Brazilian Portuguese Version of the Craniofacial Pain and Disability Inventory: Cross-Cultural Reliability, Internal Consistency, and Construct and Structural Validity

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Aims: To culturally adapt the Craniofacial Pain and Disability Inventory (CF-PDI) for a Brazilian population and to assess its psychometric properties, including internal consistency, reliability, and construct and structural validity. **Methods:** A total of 100 female and male TMD patients with temporomandibular disorders (TMD), with or without headaches, were included. Participants were assessed based on the Research Diagnostic Criteria for TMD and the International Headache Society criteria. For statistical analyses, intraclass correlation coefficient (ICC) was used for assessing reliability (test-retest), Cronbach's alpha for internal consistency, Pearson rank correlation for construct validity, and confirmatory factor analysis (CFA) for structural validity. **Results:** The CFA provided the following three factors/domains for the Brazilian CF-PDI (CF-PDI/Br): *(1)* functional and psychosocial limitation; *(2)* pain; and *(3)* frequency of comorbidities. Scores for test-retest reliability and internal consistency in each domain were acceptable (ICC > 0.9; Cronbach's α > 0.77). Correlations between CF-PDI scores and jaw functional limitation, pain-related disability, pain catastrophizing, depression, neck pain–related disability, and kinesiophobia scores were confirmed in 89% (50/56) of the comparisons. **Conclusion:** The CF-PDI/Br with three factors had sound psychometric properties. Therefore, the Brazilian Portuguese version can be used in clinical settings and for research purposes. *J Oral Facial Pain Headache 2018;32:389–399. doi: 10.11607/ofph.2141*

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Temporomandibular disorders (TMD) comprise a subgroup of orofacial pain conditions that affect the temporomandibular joint (TMJ) and masticatory structures.[1] TMD represent the most common type of chronic orofacial pain, with a higher prevalence in women and a peak prevalence between 20 and 40 years of age.[2,3]

TMD are commonly associated with other types of chronic pain, such as headaches and neck pain. Terms such as cervicocraniofacial pain have been employed in the literature in an attempt to reflect this relationship.[4–7] Previous studies have reported a prevalence of severe headaches and neck pain in TMD patients of around 50%.[8–10] In addition, the concomitance of TMD and other comorbidities, such as migraines, may worsen pain-related morbidity.[11] Thus, it is important to consider the interference of other comorbidities in the overall TMD-related disability.

Orofacial pain and related disability are the main outcomes commonly reported by patients with TMD.[7] Furthermore, TMD pain can affect a patient's ability to participate in functional daily activities.[12] The Manchester Orofacial Pain Disability Scale is an instrument available in Brazilian Portuguese that assesses pain and disability in orofacial pain patients.[13,14] However, this scale does not consider the role of interactions between orofacial pains, such as headaches, neck pain, or ear pain. Furthermore, it was designed to assess the frequency of symptoms only in the last 30 days, and there are no questions regarding the intensity or magnitude of orofacial symptoms. In view of these aspects, an instrument that encompasses the assessment of both constructs (pain and disability) without disregarding the influence of other pains

and that is designed to assess pain and disability magnitude and not only symptom frequency may be valuable. Such an instrument could help reduce the overall impact of TMD-related disability on patients' lives[12] and improve understanding of the impact of other comorbidities and their management on TMD and TMD-related disability.

The Craniofacial Pain and Disability Inventory (CF-PDI) was designed to assess both pain and disability in TMD patients with and without other sources of pain. It comprises 21 questions and two subscales: (1) pain and disability and (2) jaw functional status.[15] Preliminary findings have shown acceptable reliability and validity of the CF-PDI[15]; however, the original CF-PDI is in Spanish, which imposes the need to translate and culturally adapt the instrument for use in other languages and cultures.[16–18]

Aside from the recommendations inherent to the cross-cultural adaptation process, the guidelines[16,17] do not specify an approach for validating the culturally adapted instrument, although Beaton et al[16] strongly recommended that researchers investigate the measurement properties of the new version. In order to accomplish this, test-retest reliability, internal consistency, and construct validity should be assessed. Consensus-based standards for the selection of health measurement instruments (COSMIN) highly recommend assessing structural validity by applying the classical test theory or item response analysis approaches.[18]

In view of these findings, as well as considering the importance of the CF-PDI, the aim of this study was to cross-culturally adapt the CF-PDI for a Brazilian Portuguese population and to assess its psychometric properties, including reliability, internal consistency, and construct and structural validity, in patients with painful TMD with or without other orofacial pain disorders.

Materials and Methods

Sample

A total of 100 patients with painful TMD participated in this study. They were consecutively recruited from the Orofacial Pain Outpatient Clinic from the School of Dentistry of Ribeirão Preto, University of São Paulo between February 2016 and June 2017. The inclusion criteria for participants were as follows: A diagnosis of painful TMD based on the Research Diagnostic Criteria for TMD (RDC/TMD)[19]; a history of orofacial pain at least 6 months prior to the start of the study; and no cognitive deficits, with a minimal cut-off score of 22[20] on the Mini Mental State Examination (MMSE).[21] The RDC/TMD assessment was conducted by an experienced, trained, and calibrated dentist.

