Original Research
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Oral health related quality of life among pregnant women: a randomized controlled trial

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Abstract: The aim of the present study was to compare negative impacts of oral conditions in Oral Heath Related Quality of Life (OHRQoL) assessed by the Oral Health Impact Profile-14 (OHIP-14) scores in pregnant women receiving or not comprehensive periodontal treatment. This randomized controlled clinical trial included pregnant women aged between 18 and 35 years old. Participants were randomized in a test group with 96 and a control group with 114 women. Patients in the test group received comprehensive periodontal treatment, supra and subgingival scaling and root-planning and periodontal maintenance appointments. The OHIP-14 was applied before and after treatment. The primary outcome was changes in OHIP-14 scores after follow-up period. The impact of having received or not comprehensive periodontal treatment on the change of the OHIP-14 scores was also investigated. Both groups showed significant reduction in OHIP-14 scores and effect size for the test group was 0.60 and 0.36 for the control group. Multinomial logistic regression analysis showed that participants of the control group had 5.9-fold odds (CI 95% 1.88-18.52) of worsening in OHIP-14 scores and their perception of oral conditions in relation to test group. Comprehensive periodontal treatment during pregnancy can reduce the negative impacts in OHRQoL.

Keywords: Periodontal Diseases; Pregnancy; Quality of Life.

Introduction

Pregnancy is a period which physical, hormonal, and emotional changes occurs in women's health status, having notable impact in quality of life.[1,2,3] The oral environment undergoes a series of changes during pregnancy.[4,5,6] The most significant changes concerns to pregnancy-associated periodontal diseases, exacerbated by hormonal variations of pregnancy.[7,8,9,10] The common signs and symptoms of gingival inflammation, such as bleeding, redness, and swelling, are more prominent during pregnancy.[11] It is conceivable that these symptoms may impair the perceptions of oral condition and Oral Health Related Quality of Life (OHRQoL). Studies have generally shown that perceived OHRQoL is lower in patients with periodontal disease than in healthy people.[12,13,14]

Pregnancy-associated changes in oral health may therefore play a major role in self-perceived quality of life among pregnant women. The

conceptual model of oral health developed by Locker shows how disease promotes the deterioration of the oral health and impacts on people's well-being. Disease leads to impairment resulting in functional limitation or discomfort and pain, a disability stage (physical, psychological or social) and, finally a handicap, that represents the disadvantages caused by oral conditions.[15] This is demonstrated by the patient reports of the negative impacts of periodontal disease on their daily lives. Tooth mobility, sensitive teeth and halitosis are examples of symptoms reported by periodontal patients.[16] Furthermore, patient's perceived associations between oral health status and well-being currently are a crucial aspect in the decision to seek for dental care.[17]

Even as the periodontal diseases impair individual's OHRQoL, the periodontal treatment is related to reduce the negative impacts and to better OHRQoL in patients who received dental treatment.[18,19,20] The Oral Health Impact Profile-14(OHIP-14) is an instrument developed to measure perceptions of the impact of oral conditions on people's well-being and on OHRQoL. It was based on Locker's conceptual model of oral health.[21] Studies performing periodontal treatment demonstrated improvement of OHIP-14 scores after treatment.[18,19,20] Mendez et al demonstrated that periodontal treatment was able to reduce the OHIP-14 scores, and that gingivitis treatment contributed mostly on this improvement.[20] A systematic review performed to assess if periodontal therapy could improve the perceptions of the impact of oral conditions in adults with periodontal disease demonstrated that periodontal treatment improved the OHRQoL in both short and long term period and, therefore, it is beneficial from a patient centered perspective.[20]

Considering that the presence of periodontal disease is associated with negative impacts in different populations,[12,13,14,22] it would be important evaluate if, when treating periodontal disease, it would be possible reduce these negative impacts, improving OHRQoL in pregnancy. There is no evidence about the perceived impacts of periodontal treatment in oral health and well-being in pregnant women. Our hypothesis is that the comprehensive periodontal treatment will be able to improve the perceptions of oral conditions impacts also in this particular population. For this reason, the aim of the present study is to compare negative impacts of oral conditions in OHRQoL assessed by OHIP-14 scores, in pregnant women receiving or not comprehensive periodontal treatment.

