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Original Article

Evaluation of periodontal indices in young adults submitted to chlorhexidine 0.12% mouthwash: a randomized clinical trial

Avaliação dos índices periodontais em adultos jovens submetidos a enxaguatório bucal a 0,12% de clorexidina: um ensaio clínico randomizado

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Resumo

Introdução: A gengivite é uma inflamação gengival que geralmente pode ser tratada com higiene oral, como escovação, uso do fio dental e um anti-séptico bucal. **Objetivo:** O objetivo deste ensaio clínico randomizado foi avaliar clinicamente a eficácia da solução de clorexidina 0,12% (CHX) como um agente antiinflamatório e na redução da presença de placa e inflamação em adultos jovens. **Material e método:** Trinta pacientes com gengivite com idade entre 18 e 30 anos com profundidade de sondagem ≤ 3 mm com mínimo de 20 dentes em toda a boca foram selecionados e avaliados no início do estudo e 30 dias após o tratamento. Foram verificados os parâmetros clínicos periodontais: índice de placa (IP), índice gengival (GI), Índice de Higiene Oral Simplificado (IHO-S), Índice de Debris Simplificado (DI-S) e Índice de Cálculo Simplificado (IC-S). A seguir, os pacientes foram alocados aleatoriamente em dois grupos: Grupo CHX, recebeu clorexidina 0,12% previamente identificada como solução 1 e grupo placebo, recebeu solução salina identificada como solução 2. Ambos os grupos foram incluídos em programa de higiene e receberam enxaguatório bucal. **Resultado:** Diferença estatisticamente significante entre os grupos CHX e Placebo foi observada para as variáveis PI, GI, DI-S, CI-S e OHI-S (p <0,05 - Teste T Pareado) após 30 dias. O grupo CHX melhorou a resposta ao GI em comparação ao placebo em 30 dias. Clorexidina 0,12% foi eficiente no controle da inflamação do periodonto. **Conclusão:** Pode-se concluir que a eficácia da clorexidina como enxaguatório bucal na melhora dos índices periodontais foi confirmada em adultos jovens, mas ainda é controverso que a idade pode influenciar o IG e IHO-S.

Descritores: Gengivite; clorexidina; periodontia; índice periodontal; estudo clínico.

Abstract

Introduction: Gingivitis is a gingival inflammation which can often be treated with oral hygiene such as brushing, flossing, and an antiseptic mouthwash. **Objective:** The aim of this randomized clinical trial was to clinically evaluate the effectiveness of 0.12% chlorhexidine (CHX) solution as an anti-inflammatory agent and for reducing the presence of plaque and inflammation in young adults. **Material and method:** Thirty patients with gingivitis aged 18 to 30 years with a probing depth ≤ 3 mm and a minimum of 20 teeth in the whole mouth were selected and evaluated at baseline and 30 days after treatment. Periodontal clinical parameters were verified: plaque index (PI), gingival index (GI), Simplified Oral Hygiene Index (OHI-S), Simplified Debris Index (DI-S), and Simplified Calculus Index (CI-S) Patients were then randomly allocated into two groups: CHX Group, received chlorhexidine 0.12% labeled as solution 1, and Placebo Group, received saline solution labeled as solution 2. Both groups were included in a hygiene program and received mouthwash. **Result:** Statistically

significant differences between CHX and Placebo groups were observed for the variables PI, GI, DI-S, CI-S, and OHI-S ($p \leq 0.05$ - Paired T Test) after 30 days. The CHX group presented improved GI compared to Placebo at 30 days. Chlorhexidine 0.12% was efficient in the control of periodontium inflammation. **Conclusion:** It can be concluded that chlorhexidine as a mouthwash is efficient in improving periodontal indices in young adults, but it is still controversial whether age can influence GI and OHI-S.

Descriptors: Gingivitis; chlorhexidine; periodontics; periodontal index; clinical study.

INTRODUCTION

Gingivitis is an inflammation that occurs around the tooth and can lead to swelling, bleeding, and redness[1]. Gingivitis can often can be treated with oral hygiene such as brushing, flossing, and an antiseptic mouthwash that can reduce gingival inflammation[2]. Gingivitis is one of the most frequent periodontal diseases, affecting individuals around the world[1,2]. Gingivitis and periodontitis are a continuity of the same inflammatory disease, and the management of gingivitis is a primary prevention strategy for periodontitis and a secondary prevention strategy for recurrent periodontitis[3].

