Photobiomodulation therapy and 3% potassium nitrate gel as treatment of cervical dentin hypersensitivity: a randomized clinical trial

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Abstract

Objectives This randomized controlled trial aimed to evaluate different protocols for dentin hypersensitivity treatment with low-power lasers and desensitizing agents, and the association between low-power lasers and desensitizing agents.

Materials and methods Fifty-four patients (303 teeth) were randomly allocated to three groups: G1, 3% nitrate potassium gel, UltraEZ (n = 17); G2, photobiomodulation therapy (PBM) with a low-level infrared laser (n = 17), 100 mW, spot size of 0.028 cm², and dose of 1 J per point; and G3, nitrate potassium + PBM (n = 20). Treatments were applied to the buccal cervical region at intervals of 72 h, and all protocols were performed in three sessions. The patients’ response to evaporative stimuli was rated using the visual analog scale (VAS). Re-evaluations were performed immediately after each application and 1 week, 1 month, and 3 months after treatment. A two-way repeated measures test and Tukey’s post hoc test were used for multiple comparisons (α = 5%).

Results There was a reduction in pain levels at the end of treatment in all groups. There were no significant differences in VAS score changes between the groups immediately after treatment and after the third month, compared to the baseline (p > 0.05).

Conclusion Under the limitations of this in vivo study, the proposed three-session protocol was effective in reducing dentin hypersensitivity after 3 months, regardless of the desensitization mechanism used. Conservative and long-term protocols are interesting for the control of pain caused by dentin hypersensitivity.

Clinical relevance The increase in cervical dentin hypersensitivity prevalence warrants easy-to-apply and long-lasting desensitizing protocols for pain control.

Keywords Cervical dentin hypersensitivity · Clinical trial · Low-power laser · Potassium nitrate
Introduction

Cervical dentin hypersensitivity (CDH) is defined as short, sharp pain that occurs in response to thermal, chemical, evaporative, tactile, or osmotic stimuli [1]. A recent systematic review found that the prevalence of CDH is variable in the adult population, ranging from 1.3 to 92.1%, with a global average of 33.5% [2]. The etiology is multifactorial, involving an association of factors such as tension (parafunctional habits, traumatic occlusion, and malocclusion), friction (abrasion), and corrosion (degradation caused by acid from intrinsic and extrinsic sources) [2–5].

The hydrodynamic theory proposed by Brännström in 1964 is most accepted to explain the CDH mechanism of pain. According to this theory, when the dentinal tubules are exposed to the oral environment and there is stimulation on the tooth surface, the fluid inside the tubules moves inward and outward, depending on the type of stimulus. This displacement of intratubular fluid can activate mechanical receptors in the nerves, stimulating and deforming the nerve fibers present between odontoblasts, generating a painful sensation. Therefore, blocking the dentinal tubules or depolarizing nerve fibers is necessary to control CDH. Examples include the application of potassium oxalate, potassium nitrate, strontium chloride, fluorinated varnishes, and sodium fluoride, irradiation with high- and low-power lasers, application of adhesive systems, and restorative procedures [6–9].

Potassium-based agents promote an increase in the concentration of potassium ions in nerve endings, decreasing the nerve’s ability to conduct sensory stimulation and altering its action potential [10, 11]. However, laser irradiation interacts with the tissue, causing different tissue reactions, according to its active medium, wavelength, power density, and optical properties of the target tissue. High-power lasers can create a melting surface in dentin and block the entrance of dentinal tubules. However, low-power lasers through photobiomodulation therapy (PBM), whose action is a biomodulator of cellular responses, will promote a decrease in pain levels through the depolarization of nerve fibers and increase the formation of tertiary dentin [8, 12, 13].

The literature demonstrates a lack of clinical trials and divergent results [8] concerning the use of low-level lasers. There is a need for more controlled studies emphasizing the effectiveness of PBM and nitrate potassium gel in controlling CDH. In view of the treatments mentioned above, it is necessary to evaluate clinical protocols for the control of CDH over time, to support its use, and establish measures to prevent and control pain.

