming malignant.

Oral leukoplakia is a thickened white patch formed in the mouth lining that cannot be rubbed off. Leukoplakia is a lesion that sometimes becomes cancerous (a tumour that invades and destroys tissue, then spreads to other areas). Preventing this change is critical as survival rates of more than 5 years after diagnosis with oral cancer is low. Drugs, surgery and other therapies have been tried. The review of trials compared several drugs such as bleomycin, vitamin A and beta carotene supplements and mixed tea. There was no evidence found to show the effects of these treatments. More research is needed.