



Impact of gingivitis treatment for diabetic patients on quality of life related to periodontal objective parameters: A randomized controlled clinical trial

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ABSTRACT

Objectives: Patients with diabetes have a poor oral health-related quality of life (OHRQoL). It is not clear if this situation could be changed with effective periodontal treatment. This study examined both patients with diabetes and systemically healthy individuals to discover the impact of a gingivitis treatment protocol on OHRQoL and its relation to objective periodontal parameters.

Design: After ultrasonic debridement, patients were randomly assigned to an essential-oils (EO) or placebo mouthwash group. At baseline and 3 months, OHRQoL was assessed with the Oral Health and Quality of Life-United Kingdom questionnaire (OHQoL-UK) along with clinical, halitometric, microbiological and inflammatory objective parameters. The primary outcome was a change in OHQoL-UK scores. A factor analysis was performed and the impact of the extracted quality of life factor (QLF) and its interactions with diabetes, treatment, and time on the objective parameters, were tested by multiple linear regression models ($p < 0.05$). Chi-Square test compared questionnaire-answering profiles ($p < 0.05$).

Results: Combined treatment with EO provided OHQoL improvements in both systemic conditions. Positive effect of oral health status on quality of life increased in EO groups but not in placebo groups. Question I (self-confidence) showed the greatest factorial weight, while Question A (food intake) showed the lowest factorial weight. All patients who showed OHRQoL improvements and used the EO rinse showed the lowest plaque and gingival indices and lower levels of bacteria and volatile sulfur compounds.

Conclusions: OHRQoL positively changed overtime. Most effective treatment protocols would provide better improvements in OHRQoL which is related to periodontal objective measures.

1. Introduction

Oral and periodontal statuses impact how individuals perceive their quality of life. Although clinical conditions have improved, a significant portion of the adult population (even in developed countries) frequently suffers negative effects in their daily lives as a result of oral health issues (White et al., 2012). The interaction among oral health, general health and quality of life is only poorly understood. After evaluating 1,007 adults Zucoloto, Maroco, Campos (2016) reported that oral health, referred pain and presence of any chronic disease had significant influence on health-related quality of life. In addition, when poor oral health negatively impacts quality of life there is also an

association with poor general health (de Andrade, Lebrão, Santos, da Cruz Teixeira, & de Oliveira Duarte, 2012). Most periodontal studies on adults have focused on periodontitis, while the relationship between gingivitis and quality of life has received less attention (Eltas, Uslu, & Eltas, 2016; Mendez, Melchior Angst, Stadler, Oppermann, & Gomes, 2017). Bleeding and bad breath are major complaints of gingivitis patients, although they are not always self-perceived (Kallio, Nordblad, Croucher, & Ainamo, 1994; Eli, Baht, Koriati, & Rosenberg, 2001). Halitosis is more likely to be detected in patients with gingivitis than in periodontally healthy patients (Apatzidou et al., 2013). This is due to volatile sulfur compound levels that are higher in inflamed gingiva than in healthy gingiva (Yaegaki & Coil, 1999). In addition, an increase in

Abbreviations: CONSORT, consolidated standards of reporting trials; EO, essential oils; KMO, Kaiser-Myer-Olkin; OHQoL-UK, Oral Health and Quality of Life-United Kingdom (questionnaire); OHRQoL, Oral Health-Related Quality of Life; ppm, parts per million; QLF, Quality of Life Factor

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the levels of gingival bleeding can be observed when patients with gingivitis are compared to those with good periodontal health (Pereira et al., 2012). Although gingivitis is not always self-perceived, it can affect quality of life, at least in children (Tomazoni et al., 2014).

In addition to behavioral factors, such as tobacco use (Bhat, Roberts-Thomson, & Do, 2015) and alcohol consumption (Lages et al., 2015), specific systemic diseases, such as cardiovascular disease and diabetes, have been related to periodontal disorders (Kogawa et al., 2016; Xu et al., 2017). Further, specific cytokine gene polymorphisms can influence individuals' response against the bacterial challenge and therefore host susceptibility to periodontal diseases (Cantore et al., 2014). Interestingly, cytokine profiles can vary according to the presence of systemic diseases such as diabetes (Cricoli et al., 2016). Unfortunately, diabetic individuals have other risk factors for oral disorders. Their reduced salivary flow and altered glycemic control are related to halitosis (Negrato & Tarzia, 2010), gingival bleeding, and higher dental biofilm levels (Ervasti, Knuutila, Pohjamo, & Haukipuro, 1985; Gürsoy, Yildiz Çiftlikli, Könönen, Gürsoy, & Doğan, 2014). In diabetic patients, good oral health is seldom. And this poor oral health status can be related to a poorer quality of life (Nikbin, Bayani, Jenabian, Khafri, & Motallebnejad, 2014).