Participants with headaches and neck pain were not excluded. Headaches were confirmed in accordance with the International Classification of Headaches.[22]

Patients with illiteracy; severe depression (medical diagnosis); clinical history of tumors in the craniofacial region; post–dental surgery period; infections; whiplash-associated disorders; and/or chronic degenerative inflammatory or neurologic disorders were excluded from this study.

This study was submitted to and approved by the ethics committee for research involving human subjects of the Clinics Hospital of the Ribeirão Preto, Medical School of the University of São Paulo (HCFMRP Process No. 5736/2016). Subjects had ample time to determine whether to participate in the study. Signature on the consent was attained for subjects who decided to participate.

Procedures

All participants completed a set of instruments to assess kinesiophobia, pain catastrophizing, functional jaw limitation, pain intensity, pain-related disability, and neck-related disability. Pain and disability related to TMD were assessed using the CF-PDI. A subgroup of participants (n = 40) from the total sample (n = 100) participated in the pre-testing of the CF-PDI adapted to Brazilian Portuguese. Another subgroup (n = 60) was recruited from the total sample to participate in the test-retest study, for which they had to answer the CF-PDI questionnaire on two different occasions within a 1-week interval.

Instruments

Tampa Scale for Kinesiophobia for Temporomandibular Disorders. The Tampa Scale for Kinesiophobia for TMD (TSK/TMD) is a self-report questionnaire that assesses fear of movement.[23] In this study, the TSK-TMD with 12 items validated in Brazilian Portuguese was used.[24] Each item is scored on a 4-point ordinal scale, ranging from "strongly disagree" (score = 1) to "strongly agree" (score = 4). Ratings are summed to yield a total score, which can range from 12 to 48 points. Higher scores reflect a greater fear of movement.

Pain Catastrophizing Scale. The Pain Catastrophizing Scale (PCS) in Brazilian Portuguese[25] is a self-administered questionnaire that consists of 13 items for the assessment of the catastrophizing construct. It is divided into three domains: helplessness, magnification, and rumination. In the original PCS, the items are rated on a 5-point ordinal scale on which both intensity and frequency information are represented. The Brazilian PCS total score can range from 0−52 points, with higher values denoting greater pain catastrophizing. Acceptable values for

validity, internal consistency, and test-retest reliability have been described for the Brazilian PCS.[25]

Mandibular Functional Impairment Questionnaire (MFIQ). The Brazilian Portuguese version of the Mandibular Functional Impairment Questionnaire (MFIQ)[26] consists of 13 questions. Each is rated on a 5-point ordinal scale ranging from "no difficulty" to "very difficult or impossible without help." A total score can range from 0 to 52, and a higher score reflects a higher level of orofacial disability. Acceptable values for validity, internal consistency, and test-retest reliability have been determined for the Brazilian MFIQ.

Neck Disability Index. The Neck Disability Index (NDI) assesses neck-related disability and consists of 10 questions; each scored on a 0 to 5 rating scale (0 = no pain; 5 = worst imaginable pain). The sum score of the items can range from 0 to 50. The Brazilian Portuguese version of the NDI was used in this study.[27]

Pain Disability Questionnaire. The Pain Disability Questionnaire (PDQ) measures pain-related disability and consists of 15 questions grouped into those related to functional condition (9 items: 1–7, 12, and 13) and the psychosocial component (6 items: 8–11, 14, and 15). The maximum score for functional condition is 90 points, and for the psychosocial component is 60. The total score of the PDQ can range from 0 to 150. This study used the validated Brazilian Portuguese version.[28] The original CF-PDI[15] study did not report the use of any pain-related disability instrument to check for construct validity; however, as the CF-PDI assesses jaw functioning, disability, and pain, this instrument was adopted in an attempt to run comparisons encompassing all domains of the CF-PDI.

Numeric Pain Rating Scale. The 11-point Numeric Pain Rating Scale (NPRS) was used to measure pain intensity. Scores could range from 0 to 10 (0 = no pain; 10 = worst pain imaginable[29]).

Craniofacial Pain and Disability Inventory. The CF-PDI is a self-administered questionnaire that measures the outcomes of pain and disability related to craniofacial pain. It consists of 21 items, with a total score that can range from 0 to 63 points. Each question is scored on a 4-point ordinal scale, ranging from 0 to 3. A higher score reflects higher disability levels. The original version of the CF-PDI has good structure, internal consistency, reproducibility, and construct validity.[15]

Cross-Cultural Adaptation of the CF-PDI to Brazilian Portuguese. As recommended by the ISPOR Task Force for Translation and Cultural Adaptation,[17] authorization was requested to translate the original instrument into Brazilian Portuguese. Permission from the authors of the original CF-PDI was granted.

The guideline recommendations were followed for the translation and cultural adaptation of the questionnaire.[16] The process was as follows:

- Forward translation from Spanish into Brazilian Portuguese by two translators; one an expert on the construct to be measured, and the other a layperson on the subject
- Synthesis of the translations, accomplished through a consensus between the translators
- Back-translation by two different translators blinded to the original version (both laypersons on the subject)
- A harmonization stage involving a committee of experts and translators
- A pre-testing phase consisting of a test of the pre-final version of the questionnaire

All forward and back-translations were conducted independently. The 13 participants involved in the harmonization stage included physical therapists, pain and orofacial pain researchers, dentists, and translators. The purpose of the meeting was to consolidate all the versions of the questionnaire, solve possible translation disagreements, and provide a pre-final version.