Methodology

Sample

The present study had a randomized controlled clinical trial design. The study sample comprised pregnant women who sought prenatal care at Maternal Hospital Presidente Vargas (MHPV) and who took part in a randomized controlled trial (RCT) to evaluate the effect of comprehensive periodontal treatment and strict plaque control on preterm and low birth weight. The sample consisted of all participants enrolled in the RCT and they were randomly allocated to the experimental groups using a block-stratified strategy for smoking extent (≤ or > 5 cigarettes per day). The randomization sequence was computer generated and allocation to treatment was concealed in opaque, sealed and serially numbered envelope opened after baseline examination. More detail in Weidlich et al.[23]

The sample size calculation was based on prematurity reduction in a similar South American population of 10.7% to 2%,[24] taking into account an alpha error of 5% and power of 80%, plus the dropout rate of 5%, totaling 304 patients. For this secondary outcome, power calculation considered size effect in test and control groups and resulted in 92.1%.

Briefly, the criteria for inclusion were age between 18 and 35 years and up to 20 gestational weeks. Women with multiple fetuses, receiving orthodontic treatment or in need of antibiotic prophylaxis for dental treatment were not included in the study.

Ethical approval

All procedures performed in this study were in accordance with the MHPV Research Ethics Committee (nº 04/07) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Data collection

A structured questionnaire comprising demographics, socioeconomic status, medical and dental history and OHIP-14 was used to collect maternal data. The questionnaire used was previously tested and data was collected by trained interviewers. Reproducibility was evaluated by repeated assessment of key-questions in 10% of the sample with a one-week interval (kappa = 0,79).

The OHIP-14 questionnaire was used to assess the impact of periodontal care in perceived OHRQoL among pregnant women. It was developed by Slade et al.[18] and is composed by 14 questions about the impact of oral conditions in aspects of patient's daily life. The Brazilian version of OHIP-14 was translated and validated to Portuguese by Oliveira and Nadanovski, [25] in a pregnant women sample. The answers are in a Likert scale and, for each one, is attributed a value (never = 0; hardly ever = 1; occasionally = 2; fairly often = 3; and very often = 4). The OHIP-14 score range is 0–56; higher scores denote higher frequency of negative impacts. Two trained interviewers applied the questionnaire. The mode of administration was by a face to face interview performed by two trained interviewers and patients received a hand card with the response possibilities.

The reliability of OHIP-14 was assessed by the test-retest method, with all 14 questions being repeated to 10% of the sample within 7 to 10 days of the first interview. The intraclass correlation coefficient was calculated as 0.82. The OHIP-14 was administered with the initial examination and once again around 30 days after delivery. The Figure 1 shows study design.

The initial intraoral examination of all present teeth, except third molars was performed including assessment of the Plaque Index (PI), the Gingival Index (GI), supragingival calculus, cavities, overhanging restorations, Bleeding on Probing (BOP), Periodontal Probing Depth (PPD) and Clinical Attachment Loss (CAL).

Clinical examinations were performed by three calibrated examiners (PW, CHCM and MLM). Reproducibility during the study was assessed in 10% of participants with at least one-hour intervals between clinical examinations. One experienced periodontist (PW) served as reference examiner. The intraclass correlation coefficient ranged between 0.95 and 0.96 for PPD and between 0.84 and 0.93 for CAL.

