

Evaluation of the adjuvant effect of topic Bach floral in the clinical response to non-surgical periodontal treatment in patients with type 2 diabetes: pilot study

Avaliação do efeito adjuvante do Floral de Bach em gel na resposta clínica ao tratamento periodontal não cirúrgico em pacientes com diabetes tipo 2: estudo piloto

Evaluación del efecto adyuvante del gel de flores de Bach en la respuesta clínica al tratamiento periodontal no quirúrgico en pacientes con diabetes tipo 2: estudio piloto

Received: 01/12/2023 | Revised: 01/29/2023 | Accepted: 02/01/2023 | Published: 02/05/2023

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Abstract

Objective: To evaluate the clinical response of periodontal tissues after periodontal therapy associated with the use of Bach Flower (Rock Rose gel) in participants with type 2 diabetes mellitus. **Methodology:** This randomized, double-blind, split-mouth, single-center, placebo-controlled clinical trial selected 20 participants with moderate, severe, or advanced periodontitis (stage II, III, and IV). They were divided into groups, where group 1 received Floral Rock Rose gel and group 2, saline gel. All groups received conventional periodontal treatment characterized by scaling and root planing before gel application. Clinical evaluation was performed using periodontal clinical parameters: Plaque Index (PI), Gingival Index (GI), probing depth (PPD), gingival recession (GR), and Clinical Insertion Level (CAL). Biometric parameters and hematological parameters were also evaluated. All clinical and laboratory parameters were obtained at baseline and after three months. **Results:** There was an improvement in periodontal clinical parameters before and after treatment in both groups ($P < 0.05$). There was no statistically significant difference between the intervention, control, and floral groups ($P > 0.05$). **Conclusion:** The periodontal treatment performed with Rock Rose adjuvant gel (Bach Flower) was safe, efficient, and promoted the improvement of periodontal clinical parameters. However, it did not show superior results to conventional periodontal therapy.

Keywords: Periodontitis; Floral therapy; Diabetes mellitus, type 2.

Resumo

Objetivo: Avaliar a resposta clínica dos tecidos periodontais após a terapia periodontal básica associada à utilização do floral de Bach (Rock Rose) em gel em participantes com diabetes mellitus tipo 2. **Metodologia:** Trata-se de um estudo clínico randomizado, duplo-cego, boca dividida, centro único, controlado por placebo. Foram selecionados 20 participantes com periodontite moderada, severa ou avançada (estágio II, III e IV). Foram divididos em dois grupos, onde o grupo 1 recebeu gel de Floral Rock Rose e o grupo 2, gel de soro fisiológico. Todos os grupos receberam o tratamento periodontal convencional caracterizado por raspagem e alisamento radicular previamente à aplicação do gel. A avaliação clínica foi realizada por meio dos parâmetros clínicos periodontais: Índice de placa (IP), Índice Gengival (IG), profundidade de sondagem (PS), recessão gengival (RC) e Nível clínico de Inserção (NIC). Também foram avaliados parâmetros biométricos e parâmetros hematológicos. Todos os parâmetros clínicos e laboratoriais foram avaliados nos períodos de baseline e após 3 meses. **Resultados:** Os resultados mostraram melhora nos parâmetros clínicos periodontais antes e após o tratamento em ambos os grupos ($P < 0,05$). Não houve diferença estatisticamente significativa entre os grupos de intervenção, controle e floral ($P > 0,05$). **Conclusão:** O tratamento

periodontal realizado com gel adjuvante Rock Rose (Floral de Bach) foi seguro, eficiente e promoveu a melhora dos parâmetros clínicos periodontais. No entanto, não apresentou resultados superiores à terapia periodontal convencional.

Palavras-chave: Periodontite; Terapia floral; Diabetes mellitus tipo 2.