The influence of gingival inflammation was observed in 565 Norwegian males, aged between 16 and 34 years, in a 26-year longitudinal study. The results demonstrated that when a tooth was surrounded by healthy or swollen gingiva it had an 8.4 times lower risk of being lost compared to a tooth surrounded by swollen gingiva that occasionally bled on probing, and a 45.8 times lower risk than a tooth that was always surrounded by swollen gingiva that bled on probing. This suggests that clinical health is an indicator of tooth longevity, representing not only the precursor to periodontitis but also an important clinically relevant risk factor for disease progression and tooth loss[4].

Chlorhexidine (CHX) is considered the gold standard chemical agent by several authors, and has been widely used for the treatment of inflammatory diseases associated with plaque accumulation[5]. The effectiveness of CHX is related to the presence of a strong affinity for tissue surfaces as well as dental and antibacterial activity against Gram-positive and Gram-negative species, yeast, and viruses. It is considered a safe compound, with minor and transient local and systemic effects[6]. According to a systematic review, CHX mouthwash demonstrated better control of gingivitis compared to placebo/control mouthwash, with a reduction in plaque of 33% and in gingivitis of 26%[7].

Although periodontitis has a low occurrence in the young population, the disease can develop quickly, aggressively, and destructively. Results in the literature regarding age and gingivitis are inconsistent. The development of studies with young individuals who already have all their permanent teeth, are necessary to guide strategies for prevention, to achieve early diagnosis and improve therapeutics[8]. The objective of this clinical trial was to clinically evaluate the effectiveness of 0.12% chlorhexidine solution as an anti-inflammatory agent and for reducing the presence of plaque and inflammation when compared with saline solution in young adults with gingivitis after 30 days of use.

MATERIAL AND METHOD

Study Design and Population

A randomized double blind (Participant-Care provider-investigators), clinical trial of 30 days duration was conducted among 30 volunteers from the Health Institute of Nova Friburgo, School of Dentistry, Fluminense Federal University, between 2018 and 2019. The duration of 30 days was chosen as this is sufficient time to allow the parameter study on the gingiva and to study the inflammation of the gingiva without causing any irreversible problems.

The study protocol was approved by the Ethical Committee of Nova Friburgo, Fluminense Federal University, registration number CAAE: 69912817.0.0000.5626. Prior to participation, the researcher

explained the procedures to all participants and obtained their written informed consent in accordance with the Helsinki Declaration. The study was approved by the http://ClinicalTrials.gov Protocol Registration and Results System with the number NCT04658225.

The medical and dental histories were carried out at the pre-screening visit. Thirty participants were selected based on the inclusion and exclusion criteria. The following inclusion criteria were observed: presence of gingivitis in higher than 10% of sites, probing depth (PD) ≤ 3 mm, minimum of 20 teeth in the whole mouth, and aged between 18 and 30 years. The exclusion criteria were: patients with periodontal disease (PD ≥ 4mm with clinical attachment loss) and systemic diseases, diabetes or osteoporosis, pregnant, lactating females, smokers, and users of immune suppressive medication, phenytoin, cyclosporine, calcium channel blockers, antibiotics, or nonsteroidal anti-inflammatory drugs in the previous 3 months, any medical conditions requiring immunotherapy, or diagnosed with HIV+ or AIDS, which could interfere with the periodontium status.

A single examiner, previously calibrated, determined patient eligibility for the study and enrolment of patients in the trial. The Kappa coefficient was calculated to analyze the reproducibility of intra examiner measurements (K=0.92) for the variable OHI-S. All participants were randomly assigned to different intervention groups: chlorhexidine 0.12% group (CHX) and saline solution group (Placebo) by tossing a coin. The study was double-blind. The examiner and the patient did not know which group the patient was assigned to.

The results were treated by another examiner who knew which patients belonged to the experimental or placebo group. The masking process was established by assigning a number to each patient in the study, and the treatment was the same for both the patient and examiner who did not know which group the patient belonged to.

Clinical Examination and Periodontal Therapy

The examiner (NCB) determined the clinical parameters including; plaque index (PI), Gingival Index (GI)[9], Simplified Debris Index (DI-S) [Table 1], and Simplified Calculus Index (CI-S) [Table 2], and the Simplified Oral Hygiene Index (OHI-S) was obtained by average group or individual calculus (CI-S) and debris scores (DI-S), added together[10]. The PI and GI were determined on Ramfjord teeth (16, 21, 24, 36, 41, and 44)[11]. Each of the four surfaces of the teeth (buccal, lingual, mesial, and distal) was given a score from 0-3. The scores from the four areas of the tooth were added and divided by four in order to give the mean plaque index for each tooth. The index for the patient was obtained by summing the indices for all six teeth and divided by six.