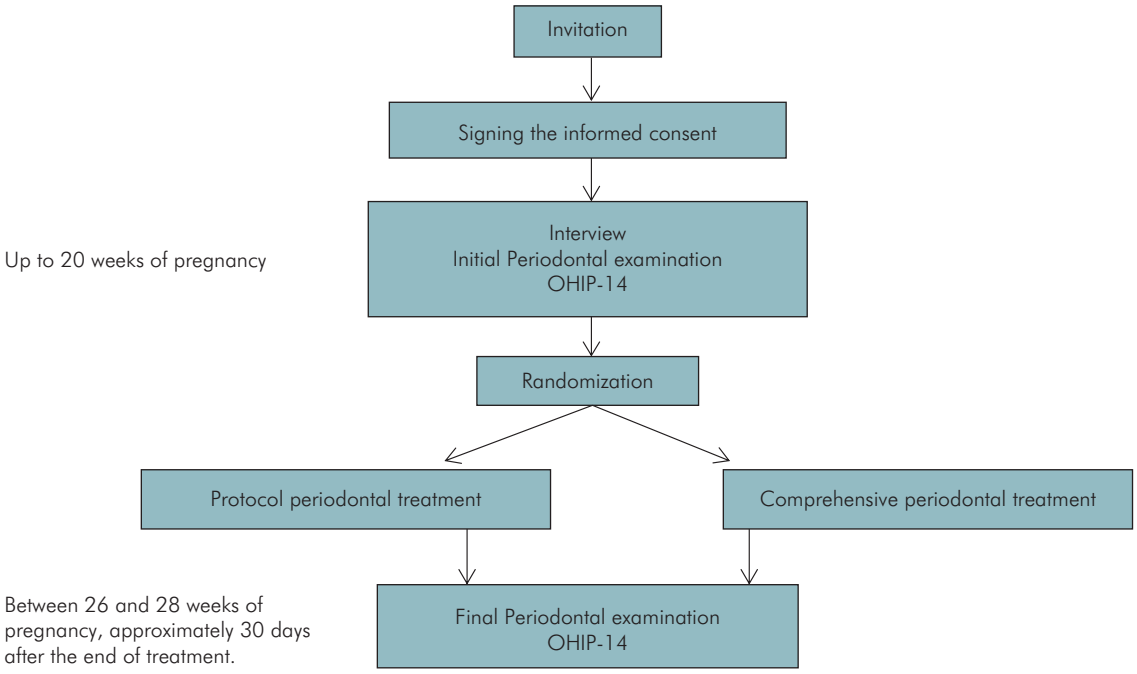

Figure 1. Design of the study.

Weighted kappa (± 1mm) ranged between 0.89 and 0.90 for PPD and between 0.84 and 0.88 for CAL.

A second complete intraoral examination, identical to the first, was carried out between gestational weeks 26 and 28, approximately 30 days after the end of the treatment, when OHIP-14 was applied again. All steps of data collection were performed at the MHPV.

Intervention

Participants of the test group (TG) received a comprehensive nonsurgical periodontal therapy provided up to the 24th week of pregnancy. Treatment consisted of an initial phase where supragingival plaque control was implemented and oral hygiene instructions was given and a second phase when subgingival scaling and root-planning was performed according to patient's needs. Maintenance appointments were conducted at least once a month according to individual needs to maintain optimal plaque control.

Participants in the control group (CG) received the standard dental treatment provided to all patients at MHPV, comprising one session of supragingival calculus removal and oral hygiene instruction. They received comprehensive nonsurgical periodontal therapy 1 to 3 months after delivery. Patients in both experimental groups received pain relief treatment whenever necessary.

Outcomes

The primary outcome was changes in OHIP-14 scores after follow-up period. The secondary outcomes were the effect size of changes in OHIP-14 in each group, changes in periodontal parameters (PI, GI, supragingival calculus, cavities, overhanging restorations, BOP, PPD and CAL).

Statistical analysis

Statistical analysis was performed with the SPSS 13.0 and Stata 9.2 software packages. Categorical data were summarized as absolute and relative frequencies and between-group comparisons were performed by means of chi-square testing. Continuous data were expressed as means and standard deviations, and between-group comparisons were performed by means of the *t* test for independent samples.

The additive method was used for computation of OHIP-14 data. Total scores were calculated by adding scores for each of the 14 questions on the instrument's Likert-type scale (never, 0; hardly ever, 1; occasionally, 2; fairly often, 3; and very often, 4). Group means were compared using a *t* test for independent samples. Internal consistency was measured by Cronbach's alpha, yielding a coefficient of 0.82.

