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Effect of chlorhexidine-thymol varnish on root caries in a geriatric population: A randomized double-blind clinical trial

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ABSTRACT

Objectives: Little is known about the effect of Cervitec®, a chlorhexidine-thymol varnish, on root caries. Our objective was to determine whether a 3-monthly application of Cervitec® over 1 year would limit the progress of existing root caries lesions and reduce the incidence of dental root caries in a group of dentate institutionalized elderly, as a complement to their usual oral hygiene practices.

Methods: A double-blind randomized clinical trial was conducted in 68 subjects (34 per group) in two residences in Almería (Spain). Twenty-one subjects with 60 root caries lesions and 25 with 65 lesions, in the Cervitec® and placebo groups, respectively, completed the study. Varnishes were applied twice in the first week, 1 month later, and every 3 months until the end of the study. Clinical parameters associated with established lesions were determined at baseline and after 6 and 12 months, as was the incidence of root caries lesions.

Results: The clinical evolution of lesions was significantly better in the Cervitec® group as opposed to the placebo group in terms of width, height, color, and texture. The increase in root caries was significantly lower ($p = 0.039$) in the Cervitec® group.

Conclusion: According to these results, Cervitec® may help to control established root lesions and reduce the incidence of root caries lesion among institutionalized elderly.

1. Introduction

Elderly patients now retain their teeth longer and are therefore increasingly susceptible to oral disease. Poor oral hygiene is a common finding in elderly populations, especially among the institutionalized elderly.[1] In these patients, the gingival margin often approximates or reaches the tooth root due to gingival recession and/or loss of attachment. In these cases, root caries may prove to be an important pathology for these subjects.

Restorative treatment of root caries is frequently difficult from a technical standpoint, while root lesions – cavitated or non-cavitated – may revert to an inactive phase through the application of non-invasive treatment, among which the use of fluoride together with mechanical control of plaque has been the most often studied.[2–4]

The incorporation of chlorhexidine (CHX), and more specifically CHX varnishes, in the control of dental caries is a relatively recent development. They have proven to be effective, to a greater or lesser degree, in the control of coronal dental caries, mostly evaluated in children, adolescents, and young adults.[5–7] The effect of CHX varnishes in relation to root caries has been reported to certain intermediate points to date, allowing us to surmise *a priori* that it may be useful in

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preventing and controlling this process: (1) there is evidence that CHX varnishes can penetrate and seal tubules in the dentine[8]; (2) they are able to reduce the levels of mutans streptococci in plaque of exposed root surfaces, whether healthy[9] or caried[10,11]; and (3) there is a decreased mineral loss *in situ*[12] and lesion depth in dentin.[13]

However, studies involving older adults or the elderly, and more specifically persons with root caries, are very scarce. The efficacy of CHX varnish (EC40) in reducing the incidence of root caries in adult patients has been demonstrated in the periodontal maintenance phase,[10] and among adults with dry mouth to whom 10% CHX varnish was applied.[14] In frail institutionalized people, the simultaneous application of fluoride varnish (Fluor Protector®) and CHX varnish (Cervitec®) was shown to be more effective than the application of fluoride varnish alone for the control and management of existing root caries lesions.[15]

Given this background, it was deemed of interest to know whether CHX-thymol varnish could benefit patients with root caries and be of particular value in the elderly who receive no preventive treatment and whose ability to perform routine oral hygiene practices is often compromised. The present study was thus aimed to determine if a 3-monthly application of CHX-thymol varnish would limit the progress of existing root caries lesions and/or reduce the incidence of dental root caries in a group of institutionalized elderly, when used as a complement to their usual oral hygiene practices.