In the pre-testing phase, the acceptability and comprehensibility of the instrument were checked by using an open-field form and cognitive interviews. In order to determine which suggestions would be incorporated into the questionnaire during the pre-testing phase, it was assumed that only questions with a percentage of doubts greater than 20% would be reworded.[30]

Reliability and Internal Consistency

To determine the test-retest reliability, 60 participants who responded to the final version of the CF-PDI/Br were asked to complete the questionnaire again 1 week after the initial application. Test-retest reliability is the extent to which scores in stable patients are the same in repeated measurements over time.[18] Patients were considered to be clinically stable when the difference in pain intensity between assessments was not greater than two units on the NPRS.[31]

Internal consistency was also assessed, defined as the degree of intercorrelation between the items in a tool. This measurement is commonly used to assess the degree of consistency among items comprised within a tool.[32] A sample of 100 participants was selected for assessing internal consistency.

Construct Validity

According to COSMIN, construct validity is defined as the degree to which the scores of an instrument are consistent with an a priori defined hypothesis. It can be verified by evaluating the internal interrelationships

of the instrument and comparisons with other instruments, assuming that the comparator instrument is a reliable measure of the construct target.[18]

To evaluate construct validity, the scores of the domains and the total score of the CF-PDI/Br were correlated with the following constructs: catastrophizing (B-PCS); fear of movement (TSK-TMD); neck pain–related disability (NDI); mandibular functional limitation (MFIQ); and pain-related disability (PDI). These constructs, except pain-related disability, were reported in the CF-PDI original version[15] to check for the construct validity.

It was hypothesized that there would be weak to moderate correlations between the scores on the CF-PDI/Br and the NDI, PCS-Br, and TSK/TMD; and moderate to strong correlations between the scores on the CF-PDI/Br and MFIQ-Br (mandibular functioning) and PDQ (pain-related disability). Acceptable levels of construct validity were assumed if at least 75% of the hypotheses were confirmed.[32]

Structural Validity

Structural validity estimates the degree to which the scores of a metric are an adequate reflection of the parameters being measured.[18] The preferred statistical method for assessing cross-cultural validity when using the classical test theory is confirmatory factor analysis (CFA).[18] CFA was used to confirm the factor structure of the original CF-PDI.[15] As recommended by Terwee et al,[32] a sample of 100 patients from the target audience was recruited for validation.

Statistical Analyses

Reliability was calculated using the intraclass correlation coefficient (ICC[1,2])[33] and its respective 95% confidence intervals (CI). ICC values were classified as poor (< 0.40), moderate (0.40–0.75), or excellent (> 0.75).[34] Internal consistency was analyzed using Cronbach's α coefficient; results between 0.70 and 0.9532 and an item-total correlation between 0.20 and 0.80 were considered acceptable.[35] The Pearson correlation coefficient and the magnitude of correlation was graded as follows: r < 0.3 = weak; 0.4 < r < 0.6 = moderate; r > 0.7 = strong.[36]

This study investigated the goodness-of-fit of three factors (functional and psychosocial limitation; pain; and frequency of comorbidities) using CFA for assessment of structural validity:

- The structure of the model[15] consisting of 2 domains and 21 items
- The same model described above without question 8 ("Do you usually hear/feel noises during mandibular movement?")
- A factor structure with 3 domains and 21 questions, in which question 13 ("Pain intensity during speaking") was allocated to the functional and psychosocial limitation domain
- A factor structure comprised of 3 domains and 21 questions, in which question 13 ("Pain intensity during speaking") was allocated to the pain domain

Exploratory factor analysis (EFA) with varimax rotation was used in this study a priori to check for the structures of models 3 and 4. The following indices were scrutinized: Kaiser-Meyer-Olkin test (KMO); Bartlett's Test of Sphericity (BTS); and the percentage of explained variance, eigenvalues, and factor loadings. The KMO evaluates the relevance of performing EFA on a group of variables.[37] Hair et al[38] suggested 0.50 as an acceptable level for KMO. The BTS evaluates how similar the covariance matrix is to the identity matrix, with 0 being indicative of a lack of correlation and thus unsuitable for EFA.[38] BTS values with $P < .05$ indicate that the matrix is factorial.[39] The percentage of explained variance is acceptable at 50%.[40] Retained factors are the ones with an eigenvalue higher than 1.[38] Eigenvalues are variances of the factors that make up a given model.[38] Magnitudes of factor loadings of 0.3 or greater[41] were considered representative of the construct being measured in each domain.

