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Dental anxiety and oral health-related quality of life among pregnant women: a cross-sectional study

Ansiedade odontológica e qualidade de vida relacionada à saúde bucal de gestantes: um estudo transversal

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ABSTRACT

Objective: This study investigated the association between dental anxiety and oral health-related quality of life (OHRQoL) among pregnant women; **Material and Methods:** A cross-sectional study was conducted with pregnant women who attended public health services in a Southern Brazilian city. A questionnaire was administered to collect information on demographic, socioeconomic, and behavioral factors. The OHRQoL was measured using the Oral Health Impact Profile (OHIP-14). The Dental Anxiety Scale (DAS) was used to assess the level of dental anxiety. Dental caries was assessed by the Decayed, Missing, and Filled Surfaces (DMFS) index and gingivitis was evaluated by the Gingival Bleeding Index (GBI). Poisson regression models assessed the association between dental anxiety and OHIP-14 scores. The results are presented as Ratio Ratio (RR) using its respective 95% confidence intervals (CI); **Results:** The sample comprised 256 pregnant women. The mean total OHIP-14 score was 8.74 (\pm 9.00). The average scores from specific domains ranged from 0.66 (functional limitation) to 2.20 (psychological discomfort). Pregnant women with dental anxiety (DAS ≥15) have 36% higher OHIP-14 scores (RR 1.36; CI 95% 1.02-1.78) showing poorer OHRQoL. Besides, participants with gingivitis have also higher OHIP-14 scores (RR 1.34; CI 95% 1.00-1.78); **Conclusion:** The present study showed that pregnant women with dental anxiety and those with gingivitis were more likely to report a poorer OHRQoL.

KEYWORDS

Dental anxiety; Observational study; Oral health; Pregnant women; Quality of life.

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RESUMO

Objetivo: Este estudo investigou a associação entre ansiedade odontológica e qualidade de vida relacionada à saúde bucal (QVRSB) entre gestantes; **Material e Métodos:** Foi realizado um estudo transversal com gestantes que frequentavam serviços públicos de saúde em uma cidade do sul do Brasil. Um questionário foi aplicado para coletar informações sobre fatores demográficos, socioeconômicos e comportamentais. A QVRSB foi mensurada através do Oral Health Impact Profile (OHIP-14). A Escala de Ansiedade Dentária (DAS) foi utilizada para avaliar o nível de ansiedade odontológica. A cárie dentária foi avaliada pelo índice de superfícies cariadas, perdidas e obturadas (CPOD) e a gengivite foi avaliada pelo índice de sangramento gengival (GBI). Os modelos de regressão de Poisson avaliaram a associação entre a ansiedade dentária e as pontuações do OHIP-14. Os resultados são apresentados como Ratio Ratio (RR) utilizando seus respectivos intervalos de confiança (IC) de 95%; **Resultados:** A amostra foi composta por 256 gestantes. A média da pontuação total do OHIP-14 foi de 8,74 (± 9,00). As pontuações médias dos domínios específicos variaram entre 0,66 (limitação funcional) e 2,20 (desconforto psicológico). As gestantes com ansiedade dentária tiveram pontuações do OHIP-14 36% mais elevadas (RR 1,36; IC 95% 1,02-1,78), o que revela uma pior QVRSB. Além disso, as participantes com gengivite também

apresentaram pontuações mais elevadas no OHIP-14 (RR 1,34; IC 95% 1,00-1,78); **Conclusão:** O presente estudo mostrou que as mulheres grávidas com ansiedade odontológica e aquelas com gengivite eram mais propensas a relatar uma pior QVRSB.

PALAVRAS-CHAVE

Ansiedade odontológica; Estudo observacional; Saúde bucal; Gestantes; Qualidade de vida.

INTRODUCTION

During pregnancy, women undergo hormonal, physical, and emotional changes that can impact on oral health [1]. Hormone fluctuations, especially progesterone and estrogen, increase proneness to inflammatory processes in the periodontium, especially if adequate oral hygiene is not performed [2]. Moreover, hormonal changes in this period increase the likelihood of mental health problems, such as anxiety and depression [3].