In view of the above discussion, the objective of this research was to evaluate, through a randomized and controlled clinical study, the effectiveness and longevity of different treatment protocols for CDH with photobiomodulation low-power lasers and desensitizing agents, and their association with low-power lasers and desensitizing agents. The null hypothesis of this study was that there would be no difference between desensitizing treatments, regardless of the experimental times analyzed.

Methods

This study was a parallel arm randomized, double-blind controlled trial conducted at the School of Dentistry of the University of São Paulo from September 2019 to March 2020. The study was approved by the university’s local ethics committee (number 3.612.518), and follows the CONSORT guidelines [14]. The study was registered with the Brazilian Clinical Trials Registry (UTN: U1111-1273-4113).

This study was conducted in accordance with the principles of the Declaration of Helsinki (World Medical Association Declaration of Helsinki, 2008). Participation in the study was voluntary, and informed consent was obtained from all participants.

Eligibility criteria

Participants of both sexes were recruited and were considered eligible if they were aged between 18 and 45 years and in good general health, had at least one tooth, and had CDH equal to or greater than 4 on the visual analog scale (VAS). The initial evaluation was performed using an evaporative test with air jets from a dental syringe. Participants who had active carious lesions or defective restorations, had loss of dental tissue that required restorative treatment, performed any professional desensitizing treatment in the last 6 months, used desensitizing pastes within 3 months, used anti-inflammatory drugs or analgesics at the time of recruitment, and were pregnant or breastfeeding were excluded from this study.

Sample size calculation

The sample size calculation was based on the comparison of means, with a minimum expected difference of 2 units between groups in VAS and a standard deviation of 2. Considering an alpha of 5% and 80% power, 17 patients per group would be necessary [15]. To compensate for possible loss to follow-up, 54 participants were included.

Randomization

After the clinical examination, 54 participants were randomly allocated into three groups, with 303 teeth to be
treated. A random sequence was generated by a researcher not involved in the study using the Excel program from the Microsoft Office package. Stratified randomization was performed. The researcher allocated the groups according to cards placed in sequential numbers in opaque and sealed envelopes, which mentioned one of the three treatment groups. The envelopes were opened only at the time of the procedure by operator 1. Patients and researcher evaluators (operator 2) did not know which group they were assigned to, and the evaluators were blinded to the patients’ pain level. The flowchart of the study is presented in Fig. 1.

Dentin hypersensitivity assessment

The stimulus adopted to trigger CDH was the evaporative stimulus (triple syringe), as used in previous studies [9, 13, 15–18]. The level of CDH was determined using the VAS, a one-dimensional instrument to assess pain intensity numbered from 0 to 10, with 0 being “no pain” and 10 being “worst pain.” The participants were then asked to indicate the level of CDH felt after the application of the stimulus on the scale [9, 13, 15–18].

The clinical evaluation consisted of the application of a triple syringe air jet perpendicularly, at 1 cm from the cervical region of the tooth, lasting 2 s. Adjacent teeth were isolated with the aid of cotton rolls to avoid interference with the measurement of that specific tooth. Immediately after the evaporative stimulus test, the patient indicated the level of sensitivity experienced on the VAS and the record was included in the clinical chart. The examiner for the CDH level was previously calibrated.

All treatments were performed by the same researcher (operator 1). Stimulus and pain measurements were performed by a previously calibrated examiner (operator 2). To minimize errors and avoid bias, operator 2 (who was not aware of the treatments) assessed the response of each tooth to air stimuli, and then measured and recorded the levels of dentin hypersensitivity.

Interventions

After clinical examination, anamnesis, and total agreement to participate in the study, patients were treated according to their allocation. Two weeks before the beginning of the study, the participants went through a wash-out period, during which they used only the oral hygiene products indicated by the researchers, which should be used until the end of the study. The oral hygiene kit consisted of one soft toothbrush (Professional Lab Series, Colgate Palmolive Company), a fluoridated toothpaste (Colgate Total 12, 1450 ppm F, Colgate Palmolive Company), and one dental floss (Colgate, Colgate Palmolive Company).

