Efficacy of a Commercial Dentifrice Containing 2% Strontium Chloride and 5% Potassium Nitrate for Dentin Hypersensitivity: A 3-Day Clinical Study in Adults in China

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ABSTRACT

Background: Studies of dentifrices containing strontium chloride or potassium nitrate have documented the clinical efficacy of these formulations for dentin hypersensitivity (DH), but few studies have evaluated dentifrices containing both active ingredients.

Objective: The objective of this study was to compare the effects on DH of a dentifrice containing 2% strontium chloride and 5% potassium nitrate in a silica base (experimental dentifrice) with those of a dentifrice containing the same silica base without any active ingredient (control dentifrice).

Methods: Male and female patients aged 20 to 65 years with DH were eligible to participate in this randomized, double-blind, placebo-controlled study in China. Patients were assigned to receive the experimental or control dentifrice. At baseline, immediately after topical dentifrice use, and after 3 days, patients received an oral examination of their hard and soft tissues, followed by an evaluation of DH that used the Yeaple Probe to measure tactile hypersensitivity and the Schiff Cold Air Scale to measure the perception of pain from an air blast stimulus. Adverse events (in particular, discomfort while brushing or alteration in taste) in the oral hard or soft tissues were monitored throughout the study.

Results: A total of 81 patients were enrolled (40 in the experimental group; 41 in the control group), of whom 79 (55 women; 24 men) completed the study. After topical use, the experimental group had a significantly higher mean (SD) tactile hypersensitivity score (19.47 [14.69] vs 14.27 [5.76]; $P = 0.047$) and a significantly lower mean air blast hypersensitivity score (1.93 [0.51] vs 2.22 [0.60]; $P = 0.026$) than did the control group. After 3 days, the experimental group had a significantly higher mean tactile hypersensitivity score (19.87 [14.95] vs 14.51 [6.00]; $P = 0.045$) and a significantly lower air blast hypersensitivity score (1.80 [0.56] and 2.13 [0.60]; $P = 0.014$) than the control group. After topical use and after 3 days, the experimental group had increases from baseline in tactile scores of 54.04% and 56.67%, respectively (both, $P = 0.001$) and reductions from baseline in air blast scores of 18.51% and 24.21% (both, $P < 0.001$); the control group had increases in tactile scores of 21.14% and 21.54% ($P = 0.022$ and $P = 0.007$) and reductions in air blast scores of 10.24% and 13.41% ($P = 0.001$ and $P < 0.001$). No adverse events were reported throughout the study.

Conclusion: In these patients with DH in China, the dentifrice containing 2% strontium chloride and 5% potassium nitrate was efficacious in reducing DH when used instantly after topical dentifrice use and after 3 days of use. Clinicaltrials.gov identifier: NCT01426360. (*Clin Ther.* 2012;34:614–622)

Key words: dentin hypersensitivity, dentifrice, fluoride, potassium nitrate, strontium chloride.

INTRODUCTION

Dentin hypersensitivity (DH) is a common complaint in the general population. The prevalence of DH in the adult population ranges from 2.8% to 74%,[1–3] whereas in periodontal patients it might be as high as 72.5% to 98%.[4] In healthy teeth, dentin is physiologically covered by dental enamel or cementum, which prevents irritation from outside stimuli. However, some diseases, such as tooth abrasion, attrition, ero-

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sion, and gingival recession, can cause the dentin to be directly exposed to the oral environment. DH occurs when the exposed dentin is irritated by thermal, evaporative, tactile, osmotic or chemical stimuli, and it is characterized as a short, sharp pain that cannot be explained by any other form of dental defect or disease.[5] The intensity of the pain can range from minor to severe, and it may be severe enough to prevent a patient from eating or performing routine oral hygiene practices.

DH is typically thought to occur through a hydrodynamic mechanism in which pain-producing stimuli cause the rapid movement of fluid within the dentin tubules.[6,7] As a result, the free nerve endings at the inner ends of the tubules or the periphery of the pulp are excited, causing pain. One approach to treating DH is thus to reduce the dentin tubule fluid movement by occluding the open tubules. Strontium chloride was the first tubule-blocking ingredient used in a dentifrice, ~50 years ago.[8] Another approach is to reduce the pulp nerve excitability by depolarizing the nerve endings, for which the most widely used material is potassium salts. Various clinical trials have been performed to test the efficacy of such agents in reducing DH.[9–15] A recent meta-analysis based on 6 clinical studies reported a statistically significant effect of potassium nitrate dentifrice on tactile and air blast sensitivity at 6- to 8-week follow-up, with an air blast sensitivity score showing a mean difference of 1.25 in favor of treatment.[16] Although some clinical studies have reported that dentifrices containing strontium chloride or potassium nitrate alone as the major desensitizing agent may reduce DH,[9–11] the findings from some reports are equivocal.[16] Findings from other clinical trials reported no significant difference in reductions between dentifrices containing strontium chloride or potassium nitrate alone and active or inactive controls.[12–15] For desensitizing dentifrices, the most frequently reported method of application was brushing twice daily, with effects observable after 2 to 4 weeks. Little published evidence supports that direct topical use can accelerate the reduction of sensitivity and thereby immediately enhance the effectiveness of desensitizing dentifrices. Thus, to date, the value of using dentifrices containing both strontium chloride and potassium nitrate to instantly alleviate DH is uncertain.

The objective of the present study was to compare the instant effects on DH of a commercially available dentifrice containing 2% strontium chloride and 5% potassium nitrate in a silica base to those of a control dentifrice containing the same silica base without any active ingredient.

PATIENTS AND METHODS

This 3-day, randomized, double-blind, parallel-group study was conducted at the State Key Laboratory of Oral Diseases, Sichuan University, Chengdu, China. The clinical study protocol and informed-consent forms were reviewed and approved by the institutional review board at the West China College of Stomatology at Sichuan University.

Inclusion and Exclusion Criteria

Prospective patients aged 18 to 70 years with DH but otherwise in good oral and general health were examined during the screening visit. *DH* was defined as having ≥2 teeth (incisors, cuspids, bicuspids, and/or first molars with exposed cervical dentin) with hypersensitivity on the facial surfaces (ie, a tactile hypersensitivity stimulus score of 10–50 g of force on Yeaple probe) and an air blast stimulus score of 2 or 3 (Schiff Cold Air Scale[17]).

Patients with progressive periodontitis; teeth that had extensive restoration, suspected pulpitis, caries, and/or cracked enamel or that were used as abutments for removable partial dentures; hypersensitive teeth with a mobility >1; who had received periodontal treatment, including surgery, during the previous year; who had used any other antihypersensitivity dentifrice or taken part in any other clinical trial; who had used any desensitizing agent during the previous 3 months; and/or who were allergic to the ingredients of the dentifrices were excluded. Also excluded were pregnant or breastfeeding women, heavy smokers, and patients who had taken any of the following drugs during the previous month: anticonvulsants, antihistamines, antidepressants, sedatives, tranquilizers, anti-inflammatories, and/or daily analgesics.

Patients who provided informed consent and were available for the study duration were scheduled for a screening visit. One dentist recruited the patients, determined eligibility, and obtained informed consent.

Study Procedures

The study participants refrained from all oral hygiene procedures and from chewing gum for 8 hours as well as from eating and drinking for 4 hours prior to the baseline examinations. Two hypersensitive teeth