Although dental care during pregnancy is considered safe, it remains shrouded in myths related to possible harm that could be caused to the baby's health, which can trigger emotional problems in pregnant women [4]. In addition, dental anxiety can be one of the factors that compromise oral health care [5,6]. Dental anxiety is defined as a state of persistent tension accompanied by a sensation of imminent disaster, which can lead to fear [5], and is triggered specifically by dental care [7]. Dental anxiety has been related to worse oral outcomes and poorer oral health-related quality of life (OHRQoL) previously in the literature [5-8]. A study that sought to assess the impact of mothers and children's dental anxiety on their infant's OHRQoL found that dental anxiety negatively impacted OHRQoL [8].

Oral problems, such as periodontal disease, and emotional problems as dental anxiety, can exert an influence on self-rated health and quality of life in pregnant women and their fetus [9,10]. The impact of oral conditions on activities of daily living, quality of life, and wellbeing is assessed using OHRQoL [11], which is a multidimensional construct involving the negative impact of oral problems on oral functions, physical and social aspects, appearance, the performance of activities of daily living and self-rated oral health status [11]. Studies have demonstrated that oral diseases such as dental caries and

gingivitis negatively affect the quality of life during pregnancy, impairing daily activities and self-perception of oral health by pregnant women [9,12]. Furthermore, studies have shown that socioeconomic and demographic variables can also impact the OHRQoL [9].

Although some studies have investigated the impacts of dental anxiety and other factors psychological in adults [5-7], and children [8], data on dental anxiety in pregnant women are scarce [3]. The physical and emotional wellbeing of the future mother has repercussions for her health as well as the adequate development of the infant, enabling the child to grow up healthy [8,12]. It is therefore relevant to identify factors associated with OHRQoL in this population group. To the best of our knowledge, no study has described the association between dental anxiety and OHRQoL among pregnant women.

Therefore, the present study aimed to investigate the association of dental anxiety on OHRQoL of pregnant women attending public healthcare services. Our conceptual hypothesis is that dental anxiety in pregnant women is correlated with poor OHRQoL.

MATERIAL AND METHODS

Study design and participants

This cross-sectional study was nested in a cohort study entitled "The oral health status of pregnant women and their children" (data not published yet). The cohort study was designed to follow pregnant women who attended at public health services (primary care units and Family Health Strategy) in Santa Maria, RS, Brazil. The cohort study aimed to follow these pregnant women and their children through periodic assessments of a set of health-related outcomes in the mothers and children until the children reach five years of age.

At the onset of the cohort study in 2017, the city had 273,489 residents, with an estimated 2,389 pregnant women attending primary care units, according to official data from the city government. A two-stage sampling procedure was performed, where public healthcare centers were considered the first and pregnant women were the second unit of sampling. Eighteen of the 30 centers distributed among the eight administrative districts of the city were randomly

selected, considering the proportion of the population size covered by each healthcare center. All pregnant women regularly registered at public primary health centers providing prenatal care were considered eligible to participate in the study. For recruitment, the researchers scheduled visits to these health centers on days designated for prenatal medical appointments. During these visits, pregnant women were invited to participate in the study, with every fifth woman attending the health center being selected. If a selected woman declined to participate, the next eligible pregnant woman was invited. As soon as the pregnant women agreed to participate, they were invited to sign the consent form at the health center.

The sample size was calculated considering the following parameters: 95% confidence level, power of 80%, the ratio of exposed and non-exposed of 1:1, and an effect size of 0.5 [12]. Twenty percent was then added to compensate for possible refusals and a design effect of 1.2 was applied, resulting in a minimum sample of 184 pregnant women.

Eligibility criteria

Only pregnant women registered at healthcare units were included in the present study. Women with a need for antimicrobial prophylaxis prior to the oral examinations, those with a fixed orthodontic appliance or retainer, those who took medications associated with an increase in gingival volume (nifedipine, cyclosporin, and phenytoin) and those with cognitive problems were excluded. In addition, pregnant women with chronic diseases or conditions that could compromise the study or influence its outcomes, such as kidney disease, cardiovascular disease, and pre-pregnancy diabetes, were excluded.