Resumen

Objetivo: Evaluar la respuesta clínica de los tejidos periodontales después de la terapia periodontal básica asociada al uso de gel de flores de Bach (Roca Rosa) en participantes con diabetes mellitus tipo 2. *Metodología:* Se trata de un estudio clínico aleatorizado, doble ciego, split- boca, centro único, controlado con placebo. Seleccionamos 20 participantes con periodontitis moderada, severa o avanzada (estadio II, III y IV). Se dividieron en dos grupos, donde el grupo 1 recibió gel Floral Rock Rose y el grupo 2, gel salino. Todos los grupos recibieron tratamiento periodontal convencional caracterizado por raspado y alisado radicular previo a la aplicación del gel. La evaluación clínica se realizó utilizando parámetros clínicos periodontales: índice de placa (PI), índice gingival (GI), profundidad de sondaje (PS), recesión gingival (RC) y nivel de inserción clínica (NIC). También se evaluaron parámetros biométricos y parámetros hematológicos. Todos los parámetros clínicos y de laboratorio se evaluaron al inicio y después de 3 meses.

Resultados: Los resultados mostraron una mejoría en los parámetros clínicos periodontales antes y después del tratamiento en ambos grupos ($P < 0.05$). No hubo diferencia estadísticamente significativa entre los grupos de intervención, control y floral ($P > 0,05$). *Conclusión:* El tratamiento periodontal realizado con gel adjuvante Rock Rose (Floral de Bach) fue seguro, eficiente y promovió la mejora de los parámetros clínicos periodontales. Sin embargo, no mostró mejores resultados que la terapia periodontal convencional.

Palabras clave: Periodontitis; Terapia floral; Diabetes mellitus tipo 2.

1. Introduction

Periodontal diseases have recently been revised in a new classification, where we can identify a variety of periodontal disorders that share bacterial plaque as a common trigger (Caton et al. 2018). Tissue destruction (periodontal ligament rupture, pocket formation, and alveolar bone resorption) is mainly caused by the host's inflammatory response to the bacterial challenge presented by the biofilm (Preshaw et al. 2019). Although periodontitis is initiated and sustained by the microbial biofilm of dental plaque, local risk factors and systemic risk factors influence the disease rate (Kinane et al. 2017; Chapple et al. 2018). Therefore, in the current classification, "periodontitis as a direct manifestation of systemic diseases" was accepted (Caton et al. 2018).

The population with Type II Diabetes (DM2) is more likely to develop periodontal disease (estimated at twice as much as in a healthy population), and they are often affected by a more severe form of the disease. At the same time, periodontal inflammation negatively affects glycemic control and contributes to diabetic complications development (Preshaw et al. 2019; Lalla et al. 2011). Diabetes is a serious, long-term condition that occurs when the body cannot produce any or enough insulin or cannot effectively use the insulin it produces and encompasses individuals who have insulin resistance and usually have relative insulin deficiency, taking the hyperglycemia. This type is the most prevalent form of diabetes, which accounts for 90–95% of those with diabetes (American Diabetes Association, 2014). The glycemic control of patients with type 2 diabetes mellitus is the primary factor for reducing the complications of this disease (American Diabetes Association, 2006). The chronic hyperglycemia of diabetes can cause damage to many of the body's organs, leading to disabling and potentially fatal health complications, such as cardiovascular disease (CVD), nerve damage (neuropathy), kidney damage (nephropathy), and eye disease (leading to retinopathy, loss of vision and even blindness) (International Diabetes Federation, 2019).

Conventional periodontal therapy consists of scaling and root planning (Cao et al. 2019). Recent systematic reviews have shown that this treatment, with or without antibiotics, has clinical benefits, including reduced probing depth (PD), probing bleeding (BOP) and suppuration (SUP), and again in the clinical attachment level (CAL). In addition to improving periodontal indices, it provides improved glycemic control for patients with periodontal disease and diabetes.

However, some factors are related to the failure of mechanical therapy, such: failure in the elimination of pathogens,

due to the difficulty of accessing the instruments to the base of the periodontal pocket, root anatomical variations and systemic factors modifying the host response, such as diabetes mellitus type 2, where patients with poor metabolic control have a worse response to treatment (Adriaens et al. 1988; Santos et al. 2009). On the other hand, antimicrobials directly in the periodontal pocket, as an adjunct to non-surgical therapy, can mitigate the occurrence of therapeutic failures and have been suggested to avoid possible systemic complications (Ganguly et al. 2017).

