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RESEARCH ARTICLE

Poor Oral Health-Related Quality of Life in Pre- and Post-Liver Transplantation Patients

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Abstract:

Background:

Oral health is associated with Chronic Liver Disease (CLD) and may play a relevant role in oral (OHRQoL) and general health-related quality of life (HRQoL) among people with chronic liver disease (CLD).

Objective:

To explore the correlations between OHRQoL and HRQoL in pre- and post-liver transplantation (LT) patients.

Methods:

A cross-sectional study with 189 patients: 63 per group (pre-LT, post-LT, and without liver disease). The Oral Health Impact Profile-14 (OHIP-14), the 36-Item Short-Form Health Survey, and the Work Ability Index (WAI) were used to measure oral health-related quality of life, health-related quality of life, and work ability, respectively. Oral health was evaluated according to the World Health Organization criteria. The relationship between the OHIP-14 and independent variables was analysed by multiple linear regression.

Results:

Pre-LT group presented the highest OHIP-14 total mean score, followed by the post-LT group, compared to the group without liver disease (p=0.001). All HRQoL and WAI mean scores were lower in the pre-LT group than in the other groups (p≤0.013). In the pre-LT group, the OHIP-14 total mean score was negatively correlated with the Mental Health, Physical Functioning, and General Health mean scores (p=0.01) and negatively and significantly (p<0.05) associated with decayed teeth and with poor workability. In the post-TL group, OHRQOL of life was associated with decayed and missing teeth, lower educational level, and poor workability.

Conclusion:

Patients in the pre- and post-LT groups presented poorer OHRQoL compared to patients without liver disease. OHRQoL was strongly correlated with HRQoL in the pre-LT group.

Keywords: Oral Health, Health-Related Quality of Life, Liver Transplantation, Periodontal Diseases, Dental Caries, Oral Medicine.

1. INTRODUCTION

Liver Transplantation (LT) is an effective treatment for advanced-stage Chronic Liver Diseases (CLD). Uncontrolled infections associated with shorter survival time, including oral infections, are among the medical contraindications for liver transplantation [1 - 3]. Patients in LT may also present hemorrhagic complications during dental procedures, while oral infection treatment is associated with a reduction in morbidity and mortality in cirrhotic patients [2]. After LT, immunosuppression therapy increases the risk of systemic infections from oral diseases. Reports in the literature include manifestations of opportunistic diseases (herpes virus, Epstein-Barr virus, cytomegalovirus, candidiasis) and oral cancer [4 - 6].

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The etiology of chronic liver disease is associated with oral health conditions. Similarly, severe CLD may lead to poor dental health. Oral infections in pre- and post-LT may impact the general health status [7] and health-related quality of life (HRQoL) of patients undergoing liver transplantation [8]. Aspects of LT patients' physical and mental health are associated with complications, such as ascites and hypoproteinemia [9]. Poor physical HRQoL is associated with a high frequency of decayed teeth and periodontitis, while the reduced salivary flow is associated with poor mental health in people with hepatitis C [8].

Some studies have reported an association between LT patients and poor HRQoL [8, 9] and poor oral health (caries, periapical lesions, root fragments, and severe periodontal disease) [2, 8, 10, 11]. Three studies have reported high HRQoL in patients post-LT [12 - 14], although poor oral health [11, 15] and oral mucosa lesions [16] were still prevalent in the investigated populations. However, to the best of our knowledge, there are no data about the association between OHRQoL and HRQoL in pre-LT and post-LT compared to patients without liver disease. Therefore, the aims of this study were to explore the correlations between the OHRQoL and HRQoL of patients pre- and post-liver transplantation (LT).

2. MATERIALS AND METHODS

A cross-sectional study was conducted at the Professor Edgard Santos University Hospital Complex (*Complexo Hospitalar Universitário Professor Edgard Santos:* C-HUPES) of the Federal University of Bahia, Brazil. The data were collected between June 2017 and December 2019. There were 189 patients, 63 per group. The pre-LT and post-LT groups were examined at the Liver Transplantation Outpatient Clinic. The group without liver disease was undergoing monitoring at the Oral Surgery Service. Patients were included in the post-LT group three months after surgery.