Table 1. Criteria for classifying debris (Löe et al.[9])

0 No debris or stain present
1 Soft debris covering not more than one third of the tooth surface, or presence of extrinsic stains without other debris regardless of surface area covered
2 Soft debris covering more than one third, but not more than two thirds, of the exposed tooth surface.
3 Soft debris covering more than two thirds of the exposed tooth surface.

Table 2. Criteria for classifying calculus (Löe et al.[9])

0 No calculus present
1 Supragingival calculus covering not more than third of the exposed tooth surface.
2 Supragingival calculus covering more than one third but not more than two thirds of the exposed tooth surface or the presence of individual flecks of subgingival calculus around the cervical portion of the tooth or both.
3 Supragingival calculus covering more than two third of the exposed tooth surface or a continuous heavy band of subgingival calculus around the cervical portion of the tooth or both.

The Simplified Oral Hygiene Index, OHI-S, was determined differently from the original OHI considering the number of surfaces scored, 6 rather than 12, the scores which can be obtained, and the

method of selecting the surfaces to be scored. The OHI-S is the result of the sum of two components, the Debris Index (DI-S) and the Simplified Calculus Index (CI-S), both of which received a score from 0-3 (Table 1 and Table 2). Once the scores had been recorded, the OHI-S index values were calculated.

After the careful clinical evaluation and recording of indices, the baseline scores of all indices were brought down to near 0 in all the patients of the study through prophylaxis and supragingival scaling with an ultrasonic device by a different researcher, blinded to the clinical exam (CPP). Ultrasonic scalers (Dabi Atlante, Rio de Janeiro, RJ, Brazil) were used to remove all calculus and biofilms in both the CHX and Placebo groups. After plaque removal, the volunteers started using the allocated mouthwash twice a day.

Two types of mouthwash were prepared and labeled in similar bottles as solution 1 (CHX-chlorhexidine 0,12% - Periogard, Colgate-Palmolive Industrial Ltda, São Bernardo do Campo, São Paulo, Brazil) and solution 2 (Placebo - saline solution 0.9% - Bifarma, Demac Produtos Farmacêuticos Ltda, São Paulo, Brazil). The labeling was performed by a person outside the study (IAVPP) so that both the patients and the investigator of the program as well as the person responsible for the statistics (EPJ) remained blinded about the labeling. The participants of the study were instructed to use 15 mL of the mouthwash solution twice a day (morning and evening) for 1minute, 30 minutes after tooth brushing, for four weeks consecutively. After the mouthwash the participants were instructed to expectorate the residual mouthwash and then avoid eating and drinking for 30 minutes and not use another mouthwash during the study period. Each bottle contained 1 liter of mouthwash and the solutions were the same color. The protocol for mouthwash use was also provided to patients in written form.

All patients were included in a hygiene program for maintenance of oral health. The hygiene program included instructions for home care procedures. The patients were given guidance on tooth-brushing technique, using the Bass technique, and interdental cleaning with dental floss. Patients were re-examined after 30 days of using mouthwash to re-evaluate the above mentioned indices. The data were recorded to compare the conditions between before (baseline) and after mouthwash use (30 days).

Statistical Analysis

The statistical analysis was performed using Prism for Windows (GraphPad Prism, version 9.0, San Diego, CA, USA). Variables from the clinical analyses were compared between CHX and placebo groups at baseline and 30 days after therapy, using the Paired T Test. Differences were considered significant when $p \leq 0.05$.

RESULT

Clinical Results

The baseline data confirmed the groups were homogeneous at the beginning of the study. There were no statistically significant differences (Paired T Test - $p \leq 0.05$) between CHX and Placebo for age, sex, ethnicity, PI, GI, DI-S, CI-S, and OHI-S.

After 30 days, there was a statistically significant reduction in PI, GI, DI-S, and CI-S (Paired T Test - $p \leq 0.05$) for both Placebo and CHX groups (Table 3). These results confirm the efficiency of the hygiene program and CHX mouthwash to control gingivitis. Means of GI were higher in the placebo (0.61 ± 0.33) compared to CHX group (0.27 ± 0.21). The CHX group presented an improved response to GI compared to Placebo at 30 days (Table 3). These results confirm the efficiency of CHX in the control of periodontium inflammation. Pearson Correlations between age and GI and PI were statistically significant after 30 days for the Placebo group (GI: p=0.0249 and PI: p=0.0178).