Bach Flower Remedies are the collection of 38 individual remedies made mainly from the flowers of the plants discovered by Dr. Edward Bach (1886–1936). This complementary alternative medicine (CAM) therapy usually suggested correcting mild emotional and psychological disturbances, for Bach, the "true cause" of the disease (Bach 1941). Its use as an antimicrobial is scarce in the literature, but its potential was shown by *in vitro* studies, where it was shown to be efficient in inhibiting the growth of bacteria, of the two most prevalent oral diseases, caries, and periodontal disease.

This clinical trial's objective was to clinically evaluate the effectiveness of Floral de Bach (Rock Rose) as an adjuvant agent in periodontal therapy in patients with type 2 diabetes mellitus.

2. Methodology

This study was approved by Ethics Committee of the Fluminense Federal University of Nova Friburgo, Rio de Janeiro, Brazil (CAAE: 89966418.8.000.5626). That is one This study is a split-mouth double-blind randomized controlled clinical trial (Castro Dos Santos et al. 2016). Before participation, the purpose and procedures were explained to all participants, who gave their informed consent in writing.

2.1 Patient selection

Twenty patients from Fluminense Federal University of Nova Friburgo, Rio de Janeiro, Brazil, were selected in 2020 to participate in this study by a single calibrated examiner. Participants were submitted to anamnesis; evaluation of medical and dental history; clinical and laboratory tests to identify the conditions that either elected or prevented them from participating in the study. Sample-size estimation for this study was based on clinical attachment level (CAL), where the mean and standard deviation values were used. The calculation considered a 5% significance level and 90% study power. It was performed using the OpenEpi software (<http://www.openepi.com>), and the sample size resulted in 36 sites. Therefore, as this is a split-mouth study, 18 volunteers were selected for the study. The randomization performed was simple, using the coin heads or tails method, where each patient was drawn by a lot to define the quadrant to receive the treatment.

2.2 Inclusion and exclusion criteria

Criteria for selecting the subjects were as follows: presence type 2 diabetes and periodontitis. Diabetes mellitus established according to the American Diabetes Academy, with HbA1c higher than or equal to 6.5%, fasting blood glucose > 126mg / dl. (Caton et al. 2018). Periodontitis established according to new criterion, participants with severe and advanced periodontitis were included (stage III and IV: - at least interdental CAL \geq 5mm and PPD \geq 6mm). (American Diabetes Association, 2014).

The subjects were excluded when: they showed hypersensitivity to the floral components and any evidence of systemic factors that modify periodontal disease, except for diabetes mellitus, and, therefore, may directly interfere in the completion of the work (bias). The factors described in the literature include osteoporosis types I and II, alcoholism, acquired or induced immunosuppression, any change described in the novel as a potential modifier of the periodontal disease profile, and physical/emotional stress drugs that influence periodontal tissues. Samples from pregnant or lactating women, individuals

who have taken antibiotics in the past six months, clinical manifestations of oral candidiasis, anti-inflammatories, or hormone replacement therapy, and who have received periodontal treatment in the last six months before the procedure will be excluded. The clinical study was divided into two groups, who received rock rose therapy and the placebo group.

2.3 Clinical evaluation and Periodontal Therapy

An experienced periodontist (GACGC) examined the clinical periodontal parameters, including plaque index (PI) and bleeding on probing (GI) (Ainamo & Bay 1975), probing depth of pocket (PPD), gingival recession (GR) and clinical attachment level (CAL). For the examination, a periodontal probe PCP15 (PCP-UNC15, Hu-Friedy, Chicago, IL) was used in six locations per tooth in all teeth, excluding third molars. The intraexaminer agreement of the categorical variables (PI, GI) using the kappa calculation, at the tooth level, was 0.75. Reproducibility of continuous variables (PPD, GR and CAL) was 0.70, as evaluated by the intraclass correlation coefficient (ICC). The examiner (GACGC) had no access to the previous recordings.

Hematological parameters were also recorded: fasting blood glucose and glycosylated hemoglobin, to assess the influence of treatment on type 2 diabetes mellitus.

Two treatments were tested, at randomly chosen sites, Bach's floral gel (Rockrose, Mona's, SP, Brazil) and saline gel, as a negative control. To avoid carry across (interference between one treatment and the other), the sextants were isolated with a cotton roll, and a sterile curette was used for each sextant. A person outside the study did the coding, so the patients, investigator, and statistician remained blinded.