2.1. Oral Health-Related Quality of Life

OHRQoL was measured by the Oral Health Impact Profile 14 (OHIP-14). The questionnaire's scoring ranges from 0 to 56, and a high score indicates poor OHRQoL. It contains 14 questions formatted in a Likert-type scale coded as 0 = "never", 1 = "hardly ever", 2 = "occasionally", 3 = "fairly often", and 4 = "very often". The OHIP-14 may be analyzed according to seven dimensions: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap [17]. The Optimal Implementation of Parallel Analysis (PA) was used [18] to evaluate the appropriate way to describe OHIP-14 scores since reports in the literature feature either one or seven dimensions. The PA suggested only one dimension, in line with the scale's developers [19].

2.2. Health-Related Quality of Life

The 36-Item Short-Form Health Survey version 2 (SF-36v2) measured HRQoL. This questionnaire is composed of 10 questions with 36 items, which generate eight domains: Physical Functioning (PF), Physical Role (PR), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Emotional Role (ER) and Mental Health (MH). These domains are aggregated into two summaries: the Physical Component Summary (PCS) and the Mental Component Summary (MCS). High scores signify good HRQoL [20]. All domains were normalized to a mean of 50 and a standard deviation of 10, using the OPTUM PRO CoRE v 1.4.7, license number QM025905.

2.3. Work Ability

The Work Ability Index (WAI) questionnaire measured workability. These questions identify perceived physical and mental health and general health status (diagnosis and diseases). The questionnaire is composed of ten questions, and its total score ranges from 7 to 49. High scores indicate good Work Ability [21, 22].

2.4. Oral Health Evaluation

Oral health status was evaluated by the World Health Organization [23] and the European Association of Public Dental Health [24] criteria. The following variables were collected: the number of Decayed, Missing, and Filled Teeth (DMFT-Index), periodontal probing depth, gingival bleeding, gingival recession or growth, and dental calculus. Periodontal diseases were measured with a World Health Organization probe and classified according to Periodontal Screening and Recording (PSR) into four categories: absence of disease, gingivitis (gingival bleeding and/or dental calculus), periodontitis (alveolar bone loss), and edentulous [25]. The stimulated salivary flow was considered low if it was below or equal to 1.0 mL per minute [26].

2.5. Variables and Statistics

The independent variables were age, income, WAI, comorbidities (diabetes, hypertension, and depression), DMFT-Index, and periodontal disease. The dependent variables were OHRQoL and HRQoL.

Our calculation of study sample size was based on a pilot study comprising 78 patients. We compared HRQoL means, considering the groups two at a time. Comparing pre-LT and post-LT patients, the highest value obtained was 63 per group (95% confidence interval, 80%power). The final sample size was 189 patients (OpenEpi, Version 3).

Statistical analysis was performed by using the Statistical Package for the Social Science (SPSS) version 21 (IBM Corporation, Armonk, NY, USA). The Pearson's chi-square test compared proportions between groups. The Kruskal-Wallis test followed by the Mann-Whitney test compared the means of groups with non-parametric distributions. The significance level was always 5% (0.05). Spearman's correlation measured the correlation between OHIP-14 data and the SF-36v2 domains and summaries. These results were interpreted in line with Cohen's classification [27]. Multiple regression analysis was used to analyze the relationship between the OHIP-14 and the independent variables. Variables for the model were selected if they had a p-value less than 0.25 [28] in the bivariate analysis. The Institutional Review Board of the School of Medicine at the Federal University of Bahia approved this protocol (number 2.780.060), following the

Ethical guidelines of Brazilian National Health Council Resolution 466/2012 and the 2013 Declaration of Helsinki. All patients signed an informed consent form. This study was funded by the Bahia State Research Support Foundation [*Fundação de Amparo à Pesquisa do Estado da Bahia*: FAPESB], (Grant PPSUS 0018/2014).

3. RESULTS

The pre-LT and post-LT groups were similar in terms of age, sex, smoking, and drinking habits. The post-LT group revealed higher family income, educational level, and a higher proportion of white patients than the pre-LT and no liver disease groups. The three groups did not differ according to marital status. In the pre-LT group, 24 patients (38.1%) were retired, 12 (19%) received government sickness benefits, while 12 (19%) were unemployed. In the pre-LT group, most patients (49.2%) presented cirrhosis due to alcoholic liver disease (ALD); in the post-LT, this was due to hepatitis C (27.0%). Other causes (schistosomiasis, Wilson's disease, cryptogenic hepatitis, and primary biliary cholangitis) were less common in both groups (Table **1**).