Before treatment, all teeth received dental prophylaxis with a rubber cup, 2% chlorhexidine, and a pumice stone. The area was then washed with air/water spray and dried with cotton. Sequentially, relative isolation was performed with the aid of cotton rolls, and treatments were performed according to the groups.

The treatments were carried out in three sessions, with an interval of 72 h between applications, as previously reported in the literature [9, 12, 15, 17]. The effectiveness of the products was measured immediately after each treatment session using the VAS scale. The participants were called back at 1 week, 1 month, and 3 months, and the VAS level was measured using the same evaporative stimuli. Table 1 summarizes the application of desensitizing therapies in the three groups. Laser parameters were tested before each irradiation using a power meter (Laser Check, MMOptics, São Carlos, SP, Brazil).

The evaluator and patients were blinded to the study. Additionally, patients were unaware of the treatment they were receiving. In group 1, the equipment that simulated the laser irradiation was used. The laser tip was positioned on the tooth surface; however, no emission was observed. In group 2, a placebo gel (water) was applied in the same way as the KNO3 desensitizing gel, according to the manufacturer’s instructions. The desensitizing and placebo gels were placed in identical containers so that patients could not identify which product was being applied.

Group 1—3% potassium nitrate desensitizing gel

After prophylaxis, a #000 retraction cord (Ultrapack, Ultradent, South Jordan, UT, USA) was inserted into the gingival sulcus, and the desensitizing gel (Ultradent) was applied to the non-carious cervical lesion using a micro-applicator (KG Sorensen, Cotia, Brazil) spreading throughout the cervical region from mesial to distal. The desensitizing gel was removed after 5 min. Then, the retractor cord was detached, excess was removed, and gel was applied again for 5 min. The surface was then washed with water until all the visible gels were removed. This protocol followed the manufacturer’s recommendations. As the patients did not know which treatment was allocated to them, the researcher simulated irradiation with laser equipment (DMC, São Carlos, São Paulo, Brazil) with the same characteristics as the one used in the research, but without the emission of radiation.

Group 2—photobiomodulation/low-level laser irradiation

In this group, all participants received photobiomodulation therapy (Laser Therapy EC, DMC Equipment LTDA, São Carlos, Brazil) at a wavelength of 808 nm (infrared laser) under relative isolation with a fixed power of 100 mW, spot size of 0.028 cm², and dose of 1 J per point. The
Assessed for eligibility (n=89)

Excluded (n=35)
- Not meeting inclusion criteria (n=27)
- Declined to participate (n=8)

Randomized (n=54) teeth=303

Allocated to intervention (n=17)
Potassium nitrate gel + Low-level laser irradiation simulation
- Received allocated intervention (n=17, teeth=80)

Allocated to intervention (n=17)
Low-level laser irradiation + Gel simulation
- Received allocated intervention (n=17, teeth=103)

Allocated to intervention (n=20)
Potassium nitrate gel + Low-level laser irradiation
- Received allocated intervention (n=20, teeth=120)

Lost to follow-up (n=8)
Discontinued intervention due to the Covid-19 pandemic

Lost to follow-up (n=9)
Discontinued intervention due to the Covid-19 pandemic

Lost to follow-up (n=11)
Discontinued intervention due to the Covid-19 pandemic

Analysed:
17 were included in intention-to treat

Analysed:
17 were included in intention-to treat

Analysed:
20 were included in intention-to treat

Fig. 1 CONSORT flow diagram of the clinical trial
tip was placed perpendicular to the tooth with irradiation at the cervical and apical points, with a total dose of 2 J. In molar teeth, irradiation was performed on the cervical mesial, mesial apical, distal cervical, and distal apical teeth, totaling 4 points and 4 J. The treatment was carried out in three sessions, with an interval of 72 h between sessions.

