Original Contributions

Effect of an experimental desensitizing agent on reduction of bleaching-induced tooth sensitivity

A triple-blind randomized clinical trial

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ABSTRACT

Background. In this randomized study, split-mouth, triple-blind clinical trial, the authors evaluated the efficacy of a desensitizing gel that contained 5% potassium nitrate and 5% glutaraldehyde applied before in-office bleaching with 35% hydrogen peroxide (HP).

Methods. Treatment with the desensitizing or placebo control gels was randomly assigned to one-half of the maxillary teeth of 42 patients in a split-mouth design. The desensitizing gels were applied and maintained in contact with the tooth enamel for 10 minutes, followed by 2 HP bleaching sessions separated by 1 week. The primary outcome variable was pain intensity assessed with a numeric rating scale and a visual analog scale. Color was evaluated by means of a digital spectrophotometer and a value-oriented shade guide.

Results. The difference in risk of developing tooth sensitivity between the desensitizing gel group (31.7%, 95% confidence interval [CI], 19.6 to 46.9) and the control group (70.7%; 95% CI, 55.5 to 82.3%) was statistically significant ($P < .0001$), as well as the difference in pain intensity in the first 24 hours ($P < .001$). No statistically significant difference was found in color change between teeth that received the desensitizing gel and those that received the placebo gel.

Conclusions. Application of desensitizing gel that contained 5% potassium nitrate and 5% glutaraldehyde before HP whitening reduced the risk and severity of dental sensitivity, without altering the effectiveness of whitening.

Practical Implications. A single application of desensitizing gel that contained 5% potassium nitrate and 5% glutaraldehyde can reduce tooth sensitivity after dental bleaching systems.

Key Words. Tooth bleaching; dentin sensitivity; randomized controlled clinical trial; hydrogen peroxide.

Brazilian clinical trials registry: RBR-7B7CMN

JADA 2018:■(■):■-■

https://doi.org/10.1016/j.adaj.2017.10.025

Bleaching-induced tooth sensitivity (TS) is the most common clinical adverse effect of tooth bleaching procedure. There is a wide range in the reported risk of developing TS; however, the highest risk is usually seen in in-office tooth bleaching (reported range between 60% and 98%).[1-7] This could be explained by the higher concentration of hydrogen peroxide in the in-office bleaching agent.

Although pain and discomfort caused by bleaching-induced TS are generally mild and transient, they can occasionally be severe and irritating, leading to patient's withdrawal from the bleaching treatment. Investigators have hypothesized that bleaching-induced TS has been associated with the passage of hydrogen peroxide, through enamel and dentin, to the pulp where it produces an inflammatory reaction,[8,9] and it may directly activate nerves that cause pain.[10,11] Some attempts have been used to prevent this adverse effect. The administration of selective anti-inflammatory drugs,[3] ibuprofen,[2,12] ascorbic acid,[13] and dexamethasone[14] did not reduce the risk and intensity of bleaching-induced TS.[15]

Topical application of potassium nitrate and fluoride as desensitizers was found to have promising results for at-home and in-office bleaching.[6] The previous application of a gel composed of 5% potassium nitrate and 2% sodium fluoride for 10 minutes reduced the risk of in-office bleaching–induced TS by one-half and the intensity of TS in a clinical trial.[1] Potassium nitrate is the primary agent for at-home desensitizing toothpastes that works by preventing nerve transmission that leads to sensations of pain.[16]

In addition, 2 clinical trials found that the previous desensitization with Gluma desensitizer liquid or gel (Heraeus Kulzer), composed of 5% glutaraldehyde by weight and 35% 2-hydroxyethyl methacrylate by weight,[17,18] significantly reduced in-office bleaching–induced TS during and after whitening compared with a placebo before treatment.[4,19] Glutaraldehyde has been added to some desensitizing gels[20] and adhesive systems[21] to reduce TS. Glutaraldehyde is a low-molecular-weight aldehyde and is used as a cross-linking material,[22] an ingredient used in cosmetic and toiletry industries and in chemical specialty products. In addition, it is an effective fixative or flocculating agent and forms a physiological seal by coagulating the plasma proteins within the dentinal tubules.[23]

Because both potassium nitrate[1,6,24] and glutaraldehyde[4,19] were tested separately in several clinical studies and were found to have reduction, but not prevention, of bleaching-induced TS, we hypothesize that the formulation of a desensitizing gel composed of 2 active agents, with different mechanisms of action, could reduce even more the risk of developing bleaching-induced TS. To the best of our knowledge, there is no report about the effect of a desensitizing gel composed of potassium nitrate and glutaraldehyde. Considering the high risk of developing bleaching-induced TS reported by patients submitted to in-office bleaching,[7] the aim of this randomized clinical trial (RCT) was to evaluate the risk and intensity of bleaching-induced TS after in-office bleaching with topical application of an experimental desensitizing gel that contained potassium nitrate and glutaraldehyde.

METHODS

Study design and protocol registration

This was a split-mouth and placebo-controlled RCT with an equal allocation ratio. The clinical investigation was approved (protocol 843.554) by the scientific review committee and by the committee for the protection of human participants of the local university.

This research protocol was registered in the Brazilian clinical trials registry (RBR-7B7CMN). We prepared this article using the protocol established by the Consolidated Standards of Reporting Trials statement 2010 with extension for reporting within-person randomized trials.[25] Two weeks before the bleaching procedures, all volunteer participants received a dental prophylaxis with pumice and water in a rubber cup and signed an informed consent form.

Eligibility criteria

Participants included in the clinical trial were at least 18 years old, had good general and oral health, and did not report any type of TS. The participants were required to have 6 caries-free maxillary anterior teeth without restorations. The participants had to be free of periodontal disease and willing to review and sign the informed consent form. The canine had to be shade A2 or darker as judged by comparison with a value-oriented shade guide (VITA Classical, VITA Zahnfabrik). Two calibrated investigators performed the color evaluations with the shade guide, independently. The 2 examiners were required to have an agreement of at least 85% (κ statistic) before beginning the study evaluation.

Participants with anterior restorations or dental prosthesis, with orthodontics apparatus, with severe internal tooth discoloration (tetracycline stains, fluorosis, pulpless teeth) were not included in the study. In addition, pregnant and lactating women, smokers, participants with any other pathologic disorder that could cause sensitivity (such as recession, dentinal exposure, and visible cracks in teeth), taking anti-inflammatory or analgesic drugs, or had undergone tooth-whitening procedures and with bruxism habits were excluded.

Settings and locations

From preestablished criteria, we selected 42 volunteers for this study. The study was performed from November 13, 2014, through December 20, 2015, in the school of dentistry at the local university.

ABBREVIATION KEY

ΔSGU: Change in the number of shade guide units.
ΔE: Difference between the 2 colors.
HP: Hydrogen peroxide.
NNT: Number needed to treat.
NRS: Numeric rating scale.
TS: Tooth sensitivity.
VAS: Visual analog scale.