Table 1. Sociodemographic, clinical characteristics and habits of 189 patients according to liver disease condition, Salvador, Brazil, 2020.

Characteristics	Pre-LT (A) N=63	Post-LT (B) N=63	No LiverDisease (C) N=63	p-value
Age - M ± SD	-	-	-	<0.001*
	55.06 ±11.9	54.02 ± 11.5	46.84 ± 12.8	-
Sex - N(%)	-	-	-	0.024**
Male	46 (73.0)	43 (68.3)	32 (50.8)	-
Female	17 (27.0)	20 (31.7)	31 (49.2)	-
Race - N(%)	-	-	-	0.009**
White	6 (9.5)	20 (31.7)	14 (22.2)	-
Black/ Brown	57 (90.5)	43 (68.3)	49 (77.8)	-
Educational level - N(%)	-	-	-	0.016**
Up to Elementary	32 (50.8)	17 (27.0)	29 (46.0)	-
High School/College	31(49.2)	46 (73.0)	34 (54.0)	-
Marital status - N(%)	-	-	-	0.296**
Single	23 (36.5)	15 (23.8)	20 (31.7)	-
Stablerelationship	40 (63.5)	48 (76.2)	43 (68.3)	-
Family Income - N (%) (In Brazilian Minimum Wages†)	-	-	-	0.003**
<2	31 (49.2)	14 (22.2)	29 (46.0)	-
≥2	32 (50.8)	49 (77.8)	34 (54.0)	-
Smoking N(%)	-	-	-	0.194**
Past	29 (46.0)	28 (44.4)	20 (31.7)	-
Current	5 (8.0)	2 (3.2)	2 (3.2)	-
Never	29 (46.0)	33 (52.4)	41 (65.1)	-
Drinking N(%)	-	-	-	0.001**
Past	52 (82.5)	45 (71.4)	32 (50.8)	-
Current	2 (3.2)	2 (3.2)	9 (14.3)	-
Never	9 (14.3)	16 (25.4)	22 (34.9)	-
Alcoholic liver disease - N (%)	31 (49.2)	14 (22.3)	-	-
Hepatocellular carcinoma - N (%)	4 (6.3)	2 (3.2)	-	-
Hepatitis C - N (%)	9 (14.3)	17 (27.0)	-	-
Hepatitis B - N (%)	0 (0.0)	4 (6.3)	-	-
Autoimmunehepatitis - N (%)	4 (6.3)	9 (14.3)	-	-
Non-alcoholic steatohepatitis - N (%)	1 (1.6)	2 (3.2)	-	-
Other hepatic diseases - N (%)	14 (22.3)	15 (23.7)	-	-
Diabetes - N(%)	15 (23.8)	26 (41.3)	2 (3.2)	-
Systemic arterial hypertension - N(%)	17 (27.0)	27 (42.9)	11 (17.5)	-

M: Mean; SD: Standard deviation; *Kruskal-Wallis test followed by Mann-Whitney test: (A vs. B >0.05); (A vs. C and B vs. C <0.05); **Pearson's Chi-square; †Family income (Minimum Wages): 188 USD.

Table 2. Oral Health profile of 189 patients according to liver disease condition, Salvador, Brazil, 2020.

Oral Health Characteristics	Pre-LT (A)	Post-LT (B)	No LiverDisease (C)	p-value
	N=63	N=63	N=63	
Decayed - M±SD	1.17 ± 2.1	1.02 ± 2.4	2.05 ± 2.0	<0.001*
Missing - M±SD	15.16 ± 10.3	12.90 ± 9.2	4.83 ± 2.6	<0.001*
Filled - M±SD	4.46 ± 5.2	5.90 ± 5.7	5.00 ± 4.2	0.198*
DMFT-Index - M±SD	20.35 ± 8.3	19.83 ± 8.7	11.84 ± 5.1	<0.001*
Periodontal disease - N (%)	-	-	-	<0.001**
Gingivitis	20 (31.7)	27 (42.9)	20 (31.7)	-
Periodontitis	37 (58.7)	33 (52.4)	8 (12.7)	-
No disease/edentulous	6 (9.5)	3 (4.8)	35 (55.6)	-
Salivary flow - N (%)	-	-	-	0.764**
Reduced	22 (34.9)	24 (38.1)	26 (41.3)	-
Normal	41 (65.1)	39 (61.9)	37 (58.7)	-

M: Mean; SD: Standard deviation;

*Kruskal-Wallis test followed by Mann-Whitney test: (A vs. B >0.05); (A vs. C< 0.05 except Filled); (B vs. C<0.05 except Filled);

** Pearson's Chi-square.

Table 3. Oral Health-related Quality of Life (OHIP-14), Health-related Quality of Life (SF-36 v2), and Work Ability Index (WAI) of 189 patients according to liver disease condition, Salvador, Brazil, 2020.