The IBM SPSS AMOS (version 22) was used to run CFA. The maximum likelihood method was used to assess the fit of the models. The goodness-of-fit of each factor structure was evaluated using several descriptive criteria: consistent Akaike information criterion (CAIC); root mean square error of approximation (RMSEA); comparative fit index (CFI); incremental fit index (IFI); Tucker Lewis index (TLI); expected cross-validation index (ECVI); and chi-square (CMIN). RMSEA values below 0.08 indicate an adequate fit.[42] For the CFI, IFI, and TLI, values above 0.90 indicate an adequate fit. The model with the lowest ECVI value (29) represents the best fit. Acceptable CMIN/DF (degrees of freedom) should be less than 3.[42] The same magnitudes of factor loadings for EFA and CFA were considered.

The standard error of measurement (SEM) was analyzed using the following formula[33]:

$$SEM = SDx \sqrt{(1 - ICC)}$$

. . . in which SD = standard deviation. The smallest detectable change (SDC) was calculated using the following[33] formula:

$$SDC_{95} = 1.96 \times \sqrt{2} \times SEM$$

Statistical Package for the Social Sciences (SPSS) for Windows and IBM SPSS AMOS, version 22 (IBM, SPSS) were used for analyses.

Table 1 Mean and Standard Deviation (SD) of Anthropometric, Scholarly, and Cognitive Performance and the Mean Scores on the CF-PDI/Br from Each Study Phase

	Stages of the study, Mean (SD)			
	Validation phase (n = 100)	Pre-test phase (n = 40)	Reliability phase (n = 60)	ANOVA ($F_{2,197}$; P)
Age (y)	39.77 (16.23)	38.1 (17.51)	39.27 (17.45)	0.14; .88
Years of formal education[a]	3.46 (1.36)	3.42 (1.65)	3.45 (1.45)	0.008; .91
Weight (kg)	70.57 (15.69)	67.55 (13.03)	71.38 (16.76)	0.80; .44
Height (m)	1.65 (0.08)	1.64 (0.07)	1.65 (0.09)	0.93; .39
MMSE (mean score)	27.39 (1.65)	28.03 (1.23)	27.68 (1.7)	2.37; .09
Functional and psychosocial limitation mean score (0–30)	10.82 (5.89)	11.13 (6.66)	10.07 (5.45)	0.45; .64
Pain mean score (0–21)	10.08 (3.90)	9.90 (4.65)	9.78 (3.51)	0.11; .89
Frequency of comorbidities mean score (0–12)	3.35 (2.60)	3.93 (2.31)	2.95 (2.41)	1.83; .16
CF-PDI/Br total score (0–63)	24.77 (10.61)	25.38 (11.74)	22.80 (9.97)	0.89; .41

MMSE = Mini Mental State Examination; ANOVA = analysis of variance.
[a]1 = up to 4 years of formal education; 2 = between 5 and 8; 3 = 11 years; 4 = 11 years (technician level); 5 = 15 years; and 6 = more than 15 years.

Results

A total of 100 patients (89 women with a mean ± standard deviation [SD] age of 40.27 ± 16.37 years; mean weight of 69.64 ± 15.18 kg and height of 1.64 ± 0.07 m; and 11 males with a mean age of 35.73 ± 15.13 years, weight of 78.9 ± 18 km, and height of 1.75 ± 0.05 m) were recruited for this study. Subsamples from the total sample were consecutively recruited to participate in the different stages of the study. No differences in anthropometric data or cognitive profiles were observed between the different subsamples (pre-testing subsample [n = 40], test-retest subsample [n = 60], and total sample [n = 100]) (Table 1).

According to the RDC/TMD, myofascial pain was the most common diagnosis (n = 99). One patient was diagnosed with arthralgia and joint displacement with reduction. Ninety-seven had mixed diagnoses, while the majority of the patients were diagnosed as having myofascial pain and arthralgia or joint displacement with reduction.

TMD as a unique diagnostic was observed in 25% of the sample. TMD with headache occurred in 40%, TMD and neck pain was reported by 7%, and the three conditions (TMD + headache + neck pain) were identified in 28% of the patients.

Cross-Cultural Adaptation
The following changes made to the CF-PDI during the harmonization stage were necessary in order to achieve cross-cultural adaptation: *(1)* the term "severe" was replaced with "strong"; *(2)* "feel the noise" was added to question 8, instead of only "hear the noise"; *(3)* the term "roçar" (somewhat to "brush" in English) was replaced by "light touch" in question 19; and *(4)* the term "cervical spine" was added to the final version for question 16 (in the original version, only "cuello" [neck] was used).

During the pre-testing phase, after administration of the questionnaire to 10 volunteers, 30% reported trouble understanding the first question of the CF-PDI/Br: "Do you feel pain in your face?" The volunteers were not able to determine what anatomical region comprised the "face." In order to render the interpretation easier, a figure depicting a face was included in the questionnaire; in this way, the face region received an anatomical and concrete representation. This initial sample of 10 volunteers were then excluded because of the reformulation of the instrument.

After the rewording of the CF-PDI, a new sample of 40 volunteers was recruited, and no trouble understanding the revised questionnaire was reported. These volunteers also answered the other questionnaires included in this study; they were a subsample of the total sample (n = 100).

Reliability
Excellent levels of reliability for both the total score and the domain scores of the CF-PDI/Br were found (ICC > 0.90) (Table 2). No more than 5% of missing items were observed. Additionally, no ceiling or floor effects were observed. The SEM/SDC values for functional and psychosocial limitation, pain, and frequency of comorbidities domains were 1.02/2.82, 0.87/2.41, and 0.45/1.24, respectively, and the total CF-PDI/Br scores were 1.8/5.08, respectively.