Calibration process and pilot study

Before the data collection, a pilot study was conducted with 10 pregnant women to determine the feasibility of the methods. Four examiners were instructed to perform periodontal assessments on 10 women, examining six sites on each tooth (mesial-buccal, buccal, distal-buccal, mesial-lingual, lingual, and distal-lingual) for all permanent teeth, except the third molars. These women were not included in the final study sample. The Training addressed the definition of

the clinical and physical variables, measurement instruments, proper measurement techniques and the analysis of clinical photographs. An experienced examiner was considered the "gold standard" for the inter-examiner calibration of the four examiners regarding Clinical Attachment Loss. The Decayed, Missing and Filled Surfaces (DMFS) index training and calibration were performed following the method described by the World Health Organization [13]. The examiners underwent training by analyzing clinical images of healthy and decayed teeth, reviewing the index's conceptual foundations, and practicing on extracted teeth. The conceptual basis of the index was discussed, followed by training with extracted teeth. The DMFS index calibration involved the clinical assessment of 10 women by the examiners and an experienced researcher who served as the gold standard. During this process, two examinations were conducted, with a one-week interval between them. The four examiners and the gold-standard examiner performed periodontal and dental caries assessments consecutively, and this procedure was repeated the following week. Intra-examiner reproducibility was evaluated through duplicated examinations with a one-week interval, for which Kappa coefficients ranged from 0.88 to 0.93. Inter-examiner reproducibility was evaluated through Kappa coefficients and ranged from 0.88 to 0.96. This reproducibility remained consistent throughout the study.

Data collection and variables

After the pilot study, data collection was performed between January 2017 and December 2018 by four teams composed of an examiner (post-graduate students) and an interviewer (undergraduate students).

Regarding the clinical variables, the DMFS index and Gingival Bleeding Index (GBI) were determined through an examination with the aid of a flat mouth mirror (Golgran, São Caetano do Sul, SP, Brazil) and a millimeter periodontal probe (CP 15 UNC, Neumar, São Paulo, SP, Brazil). All participants were examined individually under the same conditions seated on a common chair in a room with both natural and artificial lighting as well as artificial white light from the headlamp and relative isolation [13].

The supragingival examination recorded the GBI [14]. Clinical Attachment Loss was

considered the distance from the cementoenamel junction to the most apical portion of the pocket/sulcus and was measured in millimeters and rounded off to the closest whole millimeter.

Dental anxiety was measured using the Dental Anxiety Scale (DAS) and the questionnaire was applied through face-to-face interviews. It is a psychometric scale composed of four items addressing the reactions of the patient in situations involving dental care. Each item is scored from 1 to 5 points and the total score ranges from 4 to 20 points, with a score of \geq 15 points indicative of high dental anxiety [15].

An interview was held for the demographic data gathering (age, skin color and education), socioeconomic factors (monthly income, by means of Brazilian monthly minimum wage [BMMW]) and behavior information (smoking during pregnancy, frequency of visits to a dentist and previous endodontic treatment). The interviewers and assistants were trained for the questionnaire administration.

For the data analyses, the independent variables were categorized: age was categorized according to the WHO classification [16], considering "adolescents" (< 20 years), "young adults" (20-30 years) and "adults" (> 30 years); skin color was assessed based on the IBGE criteria [17], and then dichotomized into "white" and "non-white"; education was collected in terms of years of schooling and classified as (≥ 8 years / < 8 years, with the cutoff point corresponding to the completion of primary school); household income ($\leq 2 \text{ BMMW} / > 2 \text{ BMMW}$); smoking during pregnancy (no/yes); frequency of dental attendance (≥ 1 times per year / <1 time per year); previous endodontic treatment (no/yes); gingivitis (marginal bleeding < 10% / marginal bleeding $\geq 10\%$) [18]; tooth loss (no missing teeth $/ \ge$ one missing tooth); decayed surface (no decayed surface $/ \ge$ one decayed surface); Dental Anxiety Scale (DAS < 15 = low level ofanxiety / DAS \geq 15 = high level of anxiety) [19].

Oral Health-Related Quality of Life

The dependent variable was the OHRQoL, measured using the *Oral Health Impact Profile* (OHIP-14) [20]. The questionnaire was applied through interviews and comprises 14 items distributed among seven domains: functional limitation (items 1 and 2), physical pain (items 3 and 4), psychological discomfort (items

5 and 6), physical disability (items 7 and 8), psychological disability (items 9 and 10), social disability (items 11 and 12) and handicap during the performance of activities of daily living (items 13 and 14). The answers are given on a five-point scale: never = 0; hardly ever = 1; occasionally = 2; often = 3; very often = 4. The total score possible range is from 0 to 56, with higher scores representing a greater negative impact on OHRQoL [20].