Variable	Cronbach's alpha	Pre-LT (A)	Post-LT (B)	No LiverDisease (C)	p-value
		M±SD	M±SD	M±SD	
		N=63	N=63	N=63	
Total OHIP-14	0.839	10.41± 7.9	7.35 ± 6.5	1.67 ± 2.7	<0.001*
Physical Functioning (PF)	0.939	34.33 ± 9.3	50.41 ± 7.1	52.35 ± 6.7	<0.001*
Physical role (PR)	0.980	36.11 ± 9.7	53.27 ± 8.1	50.26 ± 8.8	<0.001*
Bodily Pain (BP)	0.817	50.45 ± 12.0	56.26 ± 9.1	54.20 ± 9.0	0.013 *
General Health (GH)	0.783	41.14 ± 7.8	53.95 ± 7.0	52.23 ±8.3	<0.001*
Vitality (VT)	0.839	45.44 ± 10.8	60.28 ± 7.9	56.07 ±6.2	<0.001*
Social Functioning (SF)	0.784	38.57 ± 11.6	53.04 ± 7.9	51.51 ±7.5	<0.001*
Emotional Role (ER)	0.969	40.71 ± 12.1	52.36 ± 7.9	46.99 ±10.7	<0.001*
Mental Health (MH)	0.731	48.55 ± 9.7	55.69 ± 7.1	51.15 ±5.9	<0.001*
Physical Component Summary (PCS)	-	38.46 ± 9.0	52.86 ± 7.3	50.87 ±6.3	<0.001*
Mental Component Summary (MCS)	-	46.53 ± 10.0	55.85 ± 7.6	52.68 ±6.5	<0.001*
Work Ability Index (WAI)	0.866	22.94 ± 6.5	38.33 ± 6.6	38.46 ±6.8	<0.001*

M: Mean; SD: Standard deviation;

*Kruskal-wallis Test; Mann-Whitney test (two groups at a time); (A vs. B all categories p<0.05); (A vs. C<0.05 except MH); (B vs. C< 0.05 except PF, BP, GH, WAI).

Compared to the group with no liver disease, the pre-LT group had the most missing teeth and the highest DMFT-index. Both pre-LT and post-LT groups were similar in relation to decayed, missing, and filled teeth, DMFT-Index, and periodontal disease. Periodontitis prevailed in pre-LT and post-LT patients (58.7% and 52.4%, respectively), compared to those without liver disease (12.7%). Patients in the pre-LT and post-LT groups had higher frequencies of periodontal disease than patients without liver disease (58.7%, 52.4%, and 12.7%, respectively) (Table **2**).

The pre-LT group had the highest total OHIP-14 mean score, followed by the post-LT group, compared to that with no liver disease (two groups at a time p<0.05). All HRQoL and WAI scores were systematically lower in the pre-LT group than in the other two groups (Table **3**).

The OHIP-14 total mean score was negatively correlated with most of the SF-36v2 domains and summaries across the three groups. In patients from the pre-LT group, the OHIP-14 total mean score was significantly (p< 0.01) correlated with MH, PF, and GH scores (Table **4**).

Predictive variables for OHIP-14 were identified through multiple regression analysis. In the pre-LT group, the OHIP-14 was significantly (p< 0.05) associated with decayed teeth and poor work ability. In the post-LT group, the OHIP-14 was associated with decayed, and missing teeth, lower educational level, and poor work ability. In the no liver disease group, the OHIP-14 was associated with a number of missing teeth and low salivary flow (Table **5**).

Table 4. Spearman's correlation between OHIP-14 total mean and SF-36 v2 domains and summaries in 189 patients according to liver disease condition, Salvador, Bahia, Brazil, 2020.