The OHI-S presented a statistically significant reduction (Paired T Test - $p \leq 0.05$) for both Placebo and CHX groups after 30 days, which also evidenced the efficiency of the hygiene program and CHX mouthwash (Figure 1). Mean values of OHI-S were statistically significantly higher in the Placebo (0.89 ± 0.29) compared to CHX group (0.49 ± 0.21) at 30 days (Figure 1).

Table 3. Means and Standard deviations (SD) of clinical variables distributed between Chlorhexidine (CHX) and Placebo groups at baseline and 30 days after periodontal treatment

Parameter	Placebo (n=15)	CHX (n = 15)
Age (years)	22 ± 4.08	22.6 ± 3.64
Sex (%)		
Female	40	66.7
Male	60	33.3
Ethuicity (%)		
White	46.7	60
Black	33.3	20
Brown	20	20
PI		
Baseline	1.78 ± 0.34	2.12 ± 0.46
30 days	0.98 ± 0.33*	0.47 ± 0.27*
GI		
Baseline	1.48 ± 0.43	1.60 ± 0.43
30 days	0.61 ± 0.33*	0.27 ± 0.21* **
DI-S		
Baseline	1.96 ± 0.77	2.21 ± 0.62
30 days	1.45 ± 0.53*	0.66 ± 0.32* **
CI-S		
Baseline	1.16 ± 0.87	1.29 ± 0.67
30 days	0.34 ± 0.26*	0.33 ± 0.15*

Plaque index (PI), Gingival Index (GI), Simplified Debris Index (DI-S), Calculus Index Simplified (CI-S). *Statistically significant difference between baseline and 30 days (Paired T Test - $p<0.05$). ** Statistically significant difference between Placebo and CHX at 30 days (Paired T Test - $p<0.05$).

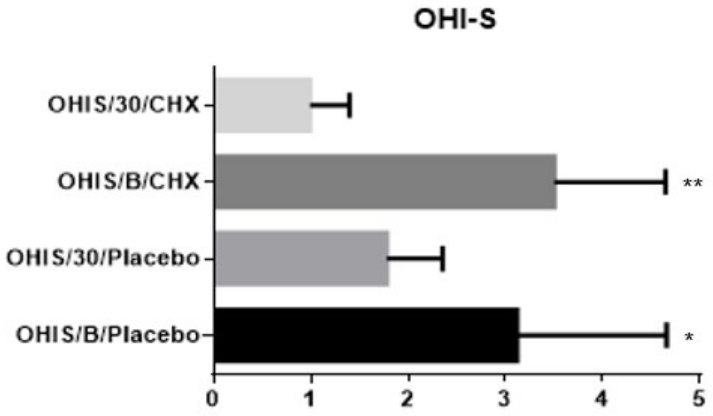

Figure 1. Simplified Oral Hygiene Index (OHI-S) for Placebo and CHX groups at baseline (B) and 30 days (30) after periodontal treatment. *Statistically significant difference between baseline and 30 days (Paired T Test - $p \leq 0.05$), ** Statistically significant difference between Placebo and CHX at baseline (Paired T Test - $p<0.05$).

DISCUSSION

The present randomized clinical trial study confirmed the effectiveness of chlorhexidine 0.12% in the control of gingival inflammation in young adults. In addition this study showed that a hygiene program improved maintenance for all participants. With respect to age, the correlations between age and GI, OHI-S, and CI-S are still controversial in young adults.

Due to the complex pathogenesis of periodontal disease, it is critical that early diagnosis and treatment are carried out and that strategies are developed for the prevention of gingivitis in order to avoid periodontal destruction[8]. In the study by Takenaka et al.[12], the authors noted that gingivitis treatment and control are still very pertinent and current topics, particularly because there is a recurring increase in plaque accumulation and gingival inflammation.

According to da Cunha et al.[13] the periodontal conditions of Brazilian adolescents and young adults are precarious and correlated with increasing age. The literature is still inconsistent where gingivitis and age are considered[8]. Therefore, the present research targeted young adults (18-30 years) with gingivitis to analyze the periodontal conditions of these individuals. Pearson correlations revealed that there were correlations between age and PI and GI only at 30 days in the placebo group. For OHI-S, DI-S, and CI-S, Pearson correlations revealed that there were correlations for the CHX group only at baseline.