2. Materials and methods

2.1. Subjects and study regimen

The indications of the CONSORT Statement[16] were followed in this double-blind randomized placebo-clinical trial conducted in 2003 and 2004 among institutionalized elderly in Almería (Spain), a city with 0.07 ppm F ion in the drinking water. The study was designed for a 1-year follow-up, though the effect on plaque and gingival indexes was evaluated at 6 months (see Clavero et al.[17]). Two residential homes for the elderly were selected at random, with a total population of 310 residents. The residents were recruited for the study if they met the following inclusion criteria: age $\geq$65 years, possession of at least six teeth; no serious disease (i.e., terminal disease or severe disability), no intake of antibiotics during 2 weeks before the start of the study, and ability to provide written informed consent. Seventy-five elderly residents fulfilled these criteria, 68 of whom participated in the study, while seven declined to participate; and 22 were later lost to the 12-month study due to death (n = 2), refusal to continue (n = 4) or transfer to another residential home (n = 16). Therefore, at the end of the study, 46 subjects were available for examination.

There was no residential home-based preventive dental program, and none was implemented during the study period. Our study was approved by the Ethics Committee of the School of Dentistry of the University of Granada. Subjects were instructed to maintain their usual oral hygiene habits.

All of the selected residents underwent scaling and root planing 30–45 days before the start of the study to remove major accumulations of plaque and tartar. In order to achieve the same sample size in both groups and, at the same time, have balanced groups in terms of the most relevant variable – the number of root surfaces with caries – a stratified (two levels, below and above the median number of root surface caries) and block randomization – computer assisted – method was used.

One group received applications of Cervitec® varnish (1% CHX + 1% thymol; Vivadent, Schaan, Liechtenstein) (n = 34) and the other group received applications of a placebo varnish (n = 34).

2.2. Data collection

The data collected at baseline included the subject's age, gender, profession, current medication, relevant medical history, and number of teeth. The plaque index of Silness and Löe[18] was used to assess the dental plaque accumulation, and the gingival index of Löe and Silness[19] was used to measure gingival inflammation at baseline and after 1, 3, and 6 months (results previously published[17]). Salivary levels of mutans streptococci and lactobacilli were determined by taking salivary samples from the surface of the tongue, pressing directly upon it with the slide and the selective culture. Results were interpreted according to the manufacturer's visual scales: absence (no colony forming units [CFUs]), levels 1–2 ($<10^5$ CFU/ml saliva), and levels 3–4 ($\geq 10^5$ CFU/ml saliva). Dental plaque was removed from all tooth surfaces using a toothbrush. Next, coronal caries was scored according to World Health Organization criteria,[20] and the numbers of exposed root surfaces and decayed and filled root surfaces were also assessed. Variables described by Brailsford et al.[15] were recorded for each root lesion as follows, based on Beighton's methods[21]: (1) color (black, dark brown, light brown or yellow); (2) texture (hard, leathery or soft); (3) height (mm) and (4) width (mm) of each lesion; and (5) distance from gingival margin (mm). Measurement accuracy was $\pm$0.5 mm. All coronal and root caries variables were assessed at baseline and after 6 and 12 months, following the same procedures under the same conditions as in the baseline evaluation.

A single dentist carried out all examinations under standardized conditions and at the same time of day throughout the study, with the participation of a second experienced dentist to test inter-examiner reliability and confirm the adequate diagnostic ability of the main examiner. Intra- and inter-examiner agreement levels for the characteristics of the caries lesions were re-evaluated in 10 subjects after an interval of 5–7 days at baseline, 6, and 12 months.

2.3. Application of CHX varnish

Cervitec® or placebo varnish was applied by the same dentist in residential homes, using portable equipment and following the manufacturer's instructions. Briefly, the teeth were cleaned with a toothbrush for 2–3 min. The teeth were then isolated from saliva with cotton rolls and dried with compressed air, followed by the application of a thin coat of varnish to all teeth and surfaces using the brush supplied by the manufacturer. The varnish was gently dried by air for 30 s. The elderly were instructed not to eat or drink for 3 h, not to clean their teeth until the following day, and not to use dental