Internal Consistency
Cronbach's α was above 0.77 for the total score of the three domains and between 0.3 and 0.66 for the total correlation of each item. If items were deleted, Cronbach's α ranged from 0.72 to 0.87 (Table 2).

Structural Validity
CFA failed to confirm models 1 and 2 (see statistical procedures), as the values of the indices were not acceptable (Table 3).

Table 2 Mean ICCs for Reliability (n = 60) and Internal Consistency (n = 100) and Correlations Between Domains, Questions, and Total Score of CF-PDI-Br

	ICC (95% CI)	Total item correlation	Cronbach's α if item excluded
Functional and psychosocial limitation			
Q2: Quality of life	0.91 (0.85–0.95)	0.66	0.84
Q4: Affective relationships	0.84 (0.73–0.91)	0.52	0.85
Q6: Avoid smiling, talking, or chewing	0.84 (0.73–0.90)	0.63	0.84
Q8: To hear/feel any noise when moving the jaw	0.96 (0.94–0.98)	0.30	0.87
Q11: To feel tired in the jaw when talking or eating	0.93 (0.87–0.96)	0.62	0.84
Q12: Troubles during mouth opening	0.93 (0.88–0.96)	0.60	0.84
Q13: Pain intensity when speaking...	0.93 (0.88–0.96)	0.61	0.84
Q14: Fear of moving jaw	0.94 (0.90–0.97)	0.64	0.84
Q15: Troubles eating several foods	0.95 (0.92–0.97)	0.60	0.84
Q21: Pain interference during work activity	0.95 (0.91–0.97)	0.56	0.85
Total	ICC = 0.97 (0.94–0.98)		Cronbach's α = 0.86
Pain			
Q1: Pain in the face	0.88 (0.79–0.92)	0.50	0.78
Q3: Pain intensity in the face	0.83 (0.71–0.90)	0.66	0.76
Q5: Pain when smiling	0.83 (0.71–0.90)	0.60	0.77
Q7: Jaw pain	0.89 (0.82–0.94)	0.49	0.78
Q10: Pain during chewing	0.86 (0.77–0.92)	0.56	0.77
Q19: Allodynia (pressure or light touch)	0.78 (0.63–0.87)	0.57	0.77
Q20: Pain interference sleeping	0.96 (0.93–0.98)	0.43	0.80
Total	ICC = 0.95 (0.92–0.97)		Cronbach's α = 0.80
Frequency of comorbidities			
Q9: Subluxation or jaw displacement	0.95 (0.91–0.97)	0.46	0.76
Q16: Neck pain frequency	0.96 (0.93–0.97)	0.62	0.72
Q17: Headache frequency	0.96 (0.93–0.98)	0.57	0.73
Q18: Ear pain frequency	0.95 (0.92–0.97)	0.63	0.74
Total	ICC = 0.97 (0.95–0.98)		Cronbach's α = 0.77
Total score CF-PDI-Br	ICC = 0.97 (0.95–0.98)		

ICC = intraclass correlation coefficient; CF-PDI-Br = Brazilian Portuguese Craniofacial Pain and Disability Inventory; CI = confidence interval.

Table 3 Confirmatory Factor Analysis Indices Obtained for the Four Factor Solutions of Craniofacial Pain and Disability Inventory (CF-PDI/Br) (n = 100)

	X^2(df)	CAIC	CFI	IFI	TLI	ECVI (90% CI)	RMSEA (90% CI)
Model 1	1.90	697.95	0.82	0.83	0.76	4.50 (4.04–5.04)	0.09 (0.08–0.11)
Model 2	2.24	541.20	0.69	0.69	0.69	4.70 (4.14–5.34)	0.11 (0.1–0.13)
Model 3	1.28	767.56	0.96[a]	0.96[a]	0.92[a]	3.78 (3.5–4.15)	0.05 (0.02–0.08)[a]
Model 4	3.19	1,174.01	0.86	0.88	0.41	5.27 (4.92–5.69)	0.15 (0.12–0.17)

Model 1 = 2 domains and 21 items; Model 2 = 2 domains and 20 items (exclusion of Q8); Model 3 = 3 domains and 21 items (Q13 in functional and psychosocial limitation domain); Model 4 = 3 domains and 21 items (Q13 in pain domain); X^2 = chi-square; df = degrees of freedom; CAIC = consistent Akaike information criterion; RMSEA = root mean square error of approximation; CFI = comparative fit index; TLI = Tucker Lewis index; IFI = incremental fit index; ECVI = expected cross-validation index; 90% CI = 90% confidence interval.
[a]Acceptable indices.

Hence, EFA was run in order to identify a new hypothetical factor structure of the CF-PDI/Br. This analysis revealed 21 questions grouped into three factors (cumulative variance= 51.54%, KMO = 0.86, eigenvalues = 1.4; factor loadings ranging from 0.3–0.74).

