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Additional effects of homeopathy on chronic periodontitis: A 1-year follow-up randomized clinical trial

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A B S T R A C T

Background and objective: The aim of this study was test the hypothesis that homeopathy (H) enhances the effects of scaling and root planing (SRP) in patients with chronic periodontitis (CP).
Materials and Methods: 50 patients with CP were randomly allocated to one of two treatment groups: SRP (C-G) or SRP + H (H-G). Assessments were made at baseline and after 3 and 12 months of treatments. The local and systemic responses to the treatments were evaluated by clinical and serologic parameters, respectively.
Results: Both groups displayed significant improvements, however, using clinical attachment gain and reductions in HDL, LDL and Total Cholesterol, Triglycerides, Glucose and Uric acid, from baseline to 1 year, as criteria for treatment success, H-G performed significantly better than C-G.
Conclusion: The findings of this 1-year follow-up randomized clinical trial suggest that homeopathic medicines, as an adjunctive to SRP, can provide significant local and systemic improvements for CP patients.

1. Introduction

Chronic periodontitis (CP) is a chronic inflammatory disease resulting from the disruption of homeostasis between subgingival microbiota and host defenses [1]. Periodontal breakdown develops when the microbial load within a periodontal pocket overwhelms the local and systemic host defense mechanisms [2].

Advanced CP with deep periodontal pockets affects approximately 10–15% of world's adult population [3]. Although severe clinical attachment loss (CAL) is usually only evident in a few sites [4], CP often becomes more severe with age [5] and, if no treatment is given, many teeth could be lost [5,6]. CP may also aggravate pre-existing diseases, because it impacts the systemic components of the host protective responses [7]. Despite the recognition that systemic factors can alter the risk to CP, only recently has evidence begun to emerge, still under investigation, that infections of the oral cavity are able to influence the occurrence and severity of certain conditions and systemic diseases [8].

Scaling and root planning (SRP) is the gold standard treatment for patients with chronic periodontitis. Nevertheless, in recent years, different therapeutic strategies have been proposed to improve the results of SRP [9], because some factors may limit the success of treatment by SRP, such as root anatomy, furcations and deep probing depths [10].

Many therapeutic options have been used in the treatment of chronic periodontitis, especially surgical and antibiotic approaches [11,12]. However, they have only been showing modest clinical attachment gain over SRP [11,12], usually associated with some adverse effects [13,14], leaving room for new treatment options. Furthermore, such approaches are only used to treat the local symptoms and often fail to treat the whole person.

Homeopathy (H) is a system based on the principle of "like cures like" [15,16]. Homeopathy states that a disease can be cured using a diluted form of a substance that induces the same symptoms in a healthy person [16]. H is effective against many pathologies, relatively inexpensive, has high patient satisfaction and a low incidence of side effects [17].

In fact, some dentists have been using homeopathic medicines in everyday practice as an adjunct to conventional treatment for a

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range of chronic pathologies, including CP [17]. However, studies assessing the efficacy of such treatments are not available yet [18].

The use of homeopathy in our first 3-month follow-up study was intended to balance the physiological and metabolic function systemic of CP patients. Patients have used specific homeopathic medicines as an adjuvant of SRP in order to promote an additional effect on the treatment of CP [19].

The aim of this randomized clinical trial was to compare the clinical and serologic effects of homeopathy plus SRP to those of conventional mechanical treatment. The present report presents the results at 3 and 12 months after treatment.

2. Materials and methods

2.1. Participants

In continuation of our previous study on the effects of periodontal treatment plus homeopathy on clinical and serologic parameters [19], potential subjects eligible for the study of both genders, aged from 35 to 70 years old, were identified from the population referred to the periodontal clinic of Center for Health at the Universidade Veiga de Almeida (UVA), Rio de Janeiro, Brazil. All of them were submitted to a complete periodontal examination for a periodontal diagnosis, after approval by the Ethics and Research Committee of UVA (CEP/UVA protocol number 285-11). Patients who fulfilled the study inclusion/exclusion criteria were invited to participate in the study.

Inclusion criteria: The presence of clinical attachment level (CAL) $\geq$3 mm in proximal sites of two non-adjacent teeth. Bone loss confirmed by periapical radiographs and bleeding on probing (BOP) should also be present [20].

The exclusion criteria were: patients who had received periodontal treatment in the last year and individuals with aggressive periodontitis. And for both groups: smokers, being pregnant or nursing, patients with a medical condition that could affect the periodontal tissues such as HIV, or any other significant systemic disease that could interfere in the periodontium (diabetes etc), patients that had used medications such as non-steroidal anti-inflammatory, or antibiotic therapy within the last 6 months.