Changes in OHIP-14 scores were calculated by subtracting the final score from that of the first assessment, and between-group comparisons were performed by means of an independent *t* test. Effect size was also calculated by subtracting the final score from the initial score and dividing this difference by the initial score standard deviation for each group. Univariate and multivariate linear regression analyses with robust variance estimates were used to evaluate any possible association between clinical or treatment variables and the primary outcome (OHIP-14 score changes). Independent and dependent *t* tests were used for between-group and within-group comparisons respectively. Multinomial logistic regression was employed to assess whether different levels of change (worsening by 5 or more points, changes of fewer than 5 points or improvement by 5 or more points) could be associated with different interventions.[26]

The level of significance was set at 5% and each individual participant was treated as the sampling unit.

Results

The Figure 2 shows the flow chart of the study. Of the 527 patients in the initial sample, 303 were randomized to the actual clinical trial portion of the study. Of these, 156 were allocated to the CG and 147 to the TG. The recruitment was carried out from April 2007 to June 2009 and follow-up extended until the time of delivery. There were four miscarriages and one intrauterine death in the TG and five miscarriages and three intrauterine deaths in the CG. One patient was excluded due to psychiatric reasons in the TG. Of the remaining participants, 45 and 34 were lost to follow-up for various reasons at various points along the study in the TG and CG respectively, for a final sample of 96 participants in the TG and 114 in the CG.

There were no significant differences between the CG and TG in baseline demographic, socioeconomic, and behavioral characteristics (Table 1). Approximately

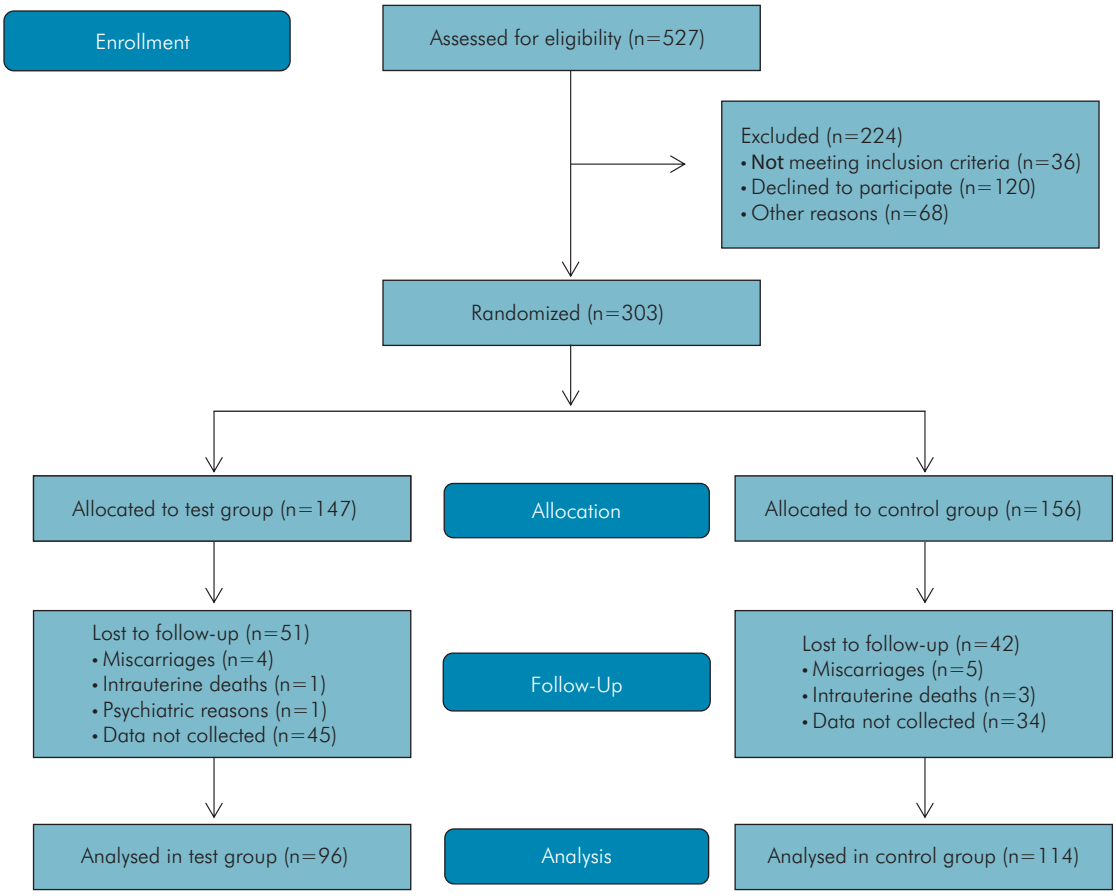

Figure 2. Flow chart of the study.