Dental procedures can positively affect one's quality of life. In contrast to people who do not receive dental care on a regular basis, those who do are found to have a better dental status and better quality of life (Montero, Albaladejo, & Zalba, 2014). Conventional non-surgical periodontal therapy for periodontitis patients can improve quality of life (Sundaram, Narendar, Dineshkumar, Ramesh, & Gokulanathan, 2013; Jönsson & Öhrn, 2014; Santuchi et al., 2016). However, no clear consensus has been achieved regarding how gingivitis treatment affects the quality of life in patients either with or without diabetes. Moreover, it is not completely understood how clinical and laboratory-monitored parameters are related to self-reported quality of life. Recently, our group verified that a protocol, which combines ultrasonic debridement with the regular use of a mouthwash that contains essential oils (EO), was effective in treating gingivitis in patients with or without diabetes. Although promising results were observed in relation to traditional objective parameters, other relevant patient-centered variables were not evaluated (Raslan et al., 2015). Therefore, this manuscript reports quality of life data, which had not been previously reported in Raslan et al. (2015), and seeks to relate them to the other objective oral parameters that have been previously reported.

This study aims to verify the impact of this specific and previously-tested (Raslan et al., 2015) gingivitis treatment protocol on the oral health quality of life for patients with diabetes and systemically health individuals. In addition, the relationship between quality of life and clinical, micro, immune, and halitometric parameters was evaluated. It was hypothesized that gingivitis treatment in diabetic patients would have a positive impact on the self-reported quality of life related to oral health status.

2. Methods

The present 3-month, double-blind, single-centered, randomized, parallel group, placebo-controlled clinical trial was registered at ClinicalTrials.gov (NCT 02123563) and was approved by the Institutional Committee on Research of the University of Taubaté (protocol #522/10), São Paulo, Brazil, in accordance with the Helsinki Declaration of 1975, as revised in 2000. Prior to selection, oral and written explanations regarding the research protocol were given to the eligible participants. All patients provided written informed consent before enrolling in the present study, which included baseline and 3-month post-treatment appointments.

2.1. Study population and gingivitis treatment

This study population had been previously described regarding their

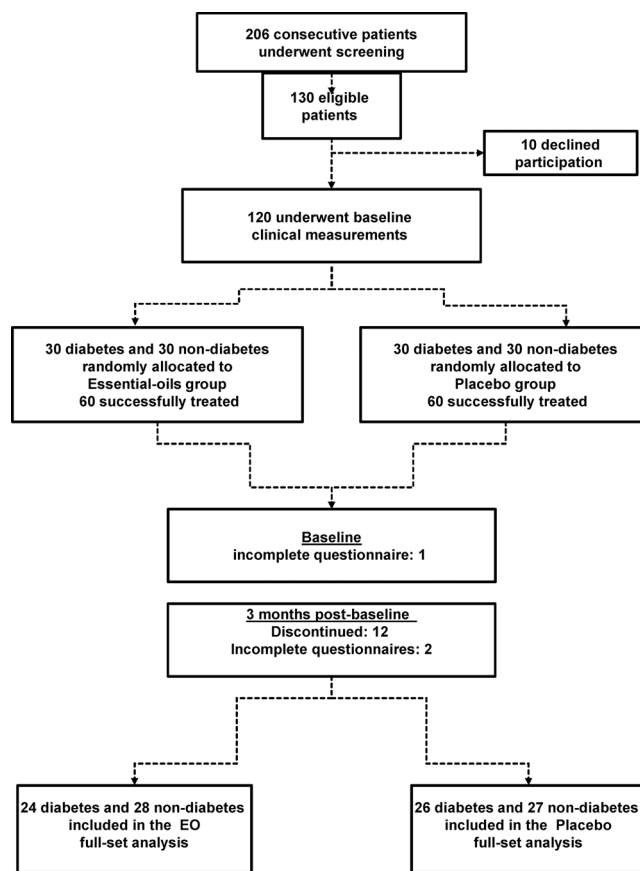


Fig. 1. Study design from screening to completion of the trial according to consolidated standards of reporting trials (CONSORT).

clinical response to a specific gingivitis treatment protocol (Raslan et al., 2015). In comparison to Raslan's study there were three additional sample lost due to incomplete questionnaires (Fig. 1). Participants in this study were male and female plaque-related gingivitis patients who were in good general health (control group) or had controlled type II diabetes (diabetes group), who were between 20 and 45 years of age (32 ± 6 years) and who underwent gingivitis treatment between January and July, 2013. Data and personal information regarding the medical and dental histories of the patients were obtained by interview. The initial sample size was determined based on efficacy of the tested treatment protocol (Raslan et al., 2015). In addition, it was verified whether or not this sample size would be appropriate for a factor analysis. Considering that the model has commonalities usable in the clinical situation according to (Mundfrom, Shaw, & Tian (2005), a minimum of 18 individuals per group would be enough for 1 factor (quality of life) with more than 7 variables (OHQoL-UK questions).

According to their systemic condition, two blocks of patients were randomly allocated to one of two groups (Fig. 1). In brief, the EO group underwent a one-stage ultrasonic debridement and a 90-day supply of mouthwash (twice daily use; 20 ml/30 s) (Listerine Total Care, Johnson and Johnson, São José dos Campos, SP, Brazil) while after identical mechanical procedures, the placebo group followed the same rinsing regime with a placebo solution (Byofórmula, Taubaté, SP, Brazil).

2.2. Oral Health and Quality of Life-UK (OHQoL-UK)

The quality of life related to oral condition was evaluated at baseline and 3 months after gingivitis treatment using the Portuguese version of the OHQoL-UK questionnaire, validated by Dini, McGrath, and Bedi (2003). This questionnaire covers 16 key issues that evaluate the effect that the teeth, mouth, gums, and dentures can have in different

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