Ultimately, once the EFA generated acceptable parameters, the three-factor solution was submitted to CFA. The model that showed the best goodness-of-fit was model 3, with higher CFI, TLI, and IFI values (above 0.90) and lower chi-square, CAIC, ECVI, and RMSEA values (Table 3). The factor loading of each question is shown in Fig 1.

Construct Validity

The correlations between the CF-PDI/Br and the other constructs are shown in Table 4. From the hypothesis determined a priori, 89% (50/56) were confirmed. For the correlations between the CF-PDI and the NDI, PCS, and TSK/TMD, there were weak to moderate correlations for 94% of the comparisons (30/32). Also, for the correlations between the CF-PDI and the MFIQ and PDQ, there were moderate to strong correlations for 83% of the comparisons (20/24) (Table 4).

Table 4 Correlations Between the Total and Domain Scores of the Craniofacial Pain and Disability Inventory Brazilian Portuguese (CF-PDI/Br) and TSK/TMD-Br, PDQ, B-PCS, MFIQ, NDI, and ProFitMap-Neck Br) (N = 100)

Scales/constructs/domains	Functional and psychosocial limitation	Pain	Frequency of comorbidities	Total Score
MFIQ				
Functional capacity	0.78**	0.79**	0.35**	0.80**
Feeding	0.64**	0.60**	0.07	0.58**
Total score	0.76**	0.75**	0.24*	0.74**
PDQ				
Functional component	0.62**	0.65**	0.47**	0.69**
Psychosocial component	0.66**	0.73**	0.34**	0.72**
Total score	0.68**	0.73**	0.45**	0.75**
TSK/TMD-Br				
Activity avoidance domain	0.60**	0.55**	0.40**	0.63**
Somatic focus	0.63**	0.58**	0.36**	0.64**
Total score	0.66**	0.60**	0.41**	0.68**
B-PCS				
Helplessness	0.60**	0.65**	0.37**	0.66**
Amplification	0.58**	0.55**	0.43**	0.62**
Rumination	0.63**	0.64**	0.37**	0.67**
Total score	0.64**	0.66**	0.41**	0.69**
NDI				
Total	0.29**	0.23*	0.63**	0.40**

*$P < .05$. **$P < .01$. Pearson rank correlation.

TSK/TMD-Br = Kinesiophobia for Temporomandibular Disorders; PDQ = Pain Disability Questionnaire; B-PCS = Pain Catastrophizing Scale; MFIQ = Mandibular Functional Impairment Questionnaire; NDI = Neck Disability Index; and ProFitMap-Neck Br = Profile Fitness Mapping Neck Questionnaire.

Fig 1 *(right)* Diagram showing the factor structure of the CF-PDI/Br. Q = questions; e = errors; 1 = functional and psychosocial limitation domain; 2 = pain domain; 3 = frequency of comorbidities domain.

Discussion

The objective of this study was to perform a cross-cultural adaptation of the CF-PDI into the Brazilian Portuguese language and to check for reliability, internal consistency, and structural and construct validity in patients with painful TMD with and without other orofacial pain disorders. The main findings were acceptable levels of reliability, internal consistency, and construct and structural validity for the three-factor structure.

The total scores and test-retest reliability of the CF-PDI/Br domain were excellent.[34] These findings are consistent with those reported for the original CF-PDI,[15] for which values ranging from 0.86 to 0.90 were reported. It can be argued that the short period between the assessments in the present study could have biased the answers and did not prevent recall, which in turn led to a higher reliability level. However, the 1-week period has been used in other studies and recommended throughout the literature.[32] This short period between test and retest was adopted to minimize the mediation effect of psychosocial influences on disability, even in the absence of changes in pain intensity[43] as a parameter of clinical stability,[32] which the present study controlled for by excluding patients with variations greater than two units on the NPRS.
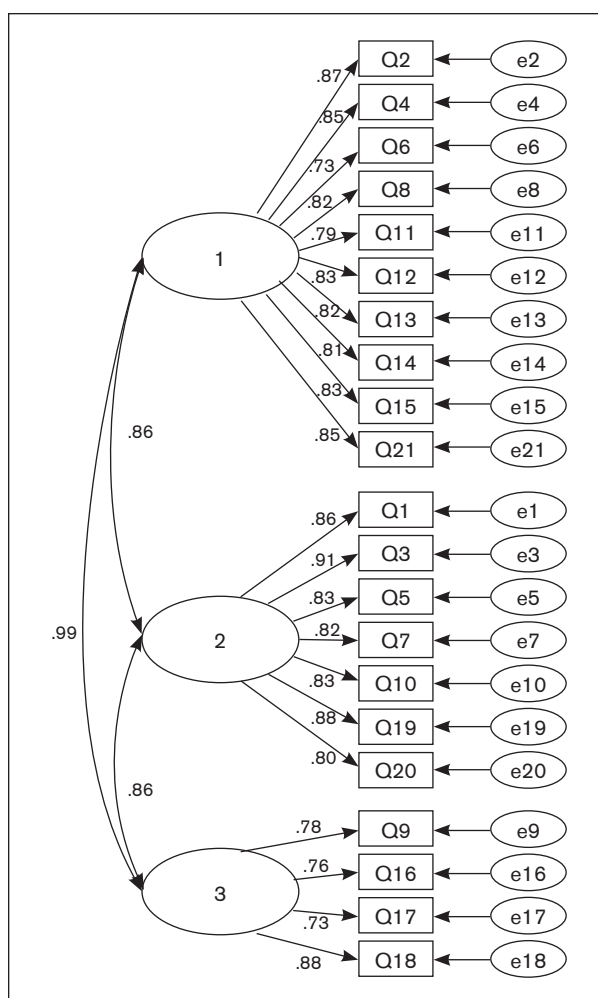
For internal consistency, the results showed a high level of scale reliability for the three domains of the CF-PDI/Br, and the present findings are comparable to those reported for the Spanish CF-PDI.[15]