half of participants in both groups were of middle socioeconomic status, over two-thirds were white and the majority had age between 20 to 25 years. Table 2 shows post-treatment changes in periodontal parameters in the CG and TG. Changes were negligible in the CG, whereas all parameters (except for clinical attachment levels) were significantly reduced in the TG.

There were no significant between-group differences in mean OHIP-14 scores (control, 13.90; test, 12.09; $p = 0.12$) at baseline. Scores declined in both groups after treatment, with mean OHIP-14 scores in the TG at the end of the study (7.30) being significantly lower than those in the CG (10.76; $p = 0.003$). Although changes from baseline to post-treatment OHIP-14 scores were higher in the test than in the CG (4.79 vs. 3.14), the difference did not reach statistical significance. Effect size was 0.36 in the CG and 0.60 in the TG. The floor effect was small (6.2%). No ceiling effect was detected.

Regression analysis was carried out to ascertain which variables were associated with the main outcome (changes in OHIP-14 score). No association was detected between inflammation-related clinical parameters (gingival bleeding index, periodontal bleeding, and probing depth) and OHIP-14 changes, both on unadjusted analysis or after adjusting for baseline OHIP-14 score, age, socioeconomic status, race, and educational level.

Multinomial logistic regression (Table 3) was performed to examine changes in OHIP-14 score depending on their extent (worsening by 5 points or more, changes of fewer than 5 points, and improvement by 5 points or more). Both on unadjusted analysis and after adjusting for baseline OHIP-14, age, socioeconomic status, skin color, and educational level, significant differences were found favoring the TG. Participants who did not receive comprehensive periodontal therapy had 5.9-fold odds of higher OHIP-14 scores.

Table 1. Demographics, socioeconomic status and behavioral information at baseline for women completing the study.

Variable	Control		Test		p-value
	n	%	n	%	
Age					
< 20	7	6,1	7	7,3	
≥ 20 to 24	36	31,6	31	32,3	0,97
≥ 25 to 29	36	31,6	28	29,2	
≥ 30	35	30,7	30	31,3	
Education					
Elementary	42	36,8	39	40,6	
High school	63	55,3	41	42,7	0,07
College/University	9	7,9	16	15,6	
Socioeconomic status*					
Low	27	23,7	16	16,7	
Medium	57	50	52	54,2	0,45
High	30	26,3	28	29,2	
Skin color**					
White	81	71,1	68	70,8	
Black	13	11,4	16	16,7	0,38
Other	20	17,5	12	12,5	
Smoking					
Never	66	57,9	50	52,1	
Current	15	13,2	15	15,6	0,69
Former	33	28,9	31	32,3	
Total	114	100	96	100	

*Socioeconomic status was categorized accordingly to the Brazilian Criteria for Economic Classification (CCEB), and combines information about family income and level of education; **Skin color was self-reported according to criteria proposed by Brazilian Institute of Geography and Statistics (IBGE).

Table 2. Change in periodontal characteristics of control and test groups between baseline and final measurements.

Parameters	Change control	Change test	p-value
Visible plaque (% sites)	- 11,75	- 45,09	< 0,001
Gingival bleeding (% sites)	- 3,46	- 21,62	< 0,001
Supragingival calculus (% sites)	- 5,18	- 22,89	< 0,001
Bleeding on probing (% sites)	- 2,92	- 35,28	< 0,001
Probing depth (mm)	0,07	- 0,3	< 0,001
Clinical attachment loss (mm)	- 0,01	- 0,04	0,56

Independent t test was used for continuous variables and chi-square for categorical variables.