Considering the periodontal treatment, ultrasonic prophylaxis has been shown to require less time than manual treatment, scaling and root planing[14]. The ultrasonic or manual prophylaxis were equally effective for clinical parameters[13]. James et al.[15] reported that one session of ultrasonic prophylaxis associated with oral hygiene instructions can reduce PI and GI 15 and 30 days after the intervention, justifying the improvements found in the saline solution group.

In the current study the periodontal treatment used was ultrasonic, demonstrating its effectiveness in reducing PI, GI, DI-S, CI-S, and OHI-S after 30 days of follow-up. It was observed that the use of CHX mouthwash or saline solution associated with ultrasonic prophylaxis reduced gingival inflammation. James et al.[15] evaluated the effects of chlorhexidine mouthwash used as an adjunct to mechanical oral hygiene procedures in children and adults for at least four weeks and reported that there was insufficient evidence to determine the reduction in GI scores from 1.1 to 3 (moderate or severe levels of gum inflammation) associated with CHX mouthwash. The current study found markedly reduced means of GI after 30 days (0.27 ± 0.21) compared to baseline (1.60 $\pm$ 0.43), making it possible to conclude that CHX mouthwash reduced gingivitis.

Bhat et al.[16] conducted a double-blind study including a total of 72 individuals, aged 18–24 years, comparing three groups: Herbal Mouthwash, chlorhexidine mouthwash, and saline solution. The plaque index scores at baseline were (1.22±0.25) for the CHX group and (1.34±0.48) for the S group. The highest mean plaque index values were found after 30 days in the Placebo group (1.46±0.19), the lowest means were after 1 month (0.68±0.14) in the CHX group. Although the current study used an equally homogeneous population and similar age to that reported by Bhat et al.[16], higher levels of plaque were measured at baseline and different results were found. These differences may be explained by the concentration of chlorhexidine used in the studies, Bhat et al.[16], used 2% CHX, while the current study used 0.12% CHX. Franco et al.[17] compared 0.12% and 0.2% CHX solution and found no differences in values of bleeding rate. In addition, both concentrations were able to control dental plaque.

Herrera et al.[18] evaluated GI scores, and found differences between the Chlorhexidine group and Placebo group on the 15th day; placebo (0.23 ± 0.2) vs. CHX (1.36 ± 0.57) ($p < 0.001$), respectively. The current study found values of GI in the Placebo (0.27 ± 0.21) vs. CHX vs. (0.61 ± 0.33) after 30 days. This result demonstrates that the evaluation interval and mouthwash can influence GI, after 30 days the CHX presented improved gingival inflammation.

Considering the Simplified Oral Hygiene Index (OHI-S), Debris Index (DI-S), and Simplified Calculus Index (CI-S), Balappanavar et al.[19] recorded that the simplified OHI-S scores after use of

2% chlorhexidine gluconate mouthwash presented an immediate reduction after the 1st rinse. Vadhana et al.[20] evaluated the effectiveness of sesame oil (SO), ozonated SO (OSO), and chlorhexidine (CHX) mouthwash on the oral health status of adolescents. All the groups showed statistically significant reductions in DI-S, CI-S, OHI-S, PI, and S. mutans count after 15 days. However, there are few studies in the literature that use OHI-S, DI-S, and CI-S to check the efficiency of mouthwashes in young adults. The current study used the OHI-S, DI-S, and CI-S as they are practical indices that can be used with a large number of people and showed that these indices are efficient to monitor periodontal treatment.

The current findings have practical relevance for oral hygiene, including guiding and aiding the development of preventive programs to reduce the incidence of gingivitis targeting in similar populations. In addition, the therapy used may be extrapolated to large populations to assist in the treatment of gingivitis and prevent young adults from developing periodontitis at older ages. As the data on gingivitis and age are still inconsistent, comparisons between the studies must be made with caution due to different protocols and indices applied. It was possible to conclude that the use of 0.12% chlorhexidine mouthwash demonstrated better antiplaque and anti-inflammatory activity than placebo in young adults with gingivitis.

CONCLUSION

It can be concluded that chlorhexidine as a mouthwash is efficient to improve periodontal indices in young adults, but it is still controversial whether age can influence GI and OHI-S.

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CONFLICTS OF INTERESTS

The authors declare no conflicts of interest.

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