Variable	Pre-LT (A)	Post-LT (B)	No LiverDisease (C)
	N=63	N=63	N=63
	OHIP-14	OHIP-14	OHIP-14
Physical Functioning (PF)	-.369**	-0.156	-0.231
Physical Role (PR)	-0.236	-0.124	-0.025
Bodily Pain (BP)	-.269*	-0.16	-0.106
General Health (GH)	-.447**	-0.079	0.02
Vitality (VT)	-0.218	0.015	-0.16
Social Functioning (SF)	-.273*	-0.185	0.16
Emotional Role (ER)	-0.219	-0.065	0.161
Mental Health (MH)	-.356**	-0.087	0.046
Physical Component Summary (PCS)	-.299*	-0.119	0.119
Mental Component Summary (MCS)	-.275*	0.004	-0.162
* The correlation was significant at 0.05 level (2-tailed). ** The correlation was significant at 0.01 level (2-tailed).			

Table 5. Final model of multiple regression analysis with the OHIP-14 as the dependent variable for 189 patients according to liver disease condition, Salvador, Bahia, Brazil, 2020.

Predictors	Pre-LT (A) $(R^2=33\%)$			Post-LT (B) $(R^2=53\%)$			No LiverDisease (C) $(R^2=31\%)$		
	B†	SE‡	p-value	B†	S‡*	p-value	B†	SE‡	p-value
Constant	20.42	3.90	<0.001	17.14	4.47	<0.001	-0.95	1.94	0.625
Decayed, n tooth	1.12	0.44	0.013	1.61	0.25	<0.001	0.08	0.17	0.637
Missing, n tooth	0.15	0.09	0.115	0.19	0.07	0.008	0.44	0.12	0.001
Salivary Flow, mL/min	-1.54	1.92	0.425	-0.63	1.26	0.618	-1.42	0.67	0.039
Educational level	-0.66	0.35	0.066	-0.92	0.30	0.003	0.11	0.13	0.395
Sex, male	1.26	2.09	0.550	1.55	1.35	0.225	-0.02	0.61	0.973
Work Ability	-0.44	0.14	0.003	-0.23	0.09	0.016	0.02	0.05	0.755

† Regression coefficient; ‡ Standard error.

4. DISCUSSION

In some studies, poor oral health in patients with liver disease is described as dental caries, severe periodontitis, tooth mobility, and oral lesions. All these conditions can lead to pain, dysphagia, difficult chewing food, and speech [2, 8, 11, 29, 30]. In northern Brazil, a cross-sectional study [31], with the riverine community, reported the higher impact of clinical parameters (pain, untreated caries, the necessity of oral invasive treatment) in OHRQoL.

There are few studies about OHRQoL in patients with CLD, pre- and post-LT [32, 33]. One study found that patients in pre- and post-LT had poor OHRQoL compared to a healthy control group [32]. Moreover, correlations were not found between DMFT index, periodontal status, and total OHIP-14 score. A study [33] in Denmark reported poor OHRQoL in CLD patients, most frequently related to taste and eating.

In this study, the total OHIP-14 mean score was significantly higher in the pre-LT group, followed by the post-LT, compared to those with no liver disease. Furthermore, we used the total OHIP-14 score to describe the OHRQoL in patients pre- and post-LT as the PA suggested only one OHIP-14 dimension, in line with other authors [19, 34], and a total score may better explain OHRQoL.

A cross-sectional study in Southeastern Brazil [35] evaluated the impact of oral health on HRQoL and found that OHRQoL, age, presence of pain, and chronic diseases can lead to poor HRQoL. Poor oral health status in pre- and post-LT has been noted [2, 8, 32]. Our research group has described the relationship between low SF-36 scores, high DMFT-Index, and low salivary flow in patients with CLD [30]. In another study, a significant correlation between low Mental Health Component and reduced salivary flow in patients with HCV was found [8]. In this study, we found a low negative correlation between total OHIP-14, PF, GH, and MH in the pre-LT group, meaning that higher OHRQoL scores impacted negatively on the HRQoL of this group.

Some studies have demonstrated improved HRQoL in a post-LT group compared to a pre-LT one [13, 36, 37]. Furthermore, a systematic review showed long-term benefits in HRQoL in a post-LT group compared to a pre-LT one [12]. Another study conducted by our research group describes poor HRQoL in patients pre-LT compared to a CLD group [8]. The current study demonstrated that pre-LT patients had poor HRQoL in all SF-36v2 domains and summaries than the post-LT and no liver disease groups. Moreover, other characteristics may influence HRQoL. A study of post-LT patients identified that a greater length of time since LT and health follow-ups in

large referral centers were associated with improved HRQoL [13]. A study of people living with HIV found an association between female sex and low SF-36 scores in all its domains and summaries. Further, depression, family income, and age were associated with the Mental Component Summary (SF-36), while comorbidities, age, and perceived health were associated with the Physical Component Summary (SF-36) [20].