Table 3. Uni and multivariable analysis (multinomial logistic regression) for OHIP-14 change and absent of non-surgical periodontal treatment.

Variable	Change < 5points	Worse ≥ 5 points			Improve ≤ 5 points		
	Control = 36.84%	Control = 19,30%			Control = 43,86%		
	Test = 46,88%	Test = 4,17%			Test = 48,96%		
		OR	95%CI	p-value	OR	95%CI	p-value
Unadjusted	Reference	5.89	1.88–18.52	0.002	1.14	0.64–2.03	0.66
Adjusted*	Reference	5.72	1.80–18.12	0.003	0.88	0.45–1.73	0.72

*adjusting for baseline OHIP-14, age, socioeconomic status, skin color, and educational level.

Discussion

The purpose of the present study was to compare the negative impacts of oral conditions in OHRQoL in pregnant women receiving or not comprehensive periodontal treatment, recognizing the importance of the patient's perception of the treatment results, the impact that clinical results have on everyday life and if the treatment is able to reduce the negative impacts of a disease. It was demonstrated that periodontal treatment had a statistically significant positive effect on OHRQoL in pregnant women. Participants who did not receive comprehensive periodontal therapy had almost six times more chance to present worsening in OHIP-14 scores during pregnancy.

The present study showed that both interventions led to reductions in OHIP-14 scores. Furthermore, OHIP-14 scores after comprehensive nonsurgical periodontal therapy were significantly lower than those associated with the treatment protocol provided to the CG. Despite the absence of significant differences in absolute values between baseline and post-treatment OHIP-14 scores, the effect size associated with comprehensive nonsurgical therapy was substantially larger than the effect size found in the CG. This is the first study that assessed the impact of periodontal treatment in perceptions of negative impacts in OHRQoL in pregnant women. Similar results were found in other studies that assessed impacts of oral conditions, by OHIP-14, before and after periodontal treatment.[18,19,27]

Mean baseline OHIP-14 scores were 13.9 in the CG and 12.09 in the TG — substantially higher than the mean score of 7.4 reported by Oliveira and Nadanovski in their study with 504 pregnant women enrolled at public hospitals in Brazil[25] and reported by Lu et al, which found a mean 7.92 between 512 pregnant woman in Shangai, China.[28] This result was similar to those reported in a study with pregnant women in India, which ranged from 8.5 to 12.8.[22] Periodontal status is known to have a direct influence on OHIP-14 scores. Patients with periodontal disease have higher OHIP-14 scores than people without periodontal conditions.[12,13,29,30] In a Chinese study, people reporting some sign or symptom of periodontal disease had OHIP-14 scores in the range of 9.83–15.52. Marked contrasts were observed between healthy participants (4.41), and those with advanced periodontal disease (24.19).[12] Instead, in Lu et al. study no significant association was found among scores of OHIP-14 and periodontal conditions in pregnant woman. The authors discuss that although periodontal disease has been found in this sample, other health problems inherent to pregnancy may become major concerns, which may impact the quality of life in pregnant woman.[28] In the present study, periodontitis with destructive damage was rare. Gingivitis was therefore the predominant issue in this population. The OHIP-14 values observed are in the range of populations with similar condition.[12]

The results of the present study showed reductions in mean OHIP-14 scores after both intervention approaches, with scores at endpoint being significantly lower after comprehensive nonsurgical periodontal therapy. The reduction found in the CG cannot be explained by improvement in periodontal status, which remained the unchanged throughout pregnancy. Changes may have been associated with the fact that participants in this group received some sort of care, unexpected in the public health setting present. Improvements in OHIP-14 scores are known to be associated with receiving general care.[31,32]