The current study observed an SEM/SDC of 1.02/2.82, 0.87/2.41, and 0.45/1.24 for the factors functional and psychosocial limitation, pain, and frequency of comorbidities, respectively. The original CF-PDI showed values of SEM ranging from 1.35 to 2.48 and for SDC from 3.75 to 6.87.[15] The values in the present study were lower than those of the original version. Since the base for calculation of the SEM in both studies was the ICC values, these differences are most likely related to the higher ICC values obtained in the present study.[33] It is noteworthy that in both studies, excellent levels of reliability were observed (ICC > 0.75) even though a small decrease in ICC may lead to a relevant increase in SEM/SDC values. For example, at an ICC of 0.97, the SDC of the total score was 5.08 and the SEM was 1.84. However, at an ICC of 0.90 (as reported for the original CF-PDI), the SEM was 3.40 and the SDC 9.40.

As recommended by the COSMIN initiative, the CFA was used to assess structural validity in this study.[18] Four different factor structures or models were scrutinized. The pre-specified conceptual model with two domains (pain and disability [14 questions] and jaw functional status [7 questions])[15] was not supported by the results. In the absence of other pre-specified underlying factor structures to confirm, an EFA was run to determine a hypothetical factor structure, and subsequently CFA was used to try to confirm the structure.

A three-domain (functional and psychosocial limitation [10 questions], pain [7 questions], and frequency of comorbidities [4 questions]) factor solution was derived. Compared to the original CF-PDI, pain and disability questions of the CF-PDI/Br did not fit well in the same factor. This may suggest that pain and jaw function–related disability are distinct dimensions in orofacial pain conditions and should be assessed separately. This factor structure could help to better understand subgroups of TMD patients. For instance, a previous study[44] found that different subgroups of TMD demonstrated distinct pain intensity and jaw-related disability scores. In addition, jaw function and psychosocial questions fitted better together, which means disability and psychosocial factors have better correlations between each other than with pain or symptoms related to the other orofacial pain conditions. In line with the present results, a previous report showed better correlations between psychosocial factors and disability than between psychosocial factors and pain intensity in chronic low back pain.[45]

There are several studies reporting diverse findings in regard to the factor structure of instruments being cross-culturally adapted.[46–48] Possible explanations for this could be related to the statistical analysis performed, as well as to the sample size, sample characteristics,[49] and changes applied to the CF-PDI/Br. EFA—rather than CFA—was employed in the study of the original version of the CF-PDI to check for its factor structure.[15] In contrast to CFA, EFA shows how well the items load on the different factors/domains. Interestingly, for the original CF-PDI, at least 8 questions (Q7, Q9–Q11, Q13, Q17, Q18, Q21) obtained suitable factor loadings for designation to any domain of the instrument (factor loading > 0.3). As a consequence, it can be speculated that structure of the CF-PDI was not completely determined, and further research is suggested to confirm the structure supported by the present results.

In relation to the sample characteristics, the current study recruited patients with TMD with and without other orofacial pains, whereas the study of the original CF-PDI also recruited patients with the lone diagnosis of headache without TMD (15% of that study's sample). Furthermore, 35% of the present sample complained about neck pain, and this additional information was not found in the study of the original CF-PDI. Future studies should be carried out to determine whether the factor structure of the CF-PDI differs with distinct orofacial pain subgroups.

Finally, in the CF-PDI/Br questionnaire during the pre-testing phase, a face picture was added to help volunteers understand the exact delimitation of the anatomical region questioned. The inclusion of the face picture may have worked as a guide, informing volunteers on how to answer the remaining items of the questionnaire. Also, it cannot be ruled out that a group of random participants probably would not have answered the questions related to "face," as, considering that this question had to be revised in the present study, they would not be aware of the broad extension of the word "face." These aspects may have influenced the results obtained, particularly the final structure of the questionnaire.

In regard to the construct validity, in this study, the CF-PDI/Br domains and total scores were compared to those for mandibular functional limitation (MFIQ), pain-related disability (PDQ), kinesiophobia (TSK/TMD), pain catastrophizing, and neck pain–related disability (NDI). A similar method was applied to check for construct validity of the original CF-PDI.[15] While the two main underlying constructs described for the CF-PDI were pain and functional limitation/disability, the correlations between the CF/PDI and the MFIQ and PDQ were checked in order to assess the construct validity. The authors expected moderate to strong correlations between these instruments.