During all laser treatments, protective glasses were used by both the researcher and patient, and all safety rules were followed. Sequentially, the application of a desensitizing agent was simulated using the same UltraEZ package, but containing water. A retractor cord was then inserted, and a micro-brush was used to spread the gel and left for 10 min, as in group 1.

**Group 3—photobiomodulation associated with gel desensitizer**

The subjects in group 3 received the application of the desensitizing gel and laser irradiation immediately after, as described in the protocols in groups 1 and 2.

### Statistical analysis

The VAS value for each participant was calculated as the mean of all affected teeth. Subsequently, means and standard deviations of each group were calculated at each experimental period. Adherence to the normal curve was tested using the Shapiro–Wilk test, and homoscedasticity was verified using the Levene test. As normality and homoscedasticity were observed, two-way analysis of variance was used to compare the groups and change in time in which the two factors were the group and time (repeated measures factor). Tukey’s post hoc test was used for multiple comparisons.

Two analyses were performed for the dataset: by protocol (considering all missing data) and intention to treat. In the intention-to-treat analysis, the last observation carry-forward method was used as the data-imputation method. In this method, the last observed value of each participant was used to replace the missing data. An alpha value of 5% was considered significant.

### Results

Fifty-four participants (303 teeth) were included in this study. There were participants with only one tooth with CDH and others with 15 teeth. The age range was 18–45 years (mean age of the subjects was 26.9 years). Demographic characteristics of the participants are presented in Table 2.

In Table 3, the differences in the mean value of CDH per treatment can be observed. After the three sessions, a decrease in pain levels was noticed. As shown in Table 3, CDH remained relatively stable among the other post-treatment time intervals. There was no significant difference between the groups at any time during the study (p > 0.05). There was a significant intra-group reduction in the three experimental groups compared to baseline (p < 0.05)

Table 3 shows the mean values for pain reduction (baseline and 3 months). These results were analyzed using one-way analysis of variance, and no difference was observed between the groups (p = 0.78).

### Table 1 Description of the division of the evaluated groups

| Groups | First session                                      | Second session                                      | Third session                                      |
|--------|---------------------------------------------------|----------------------------------------------------|---------------------------------------------------|
| G1     | Potassium nitrate gel + low-level laser irradiation simulation | Potassium nitrate gel + low-level laser irradiation simulation | Potassium nitrate gel + low-level laser irradiation simulation |
| G2     | Gel simulation + low-level laser irradiation      | Gel simulation + low-level laser irradiation       | Gel simulation + low-level laser irradiation       |
| G3     | Potassium nitrate gel + low-level laser irradiation | Potassium nitrate gel + low-level laser irradiation | Potassium nitrate gel + low-level laser irradiation |

### Table 2 Characteristics of the participants

| Characteristic                          | Total (%; n) |
|-----------------------------------------|--------------|
| Gender                                  |              |
| Male                                    | 25.92% (14)  |
| Female                                  | 74.07% (40)  |
| Age (years)                             |              |
| 18–25                                   | 44.44% (24)  |
| 26–35                                   | 46.29% (25)  |
| 36–45                                   | 9.26% (5)    |
| How long have you been with sensitivity?|              |
| < 1 years                               | 11.11% (6)   |
| 1–5 years                               | 44.44% (24)  |
| > 5 years                               | 44.44% (24)  |
| How much does sensitivity bother you?   |              |
| A few                                   | 1.84% (1)    |
| Medium                                  | 42.60% (23)  |
| A lot                                   | 55.55% (30)  |
| Visual analogic scale                   |              |
| Moderate sensitivity (4 to 7)           | 79.63% (43)  |
| High sensitivity (8 to 10)              | 20.37% (11)  |
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was performed using air jets (evaporative stimulus). The

choice of this specific stimulus is due to the fact that it acts

by promoting the evaporation of fluid from the interior of

the dentinal tubules. It is the easiest and most used stimulus

that can be applied by clinicians and has been used for a

long time in the literature [9, 11, 19, 20]. For the evaluation

of the level of pain, the visual analog scale (VAS) was used

precisely because it is easy to apply, is well understood by

patients, and is an adequate and reproducible method [8,

22–24].