2.1.1. Randomization and allocation concealment

Participants were randomly assigned to receive one of the two treatments by a computer-generated table. Restricted randomization was used, stratifying people by age, number of teeth and average CAL in order to avoid unequal balance between the two treatments (Table 1). The randomization table was sent to a "blind" participant (AC) that was the only one who knew the code. The randomization code was only broken when all data were collected and analyzed. The randomization list was transferred to individual sealed opaque envelopes sequentially numbered which were passed to the periodontist (LSM), each one containing the name of the next treatment in a card.

Fifty subjects with CP participated in this "Single-Blind Randomized Controlled Clinical Trial", 40 of them participated in the former study. Half of the subjects received an additional homeopathic therapy. The main characteristics of both groups are shown in Table 1.

Table 1
Main characteristics of the participants of control (C-G) and homeopathy (H-G) groups.

Characteristics	C-G	H-G
Age (Years)	48.4 ± 8.5	47.7 ± 8.7
Gender: male/female	10/15	12/13
Smoking: yes/no	No	No
Number of teeth	24.45 ± 3.15	23.65 ± 4,41
PI (%)	74.97 ± 7.26	70.64 ± 8.00
BOP (%)	50.84 ± 10.66	52.96 ± 14.33
CAL (mm)	4.66 ± 0.31	4.50 ± 0.55
PPD (mm)	4.17 ± 0.13	4.23 ± 0.24
Severity of CP (Severe/Moderate)[a]	9/16	7/18
Extension of CP (Generalized/Localized)[b]	18/7	19/6

[a] Obs: Severe CP: CAL $\geq$ 5 mm and Moderate CP: CAL $<$ 5 mm.
[b] Generalized CP: $\geq$30% of sites with CAL $>$2 mm and Localized CP: $<$30% sites with CAL $>$2 mm [23]. Non-significative.

2.2. Treatment protocols

2.2.1. Conventional periodontal therapy (SRP)

All patients were submitted to conventional non-surgical periodontal treatment by a "blind" and experienced periodontist (LSM) who did not know which patients were getting the active treatment or not.

The proposed therapy had the following stages: 1. First visit (60 min): personal oral hygiene instructions (how to use hand toothbrush and dental floss), a brief description of periodontal disease and its local and systemic effects (~20 min) and supragingival scaling (~40 min) that was performed by ultrasonic scaler tips (Profi Neo, Dabi Atlante, Ribeirão Preto, SP, Brazil). The patients were asked not to use any antiseptic mouthwashes. Other visits: consultations for subgingival SRP – the number of consultations needed to obtain clinical outcome was standardized to four (one per quadrant, in total 4 weeks). If there was no tooth in a given quadrant, the number of visits was reduced to the number of quadrants present. Instrumentation was performed by hand with subgingival curettes (Gracey curettes, Trinity, Sao Paulo, SP, Brazil), for 10 min per tooth.

Supportive treatment sessions were carried out at 3, 6, 9 and 12 months after the completion of active therapy. Oral hygiene procedures were reinforced and supragingival calculus is removed with ultrasonic scaler tips.

2.3. Additional homeopathic therapy

25 patients (H-G) were also submitted to the homeopathic protocol which had been validated in a previous study [19]:

1) Depurative medicine (helps cleanse waste products and toxins from our body): *Berberis* 6CH (Farmácia-Escola Prof. José Barros da Silva, Rio de Janeiro, Brazil). Posology: two tablets twice daily for 45 days.
2) Acute Drug (drugs that treat illness which has an abrupt onset and needs immediate attention): *Mercurius solubilis*/*Belladona*/*Hepar sulphur* – 6CH (Farmácia-Escola Prof. José Barros da Silva, Rio de Janeiro, Brazil). Posology: two tablets three times a day for 15 days.
3) Nosodes (homeopathic remedies prepared from a product of disease such as infected tissues or causal organisms): *Pyrogenium* – 200 CH (Farmácia-Escola Prof. José Barros da Silva, Rio de Janeiro, Brazil). Posology: a single weekly dose, total of 2 weeks.

2.4. Clinical parameters

A standard periodontal probe (Trinity) with graduations at 1 mm interval was used for the clinical examination. CAL was considered the primary outcome. All other evaluated parameters were secondary outcomes.

The distance from the cementoenamel junction to the bottom of the periodontal pocket (CAL) was recorded at six points of all teeth (except the third molars), three in the buccal (mesiobuccal, buccal, and distobuccal) and three lingual or palatal (mesiopalatal or mesiolingual, lingual or palatal and disto-lingual or disto-palatal).