Statistical analysis

Data analysis was performed using STATA 14 (Stata Corporation, College Station, TX, USA). Descriptive analysis (frequencies, mean and standard deviation values) was performed for the demographic, socioeconomic, behavioral, and clinical variables and for DAS and OHIP-14 scores. The variation of overall and specific-domains OHIP-14 scores by DAS and other predictors was also estimated.

Poisson regression analysis was performed to determine associations between OHRQoL and the independent variables (demographic-socioeconomic: age, skin color, education; household income; behavioral: smoking during pregnancy, frequency of dental attendance; clinical: previous endodontic treatment, gingivitis, tooth loss, decayed surface; and DAS). Variables with a p-value < 0.20 in the bivariate Poisson regression analysis were incorporated into the multivariate model. The level of significance was set at 5%. Rate Ratio (RR) was estimated considering 95% confidence intervals (CI). The model's quality of fit was defined by deviance (-2 log likelihood).

Ethical aspects

This study received approval from the Institutional Review Board of *Universidade Franciscana* (protocol number: 55197616.7.0000.5306). All participants provided informed consent. If the participant was a minor, her legal guardian also signed an informed consent form.

RESULTS

Two hundred fifty-six pregnant women between 14- and 45-years old take part in the study (72% of response rate). Most participants were white (56.7%), had >more than 8 years of formal education (77.3%), did not smoke during

pregnancy (97.1%), had gingivitis (59.6%), with dental caries (60.9%) and DAS < 15 (82.3%). The detailed information is presented in Table I. The OHIP-14 total mean was 8.74 (standard deviation: 9.00). The domain means ranged from 0.66 (functional limitation) to 2.20 (psychological discomfort) (Table II).

In the unadjusted analysis, skin color (RR = 1.31; 95% CI: 1.02 to 1.69), gingivitis (RR = 1.42; 95% CI: 1.08 to 1.85), dental caries (RR = 1.35; 95% CI: 1.03 to 1.79) and higher dental anxiety (DAS \geq 15) (RR = 1.42 95% CI:

Table 1 - Sample distribution of pregnant women according to demographic, socioeconomic, behaviors and clinical characteristics, Santa Maria, Brazil (n=256)

Variables	n	%
Demographic and socioeconomic		
Age < 20 years 20-30 years > 30 years	49 155 52	19.1 60.6 20.3
Skin color White Non-white	145 111	56.7 43.3
Education ^a > 8 years < 8 years	198 58	77.3 22.7
Family income ^b 1-2 BMMW >2 BMMW	177 74	70.5 29.5
Behaviors characteristics		
Smoke during pregnancy ^c		
No	237	97.1
Yes	7	2.8
Frequency of dental attendance		
> 1 time per year	144	56.2
< 1 time per year	112	43.8
Oral health measures		
Previous endodontic treatment No Yes	170 81	67.7 32.2
Gingivits No (< 10% marginal bleeding) Yes (≥ 10% marginal bleeding)	103 152	40.4 59.6
Tooth Loss No Yes	138 117	52.1 45.9
Decayed Surface No Yes	100 156	39.1 60.9
Dental Anxiety (DAS) Low level (<15) High level (≥15)	209 45	82.3 17.7

Values lower than 256 due to missing data. *corresponds to primary school education; *b BMMW, Brazilian monthly minimum wages; *COnly smoke during pregnancy were investigated.

1.06 to 1.90) were associated with higher OHIP-14 scores (Table III). Table IV presents the results of the adjusted Poisson regression analyses. Pregnant women with higher levels of dental anxiety (DAS \geq 15) had overall OHIP-14 scores 36% higher compared to their counterparts, indicating poorer oral health-related quality of life (OHRQoL). Similarly, pregnant women with gingivitis had OHIP-14 scores 34% higher than those without gingivitis, also reflecting worse OHRQoL.

DISCUSSION

The present study demonstrated that pregnant women with higher levels of dental anxiety had worse OHRQoL, which agrees with our conceptual hypothesis. The results of this study highlight the direct and indirect effects of oral health conditions and psychological factors on OHRQoL among pregnant women. Based on the findings, it is possible to hypothesize an indirect relationship between dental anxiety and OHRQoL, as pregnant women with a fear of dental care may avoid dental services and neglect oral hygiene practices [3]. This can lead to the development of common oral diseases during pregnancy, such as gingivitis [2]. Thus, factors resulting from the hormonal and behavioral changes typical of pregnancy, combined with poor oral hygiene and limited access to dental services, may facilitate the onset of oral diseases, negatively impacting the quality of life and wellbeing of pregnant women [1,12].