Considering the results of this study, it took at least three

sessions to achieve low levels of CDH. Probably, a single

application may not be enough, both for laser irradiation

(dose-dependent) and potassium nitrate gel (time-depend-

ent), which suggests that a multiple-session approach can

result in the maintenance of the desensitizing effect for

longer periods [8, 9, 11, 22, 25, 26].

DH can be managed using two neural strategies. The first

is related to the use of a physical method using a low-power

laser. Second, chemical agents are used to desensitize the

sensory nerves, blocking the transmission of noxious stimuli

from the dentinal tubules to the central nervous system. Both

laser irradiation and potassium nitrate are considered neural

strategies because they do not obliterate the dentinal tubules

but act directly on the transmission of pain.

Potassium nitrate for the treatment of CDH has been

used in the form of a gel or mouthwash, or incorporated

into toothpaste [27]. In this study, it was used in the gel

form, which is one of the most routinely used neural desen-

sitizing agents in dental clinics. Potassium nitrate acts in

the transmission of nerve impulses and prevents repolariza-

tion. Depolarization occurs when the concentration of

potassium ions increases in nerve endings, inactivating

the action potential and preventing pain [1]. Potassium ion

Discussion

The implementation of public health policies has increased

the life expectancy of the population. Additionally, access
to information and awareness of oral health care has led
to a decrease in caries prevalence rates. However, people
are currently living in a more stressful and anxious world
with new behavioral and eating habits. All these previous
observations result in a change in society’s lifestyle, leading
us to face new diseases such as non-carious cervical

lesions and, consequently, CDH [2–5, 19]. Epidemiologi-

cal studies suggest an increase in the prevalence of CDH

and a negative impact on daily activities such as eating,

drinking, breathing, and brushing teeth [3, 4, 19–21]. In

this study, some patients reported that the level of pain
was so intense that they needed to warm up the water to
brush their teeth. For these reasons, this condition directly

impacts the quality of life of patients [17, 18]. Studies

that investigate the efficacy and longevity of desensitizing

protocols are extremely relevant.

To the best of our knowledge, this is the first clinical
study to evaluate the control of dentinal hypersensitivity

using a combination of photobiomodulation therapy with a

low-power laser and desensitizing gel with a concentration

of 3% potassium nitrate. All protocols evaluated proved
to be effective in reducing CDH after the application of

the protocol of the three sessions in a 3-month follow-

up. However, no significant differences were observed

between our groups.

Many products with different modes of action can be

found in the market; however, there is no universally or

standardized protocol accepted for the treatment of CDH.

According to the literature, PBM with a low-power laser

is a contemporary option for controlling the CDH. It is

non-invasive, painless, and conservative therapy [9, 12,

13]. However, a recent systematic review showed that

more consistent studies should be conducted to adequately

observe the beneficial therapeutic effects of PBM.

Laser therapy is dose-dependent; therefore, it is gener-

ally used in sequential appointments with a time inter-

val. Therefore, in this study, it was decided to carry out

consecutive applications of potassium nitrate to carry out

a new standardized clinical protocol and to compare the

three treatment strategies.

Our results indicated that pain levels were significantly

reduced after 3 months in all protocols applied. However,

these data should be considered with caution as there

is a need for a larger sample size to allow a more robust

comparison.

The evaluation of CDH during treatment and follow-up

was performed using air jets (evaporative stimulus). The

choice of this specific stimulus is due to the fact that it acts

by promoting the evaporation of fluid from the interior of

the dentinal tubules. It is the easiest and most used stimulus

that can be applied by clinicians and has been used for a

long time in the literature [9, 11, 19, 20]. For the evaluation

of the level of pain, the visual analog scale (VAS) was used

precisely because it is easy to apply, is well understood by

patients, and is an adequate and reproducible method [8,

11, 22–24].