A different clinician (CPP) conducted periodontal treatment, characterized by scaling and root planning. Treatment was performed in two sessions at sites with PPD > 5mm. Monthly plaque control and oral hygiene instructions were also conducted, including brushing technique and interdental cleaning with dental floss. Ultrasonic scalers (Dabi Atlante, Rio de Janeiro, RJ, Brazil) were used to remove all calculus and biofilms.

All participants received oral hygiene instructions for home care procedures (tooth-brushing technique, interdental cleaning, and use of tongue scrapers) (RAC). Antibiotics or anti-inflammatory drugs were not prescribed after periodontal treatment. Instructions for oral hygiene and prophylaxis were administered at intervals of 30, 60, and 90 days.

The patients were re-examined after three months. The data were recorded to compare the conditions pre and post periodontal treatment.

2.4 Statistical analysis

Statistical tests were performed using the Statistics software (Statistix, Tallahassee, FL, USA, version 10.0.0.9, 2013). All variables were tested for data normality (Shapiro-Wilk Test). RM Anova was used to compare clinical parameters (PI, GI, GR, PPD and CAL) between groups and initial times and three months. The level of statistical significance for all variables is defined at 5%.

3. Results

All volunteers completed the study are presented on Table 1. The sample consisted of 9 (50%) women and 9 (50%) men, aged between 37 and 73 years (mean age: 52.98 ± 63.12 years). In Table 2, we can see that all patients remained diabetic during the follow-up period.

Table 1 – Characteristics of participants. Age (means, minimum and maximum), Sex and Skin Color (Number and percentage of frequency).

Variables	Floral and Control groups n=18
Age (years)	59 (52.98-63.12)
Sex (%)	
Female	9 (50.00)
Male	9 (50.00)
Skin color (%)	
White	13 (72.20)
Black	4 (5.60)
Brown	1(2.20)

Source: Authors.

Table 2 – Descriptive statistic, means, minimum and maximum of hematological parameters of patients with diabetes mellitus in the initial and final times.

Variables	Floral and Control groups n=18
Hba1c (%)	
Baseline	7.80 (7.16-8.57)
3 months	7.35 (7.07-8.42)
Fasting blood glucose (mmg/dl)	
Baseline	168.50 (153.19-192.16)
3 months	159.94 (154.34-191.30)

* Statistically significant difference between baseline and 3 months Wilcoxon Run Sum Test $p \leq 0.05$. Source: Authors.

In Table 3, the data are presented in mean and standard deviation and characterize the results found for the clinical parameters evaluated: PI, GI, GR, PPD, and CAL. The table also shows positive results for clinical data, with a statistically significant difference ($p < 0.05$) for % GI, PPD (mm), and CAL (mm) for both treatments and in the reassessment period, three months after periodontal therapy.

Table 3 – Clinical parameters of Control and Floral groups at baseline and after 3 months of periodontal therapy. Values are expressed as mean + standard deviation.

Variables	Groups	
	Control n=18	Floral n=18
PI (%)		
Baseline	53.68 ± 41.03	52.82 ± 42.81
3 months	31.48 ± 41.96	41.66 ± 46.17
GI (%)		
Baseline	45.34 ± 33.21	36.16 ± 37.53
3 meses	15.73 ± 21.74*	18.51 ± 26.74*
PPD (mm)		
Baseline	5.22 ± 0.64	5.61 ± 1.24
3 meses	4.11 ± 0.83*	4.22 ± 1.26*
GR (mm)		
Baseline	0.44 ± 1.33	0.61 ± 1.19
3 meses	0.44 ± 1.33	0.72 ± 1.40
CAL (mm)		
Baseline	5.66 ± 1.78	6.22 ± 1.83
3 meses	4.55 ± 1.72*	4.94 ± 2.07*

* Statistically significant difference between baseline and 3 months Repeated measure analysis of variance (RM ANOVA) $p \leq 0.05$. Source: Authors.

There was no statistically significant difference between the intervention, control, and floral groups, only for the data from the initial and three months times in the same group. In both groups, there was a similar reduction in PI, GR, PPD, and CAL.