However, we showed that having a high level of dental anxiety is related to a negative impact on OHRQoL. Dental anxiety may limit the use of dental services by pregnant women, leading to the aggravation of oral problems

Table II - Oral health Impact Profile -14 (OHIP-14) total and domain-specific scores description for pregnant women. Santa Maria, Brazil (n=256)

OHIP-14	Mean (SD)	Range
Functional limitation	0.66 (1.19)	0/6
Physical pain	1.85 (2.20)	0/8
Psychological discomfort	2.20 (2.54)	0/8
Physical disability	1.08 (1.92)	0/8
Psychological disability	1.29 (1.84)	0/8
Social disability	1.22 (1.89)	0/8
Handicap	1.22 (1.89)	0/8
Overall	8.74 (9.00)	0/42

Table III - Unadjusted association between pregnant characteristics and overall OHIP-14, determined using Poisson regression. Santa Maria, Brazil (n=256)

Variables	RR ^a (95% CI) ^b	p-value
Demographic and socioeconomic		
Age < 20 years 20-30 years > 30 years	1 0.95 (0.68-1.30) 1.10 (0.74-1.63)	0.622
Skin color White Non-white	1 1.31 (1.02-1.69)	0.030*
Education ^c 8 years ≥ 8 years	1 0.99 (0.74-1.33)	0.959
Family income ^d 1-2 BMMW >2 BMMW	1 0.97 (0.73-1.28)	0.817
Behaviors characteristics		
Smoke during pregnancy ^e No Yes	1 1.24 (0.68-2.26)	0.487
Frequency of dental attendance > 1 time per year < 1 time per year	1 0.95 (0.74-1.23)	0.722
Oral health measures		
Previous endodontic treatment No Yes	1 0.86 (0.65-1.15)	0.313
Gingivits No (< 10% marginal bleeding) Yes (≥ 10% marginal bleeding)	1 1.42 (1.08-1.85)	0.011*
Periodontitis No Yes	1 1.13 (0.86-1.48)	0.378
Tooth Loss No Yes	1 0.97 (0.75-1.26)	0.859
Decayed Surface No Yes	1 1.35 (1.03-1.79)	0.030*
Dental Anxiety (DAS) Low level (<15) High level (≥15)	1 1.42 (1.06-1.90)	0.017*

°RR, rate ratio; bCl, confidence interval; corresponds to primary school education; dBMMW - Brazilian monthly minimum wages; only smoke during pregnancy were investigated.

as well as causing pain and discomfort, with a direct impact on OHRQoL [4,7]. Studies have demonstrated that dental anxiety can hurt the mental wellbeing of pregnant women and possibly exert an impact on OHRQoL. Some authors suggest that mental health could be more vulnerable in the final stages of pregnancy and the postnatal period [21]. Moreover, dental anxiety together with a poor dental status can exert a negative influence on one's self-confidence and mental well-being, implying low self-esteem and embarrassment in the presence of a dentist

Table IV - Adjusted Poisson Regression for the association between pregnant characteristics and overall OHIP-14 scores. Santa Maria, Brazil (n=256)

Variables	RRa (95% CI)b	p-value*
Demographic and socioeconomic		
Skin color White Non-white	1 1.26 (0.98-1.60)	0.061
Oral health measures		
Gingivitis No (< 10% marginal bleeding) Yes (≥ 10% marginal bleeding)	1 1.34 (1.00-1.78)	0.043*
Decayed Surface No Yes	1 1.22 (0.91-1.64)	0.181
Dental Anxiety (DAS) Low level (<15) High level (≥15)	1 1.36 (1.02-1.78)	0.033*

^{*}p-value <0.05; aRR, rate ratio; bCl, confidence interval.

due to the fear of being judged [6,22]. Dental anxiety can be aggravated by insecurity and a lack of information that many women have, which is related to the myth that dental care is not safe during pregnancy and may cause harm to the mother and child [4].

In our study, demographic and socioeconomic characteristics were not associated with OHRQoL, which may be explained by the fact that only pregnant women at public healthcare services were included, resulting in a homogenous sample. Other authors have found similar results [12]. However, our findings contrast with results reported in a previous study conducted with pregnant adolescents, in which those with low levels of education experienced a worse OHRQoL [23]. Women's self-perceptions may be altered during pregnancy due to physical and psychological changes related to this phase [1], which may exert an impact on the results of studies on OHRQoL.