This study also found that the pre-LT group had the lowest mean scores for work ability than the other groups, which performed similarly. A study conducted in Finland [14] demonstrated that, following LT, patients reported improved work capacity compared to the week prior to LT. Another study reported poor and moderate work ability in patients with CLD [30]. Therefore, liver transplants may benefit pre-LT patients, making it possible for them to be reincorporated into society with a job and improved family income, since 38.1% of these patients were unemployed or received government sickness benefits.

We used Cronbach's alpha to evaluate the index of reliability for the OHIP-14 All the SF-36v2 domains, and the WAI. Cronbach's alpha is the most commonly used index, and its results can be compared to other studies. High values or those equal to 0.7 are considered satisfactory [38]. Cronbach's alpha coefficient for the OHIP-14 was 0.839. In other populations, the OHIP-14 behaved like a one-dimensional scale [19, 34], as it did in our study. All the SF-36v2 domains had a Cronbach's alpha coefficient of ≥0.73, while that for the WAI was 0.866.

In a cross-sectional study conducted in Germany [39], patients with heart failure and post-heart transplantation presented an association between poor OHRQoL and worse HRQoL. Further, smoking was associated with poor OHRQoL in the heart failure group. Elsewhere, in patients aged ≥ 60 years old, poor OHRQoL was associated with tooth loss [40]. Our study described the association between decayed teeth and poor work ability, with poor OHRQoL in the pre-LT group. Moreover, missing teeth was associated with poor OHRQoL in the post-LT and no liver disease groups.

Oral health may not only impact OHRQoL [32, 33] but also general HRQoL [8, 30] and severity of liver disease [2, 7]. Prospective studies are needed to understand the impact of oral health quality of life on liver disease severity and evolution.

CONCLUSION

Patients in pre- and post-LT presented poor OHRQoL compared to patients without liver disease. OHRQoL was poor in the pre-LT patients than in the post-LT group. Lower HRQoL was correlated with poorer OHRQoL in the pre-LT group. In the pre- and post-LT groups, OHRQoL was associated with a number of decayed teeth and lower work ability. In the post-LT group, OHRQoL was associated with a number of missing teeth and a lower educational level.

AUTHORS' CONTRIBUTIONS

Authors Larissa Souza Santos-Lins and Liliane Lins-Kusterer made substantial contributions to conception and design, and/or acquisition of data, and/or analysis and interpretation of data.

Authors Inácio Aguiar; Liana Codes, Maria Auxiliadora Evangelista, Alessandra de Oliveira Castro, Paulo Lisboa Bittencourt, and Andrea Cavalcanti Raymundo Paraná participated in interpretation of data.

Authors Larissa Souza Santos-Lins, and Liliane Lins-Kusterer; participated in drafting the article.

Authors Inácio Aguiar; Liana Codes, Maria Auxiliadora Evangelista, Alessandra de Oliveira Castro, Paulo Lisboa Bittencourt, Andrea Cavalcanti, and Raymundo Paraná participated in revising the article critically for important intellectual content.

Authors Larissa Souza Santos-Lins, Inácio Aguiar, Liana Codes, Maria Auxiliadora Evangelista, Alessandra de Oliveira Castro, Paulo Lisboa Bittencourt, Andrea Cavalcanti, Raymundo Paraná, and Liliane Lins-Kusterer gave final approval of the version to be submitted and any revised version.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The Institutional Review Board of the School of Medicine at the Federal University of Bahia, Brazil approved this protocol (number 2.780.060).

HUMAN AND ANIMAL RIGHTS

No animals were used in this research. All procedures performed in studies involving human participants were undertaken in accordance with the ethical guidelines of the Brazilian National Health Council Resolution 466/2012, the Helsinki declaration, and its later amendments or comparable ethical standards.

CONSENT FOR PUBLICATION

All patients signed an informed consent form.

AVAILABILITY OF DATA AND MATERIALS

The data that support this study's findings are available from the corresponding author [L.L.-K] upon request.

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CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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