Table 3 Mean, standard deviation, and comparison between groups regarding dentin hypersensitivity. Intention-to-treat analysis

| Groups                        | Baseline | 1st session | 2nd session | 3rd session | 1st week | 1st month | 3rd month |
|-------------------------------|----------|-------------|-------------|-------------|----------|-----------|-----------|
| Group 1 (potassium nitrate)   | 6.23 (1.50) | 4.49* (1.95) | 4.36* (2.00) | 3.74* (1.99) | 3.15* (2.04) | 2.87* (2.04) | 2.87* (1.97) |
| Group 2 (PBM)                 | 6.78 (1.54) | 4.68* (2.19) | 4.27* (1.98) | 3.62* (1.91) | 3.84* (1.98) | 3.47* (2.18) | 3.45* (2.27) |
| Group 3 (PBM + potassium nitrate) | 6.47 (1.19) | 4.83* (1.68) | 4.24* (1.93) | 3.72* (1.90) | 3.76* (2.06) | 3.46* (2.11) | 3.41* (2.16) |

2-way ANOVA; group effect: \( p = 0.79 \); time effect: \( p < 0.001 \); time × group interaction: \( p = 0.88 \). Alpha = 5%

*Significant difference from baseline

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Concentrations above 0.08% around the axons are required to support the nerve depolarization [28]. In this study, the product was able to reduce, on average, 47.36% of the level of pain in patients after the three sessions; after 3 months, a reduction of 74% was observed, demonstrating the efficacy of potassium in reducing the levels of CDH, in agreement with results in previous studies [11, 22, 26, 27, 29–32].

The second proposed protocol was a physical neural mechanism using a low-power laser. Laser therapy has been widely explored in the treatment of CDH, and unlike high-power lasers, it does not lead to mechanical changes in the dentinal surface. Low-power lasers act on cell membrane electrical potential, activating Na+ /K+ ATPase pumps, bringing benefits such as analgesics, modulation of anti-inflammatory effects, and biomodulation of the tissue [9]. The results of this study were satisfactory for reducing CDH levels. After three sessions of irradiation, a pain reduction of 55.75% was observed; after 3 months, it was 64.30%, corroborating the present literature [8, 9, 11, 33–35].

Comparing all tested protocols for the initial and 3-month CDH levels, no significant differences were found. In other words, all products were effective regardless of the mechanism of action. Therefore, these results support the use of three sessions to promote a stable and effective reduction of CDH. Considering the significant decrease in the VAS pain score after a few weeks, it is assumed that the performance of neural desensitizing agents may become more prominent if the observation period is longer [31]. Initially, this study followed the patients for at least 6 months, and data collection was already underway. However, due to restrictions resulting from the coronavirus disease 2019 pandemic, it was not possible to continue the research for a longer follow-up period.

In view of the above limitations and difficulties of this clinical research protocol, such as patient compliance and the necessity of teamwork for treatments and evaluations, it can be hypothesized that the combination of PBM with potassium nitrate could significantly reduce sensitivity over a longer period, even if a significant difference was not observed with other desensitization treatments over the 3-month period performed in this study. As there is a lack of literature data on this combination, more research is needed. Therefore, these results support the use of CDH. Considering the significant decrease in the VAS pain score after a few weeks, it is assumed that the performance of neural desensitizing agents may become more prominent if the observation period is longer [31]. Initially, this study followed the patients for at least 6 months, and data collection was already underway. However, due to restrictions resulting from the coronavirus disease 2019 pandemic, it was not possible to continue the research for a longer follow-up period.

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The proposed three-session protocol is an effective and conservative method in reducing CDH after 3 months, regardless of the desensitization mechanism used.

Conclusion
The proposed three-session protocol is an effective and conservative method in reducing CDH after 3 months, regardless of the desensitization mechanism used.

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Declarations
Ethics approval All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Consent to participate Informed consent was obtained from all individual participants included in the study.

Conflict of interest The authors declare no competing interests.

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