Regarding clinical conditions, pregnant women with gingivitis had poor OHRQoL. Besides hormonal changes, pregnancy also has repercussions for oral health. Pregnant women are more susceptible to xerostomia, oral thrush and, if proper oral hygiene is not performed, gingivitis and dental caries can become aggravated, exerting a negative impact on OHRQoL [9,12]. Gingivitis was related to higher OHIP-14 mean scores, which is compatible with findings described in previous studies [2,24]. A cross-sectional study conducted with 512 pregnant women in Shanghai, China, found that more than a half

of the participants had gingival bleeding at 25% of sites and consequently reported a worse impact on OHRQoL [2]. The literature describes gingivitis in the gestational period as a signs of hyperplasia, erythema, and gingival bleeding [2].

If a woman does not have adequate oral hygiene during pregnancy, she is more likely to develop gingivitis due to increased hormone production which causes an increase in the gingival blood supply and alters mediators of the inflammatory response [24]. In such cases, dental care is recommended. Dental treatment is safe and effective throughout the entire pregnancy but should be preferably performed in the second trimester, as the risk of embryological effects is lower and pregnant women feel greater comfort during dental care [25]. The effectiveness of periodontal therapy during pregnancy to reestablish oral health and exert a positive effect on OHRQoL is widely discussed in the literature [9].

The other clinical conditions evaluated in the present study, such as dental caries, missing teeth, and periodontitis, were not associated with the pregnant OHRQoL. During pregnancy, general health, such as risks to the fetus and the possibility of systemic diseases, may exert a greater impact on quality of life than oral conditions, as women understand that problems with the oral cavity do not directly threaten the infant development, which may influence their self-perception of health [26]. Moreover, this period is marked by symptoms of nausea, vomiting and discomfort, which can have a negative impact on the professional, social, and family life of these women and may mask other results related to oral health [2].

Some limitations must be considered. The questionnaire used to assess OHRQoL records oral health impacts in the last six months, and some pregnant women included had a gestational age lower than this period. Thus, this OHRQoL may be related the pre-pregnancy period. Furthermore, with our cross-sectional design, we cannot establish any cause-and-effect relations. Another limitation is related to our sample; only public health services were assessed, which prevented us from having a representative sample of the population. However, in Brazil, the public network covers a large part of the population, as it is considered a free network with universal access [27]. Despite the limitations, this is an

innovative study, as the association between dental anxiety and OHRQoL has not previously been investigated in pregnant women. Besides, we have used valid methods and instruments to assess the variables of interest. Studies should investigate more in depth the consequences of dental anxiety on pregnant OHRQoL as well as the impact of this important aspect on the infant's oral health. It could be important since dental anxiety can exert a negative impact on the use of dental services and pregnant oral health [3]. These aspects may also impact the infant oral health considering that mothers are the main ones responsible for the oral health of their children, especially during the first years of life [8].

Regarding the practical implications of this study, identifying the relation between high levels of dental anxiety and poor OHRQoL underscores the need for all health teams to plan oral health promotion measures that reach this population. Such measures should include strategic actions that enable pregnant women to feel safe and more at ease regarding prenatal dental care, which would have a positive impact on their OHRQoL, providing wellbeing for these women and, consequently, for their developing infants.

CONCLUSION

In conclusion, our findings indicated that dental anxiety was associated with OHRQoL in pregnant women attending public health centers. Higher levels of dental anxiety and gingivitis can lead to worse OHRQoL in pregnant women.

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Author's Contributions

GA: Investigation, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing. MC: Formal Analysis, Software, Writing – Review & Editing. CMS: Methodology, Writing – Review & Editing. BE: Formal Analysis, Software, Writing – Review & Editing. FT: Formal Analysis, Software, Writing – Review & Editing. BZS: Conceptualization, Methodology, Resources, Supervision, Writing – Review & Editing.

Conflict of interest

The authors have no conflicts of interest to declare.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Human Research Ethics Committee of *Universidade Franciscana*.

This study protocol was reviewed and approved by the Human Research Ethics Committee of *Universidade Franciscana*, approval number 55197616.7.0000.5306.

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