The findings gave support to the hypothesis raised a priori, except for the correlations between the feeding domain from the MFIQ and the frequency of comorbidities from the CF-PDI/Br, which showed a weak correlation. The possible explanation for this poor correlation level may be related to the specificity of the underlying constructs of both domains. While the feeding domain from the MFIQ is strictly directed toward jaw function, the frequency of comorbidities domain shifts focus toward other orofacial pains. The original CF-PDI was not correlated with the MFIQ scores, but with a similar scale that assesses the same construct (the jaw functional limitation scale).

Correlations between CF-PDI/Br scores and kinesiophobia/pain catastrophizing were also scrutinized in the current study. Weak to moderate correlations were expected in agreement with the findings described for the original CF-PDI[15]; thus, hypotheses were confirmed. Also, consistent with the present findings, a previous study reported a moderate correlation between the CF-PDI and generic TSK.[7] The fear-avoidance model recognizes the role of the persistence of pain experience in the presence of catastrophizing, which results in fear avoidance and in turn may lead to disability, depression, and disuse.[50] Also, a previous study in TMD patients reported the role of catastrophizing and depression in the progression to chronic TMD and pain-related disability.[51]

Considering that the CF-PDI takes into consideration other pain comorbidities recognized to be associated with TMD (headaches and neck pain), the correlation with neck pain–related disability was also assessed. Headache-related disability (as assessed by the Headache Impact Test [HIT6]) could not be assessed because there was no validated Brazilian Portuguese version available during the study. Weak to moderate correlations between neck pain–related disability and CF-PDI scores were assumed a priori, and weak correlations with functional and psychosocial limitation and pain domains of CF-PDI were observed. These results are in partial agreement with the findings reported in the original CF-PDI,[15] which describes only moderate-strong correlations between CF-PDI and NDI scores. Not surprisingly, better correlations were observed between neck pain–related disability and the frequency of comorbidities domain, since the latter includes a topic on neck pain. Nevertheless, NDI scores correlated moderately/strongly with all the domains of the original CF-PDI, and this may be attributed to the prevalence of neck pain in both studies. In the presence of neck pain, orofacial pain complaints may not be as specific. For questions such as "pain in the face," it is not possible to determine the exact impact of confounding by other pain conditions such as neck pain,

which in turn may inflate the magnitude of correlations obtained, considering that patients may not be able to accurately determine the source of the painful sensation. This was previously endorsed by the convergence of nociceptive afferents in the trigeminocervical complex resulting in referred pain to the orofacial region when pain originated from the neck region and vice versa.[52] Since the original CF-PDI study does not report the prevalence of complaints of neck pain, no further comparisons could be made, and future studies should investigate the role of comorbidities on CF-PDI scores.

Overall, in regard to the construct validity, the hypotheses were confirmed in 89% of the correlations investigated in the present study. This finding achieved the 75% rate recommended previously.[32]

Finally, there is another instrument available in the literature that assesses pain and disability related to orofacial pain.[13,14] The Manchester orofacial pain and disability scale assesses pain and disability considering the overlap of symptoms in the coexistence of orofacial pain conditions such as headache, neck pain, and earache. Furthermore, different from the Manchester scale,[13,14] the CF-PDI was not designed only to assess frequency of symptoms, but also includes questions regarding the magnitude of interference of such symptoms. The CF-PDI also includes questions related to ear sounds, disability level related to jaw displacement, and pain intensity in the face. Ultimately, there are some psychometric limitations of the Brazilian Portuguese version of that scale. First, it was tested in a sample of generic orofacial pain patients; ie, no information was provided about the target population in which the instrument was tested, and as a consequence it is not possible to determine for which population of orofacial pain patients the questionnaire is suitable, and the American Academy of Orofacial Pain has described at least seven major operational diagnostic categories for orofacial pain.[53] Second, a sample of only 50 patients was recruited, which is below what the literature recommends.[32] Third, structural validity of the questionnaire was not described, and therefore it is not possible to determine whether the cross-cultural adaptation process influenced the structure of the scale.

This study has several limitations. It can be argued that the sample size of this study was too small to run a CFA; however, this is a matter of debate in the field, as a previous study[32] has recommended 4 to 10 subjects per variable (or n = 100) as the minimum acceptable sample size to conduct such an analysis. Additionally, despite use of the RDC/TMD Axis I in this study, the RDC/TMD Axis II (psychosocial dimension) was not employed as a comparator instrument to check for construct validity. However, in studies of cross-cultural validation, researchers are

encouraged to follow a similar method as described in the original study in which the instrument was proposed.[15] Axis II of the RDC/TMD was not used as a comparator instrument since the original CF-PDI[15] has not reported its use. Nonetheless, further studies are needed for comparing the CF-PDI to Axis II of the Diagnostic Criteria for TMD and also for cross-culturally validating self-report instruments such as Axis II of the RDC and DC/TMD according to international recommendations (eg, COSMIN[18]).

Conclusions

The results of this study have shown that the CF-PDI/Br achieved acceptable indices for cross-cultural validity, reliability, internal consistency, and structural validity. The CF-PDI/Br may be considered a valid and reliable instrument to assess orofacial pain and disability in patients with painful TMD. The results suggest that it can be used in clinical settings and for research purposes.

Acknowledgments

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