4. Discussion

In this randomized clinical trial with a 3-month follow-up, adjuvant use during initial therapy resulted in similar clinical periodontal improvements compared with mechanical therapy alone. These results are consistent with many studies (Camargo et al. 2013; Raman et al. 2014; Gay et al. 2014; Bian et al. 2021) and confirm the effectiveness of non-surgical mechanical procedures in the treatment of periodontitis. On the other hand, there was no significant difference between the test group and the control group during the follow-up period.

The search for an adjuvant to periodontal therapy, especially in diabetic patients, is relevant due to the worse response of these patients to periodontal treatment (Santos, et al. 2009, Tsobgny-Tsague et al. 2018, Rode et al. 2019). The worst response of patients with diabetes, when compared to patients without diabetes, about clinical parameters, occurs because of the delay in tissue healing. Slower healing occurs, in turn, due to the accumulation of glycation end products, as well as greater collagen destruction (Rode et al. 2019). Therefore, the objective of periodontal treatment, in addition to the clinical advantages in periodontal tissues, is to improve metabolic control, a benefit already shown in systematic reviews with meta-analysis (Ahuja et al. 2019; Jain et al. 2019). In the present study, the HbA1c index was used to demonstrate the patient's profile and prove the presence of diabetes. We also assess at the end to check the status of the disease. In this study, it would not be valid to assess the improvement in metabolic control after treatment, as this is a split-mouth study and because of the initial mean HbA1c of the research participants, which was 7.87%. Since studies (Chen et al. 2021; Engebretson et al. 2013) have shown that patients with HbA1c levels <9% have limited potential for improvement after therapy and that even patients with HbA1c levels between 7 and 9% have a slight increase in levels after treatment.

Bach Flower Remedies are a CAM therapy generally suggested to correct mild emotional and psychological disorders such as anxiety, stress, and pain treatment, but its use for emotional disorders is controversial in the literature. Two systematic reviews (Quintero et al. 2018; Ernst 2010) was carried out on the subject, however, it is not possible to conclude whether the therapy is effective or not, only attesting to the scarcity of randomized clinical trials, as well as the low quality of the studies. These results lead to low or very low-quality evidence.

Although, its use has already been described in the literature for other purposes, which are a little less explored, such as the treatment of herpes zoster (Thaler et al. 2009), carpal tunnel syndrome (Martinez-Luque et al. 2014), and symptoms resulting from overweight and obesity such as binge eating and electrocardiogram (Rivas-Suárez et al. 2017). Resende et al. 2014, demonstrated the use of Floral Rescue Remedy to reduce risk factors for cardiovascular diseases, with statistically significant results in the control of blood glucose, triglycerides, and HDL cholesterol. The authors believe that the results provide preliminary data on the biological action resulting from the use of Floral in glucose and lipid metabolism, which may be associated with a reduction in anxiety-related to Floral. It is believed that the behavioral and biological pathways do not act in isolation, but rather are interrelated in the pathogenesis of many diseases, including diabetes mellitus. What elucidates us once again, the relevance of the search for interventions with beneficial effects on psychosocial and biological factors.

Gonçalves et al. 2019, demonstrated in their study the effect of Floral Rock Rose in inhibiting the growth of *Streptococcus mutans*, which is an important microorganism for the formation of the initial biofilm, this results according with Koo et al. 2021. The authors suggest that *S. mutans* facilitate the installation of periodontopathogens. However no reported about the use of Bach flowers as an adjunct to periodontal therapy are reported. The authors intend to evaluate these

antimicrobial effects of Bach flowers in the future due to there are few studies that report clinical and microbiological results.g

The main limitation of our study is the split-mouth design, is the lack literature with Bach Flowers to discuss this finding. Since it is not possible to report the use of florals with hematological parameters, and because there are no similar studies, to make direct comparisons with periodontal parameters and results. We also suggest that future studies include the oral use of Floral to assess emotional aspects through the application of scales, clinical evaluations of the effected on periodontal tissues and microbiological analysis.

5. Conclusion

Periodontal treatment with Rock Rose gel adjuvant (Bach Flower) was safe, efficient, and promoted the improvement of clinical periodontal parameters. However, it did not show superior results to conventional periodontal therapy.

Acknowledgments

This study was supported by CNPq/PIBIC/UFF (scholarship # 190070).

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