The comprehensive nonsurgical periodontal therapy provided to the TG was associated with a substantially greater treatment effect than that detected in the CG. Effect size for the TG was 0.60, which is regarded as moderate, whereas in the CG it was only 0.36, a small effect size.[33] Effect size is an appropriate measurement for assessments of change in perceived quality of life aspects and reflects the clinical significance of treatment.[34,35] Furthermore, as it is calculated, effect size respects the variability of each group, as it includes the observed standard deviation. Several studies have employed effect size for assessment purposes.[18,26,31,35,36] The effect of dental treatment was investigated in a study enrolling 173 participants with substantial dental treatment needs. The authors found a large effect size (0.86) of the treatment performed on OHIP-14 changes.[31] Mendez et al. found a size effect for supragingival phase of periodontal treatment (0.72) while the whole treatment achieve 0.74, demonstrate showing the big impact of gingivitis treatment on OHRQoL.[18] In this study, participants received broader, more complex

treatment than simple periodontal care. Effect sizes may depend on the degree of resolution associated with the chosen treatment.

The domains of OHRQoL more affected by periodontal disease are functional, psychological and those related with pain.[37] Periodontal treatment had impacts in domains of oral health such function (chewing/eating), psychology (emotional/social aspects) and pain,[20,37] improving these symptoms. Although the change in OHRQoL, measured by OHIP-14 had been moderate, efforts to treat periodontal disease during the pregnancy must be made. The results of the present study indicate that periodontal treatment promotes an improvement not only in periodontal parameters, but also on a patient perspective, had impacts on their daily life and well-being, extremely important during pregnancy.

No variables related to change in inflammatory parameters was associated with changes in OHIP-14 scores. This is a rather surprising finding, as substantial changes in clinical parameters were obtained. This observation cannot be explained by OHIP-14 score instability, as the intraclass correlation coefficient (0.82) was considered excellent. In a cross-sectional study, Cunha-Cruz and coworkers reported significant correlations between clinical parameters of periodontal status and perceived oral health.[13] Lu et al, assessed in a cross sectional study the impact of periodontal conditions in pregnant woman and, in other hand, showed that periodontal status was not significantly associated with severity, extent or prevalence of impacts assessed by OHIP-14.[28] Absence of these correlations may have been due to the small extent of changes in OHIP-14 scores; mean changes were 4.79 and 3.14 points in the TG and CG, respectively. Several authors consider that the lowest significant difference in OHIP-14 scores would be 5 points.[26,38] Patient perceptions of quality of life may, in fact, not be influenced by clinical parameters relevant to professional assessment of oral health status.

The profile of the observed changes was analyzed employing a set of criteria taking in consideration the minimally important difference of 5 points, which could be interpreted as a relevant difference.[26, 38] Many women in the TG and CG experienced improvements more than 5 points. A slightly lower proportion of participants experienced changes of fewer than 5 points. Interestingly, analysis of the proportion of women whose scores worsened showed a substantial difference between the CG and TG. OHIP-14 scores at the end of the study were worse than those at baseline in 19.3% of women in the CG and only 4.17% of those in the TG. Consequently, women who did not receive comprehensive periodontal care had 5.9-fold odds of experiencing worsening OHIP-14 scores than women who did receive comprehensive periodontal care.

The present study has some limitations. Attrition rate was 14% in TG and 21% in the CG. The characteristics of study population, with pregnant women or breastfeeding women, made it difficult to attend to dental appointments and might explain the percentage of non-complaints. The OHIP-14 was used because have good psychometric properties, it's easy to be applied,[21] and its widely used to assess the impact of periodontal treatment on OHRQoL.[20] Moreover, OHRQoL is considered patient-based outcomes, and is recognized as an integral part of general health and well-being.[39] Further studies should be include additional measures, such as global ratings, to capture this impacts more broadly.[40] The disease profile of the sample should also be addressed. Many of the women included in the study presented widespread gingival inflammation but mild periodontal destruction. However, it is important to remember that this disease profile is similar to the one found in women of childbearing aging this same population and the inclusion of women with moderate/advanced periodontal disease could limit the external validity of our findings.

In the present study, participants in the CG were nearly six times more likely to present worsening in OHIP-14 scores during the follow-up period than participants in the TG. This shows that pregnant women perceive improvements in their oral status when they receive periodontal care, and that comprehensive nonsurgical periodontal therapy can reduce significantly the negative impacts in OHRQoL during pregnancy.

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