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Validation of "Oral Mucositis Quality of Life (OMQoL)" instrument to Brazilian Portuguese

Validação do instrumento "Oral Mucositis Quality of Life (OMQoL)" para o Português Brasileiro

Validación del instrument "Oral Mucositis Quality of Life (OMQoL)" al Portugués Brasileño

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Abstract
To cross-culturally adapt the Oral Mucositis Quality of Life (OMQoL) instrument to Brazilian Portuguese and assess its psychometric properties. The cross-cultural adaptation was performed in six steps. In one of them, the instrument was applied to 40 participants who indicated whether items were comprehensible, which helped elaborate the final version. In the validation phase, 102 participants were interviewed. The sample included patients undergoing oncologic treatment. The softwares R version 4.0.5 and the R Studio 1.4.1717 were used, and the initial database used Dplyr, Tidyr, Gplot2. To assess the psychometric properties, confirmatory factor analysis was performed. The dimensionality of the instrument was investigated using a network analysis approach. The wording of items in a couple of questions were revised after participants indicated a lack of clarity. The relationship between the degree of oral mucositis and the different hospital groups showed statistically significant differences ($p<0.001$). Confirmatory factor analysis resulted in good index scores (RMSEA=0.08; CFI=0.91; TFI=0.89; CD=0.99), which showed that the instrument had good properties. The OMQoL was translated, adapted and its Brazilian version adequately reflected the original instrument. The OMQoL is valid for the Brazilian population, as well as its short form proposed by this study.
Keywords: Stomatitis; Quality of Life; Surveys and questionnaires; Validation study; Neoplasms.

Resumo
Realizar a adaptação transcultural do instrument Oral Mucositis Quality of Life (OMQoL) para o português brasileiro e avaliar suas propriedades psicométricas. A adaptação transcultural foi realizada em seis etapas. Em uma delas o instrumento foi aplicado a 40 pacientes. Eles indicaram se os itens eram compreensíveis, o que ajudou na elaboração da versão final. Na fase de validação, 102 participantes foram entrevistados. A amostra incluiu pacientes em tratamento oncológico. Foram utilizados os softwares R versão 4.0.5 e R Studio 1.4.1717, e o banco de dados inicial utilizou Dplyr, Tidyr e Gplot2. Para avaliar as propriedades psicométricas, foi realizada uma análise fatorial confirmatória. A dimensionalidade do instrumento foi investigada utilizando uma abordagem de análise de rede. A

redação de alguns itens foi revisada após os participantes indicarem falta de clareza. A relação entre o grau de mucosite oral e os diferentes grupos hospitalares mostrou diferenças estatisticamente significativas (p <0,001). A análise fatorial confirmatória resultou em bons índices (RMSEA = 0,08; CFI = 0,91; TFI = 0,89; CD = 0,99), o que demonstrou que o instrumento apresentava boas propriedades. O OMQoL foi traduzido, adaptado e sua versão brasileira refletiu adequadamente o instrumento original. O OMQoL é válido para a população brasileira, assim como sua forma reduzida proposta por este estudo.
Palavras-chave: Estomatite; Qualidade de vida; Inquéritos e questionários; Estudos de validação; Neoplasias.

Resumen
Realizar la adaptación transcultural del instrumento Oral Mucositis Quality of Life (OMQoL) al portugués brasileño y evaluar sus propiedades psicométricas. La adaptación transcultural se llevó a cabo en seis pasos. Em uno de ellos, el instrumento se aplico a 40 participantes que indicaron si los ítems eran comprensibles, lo que ayudó a elaborar la versión final. En la fase de validación, se entrevistó a 102 participantes. La muestra incluyó pacientes en tratamiento oncológico. Se utilizaron los programas R versión 4.0.5 y R Studio 1.4.1717, y la base de datos inicial utilizó Dplyr, Tidyr y Gplot2. Para evaluar las propiedades psicométricas, se realizó un análisis factorial confirmatorio. La dimensionalidad del instrumento se investigó utilizando un enfoque de análisis de redes. La redacción de algunos ítems em um par de perguntas se revisó después de que los participantes indicaran una falta de claridad. La relación entre el grado de mucositis oral y los diferentes grupos hospitalarios mostró diferencias estadísticamente significativas (p <0.001). El análisis factorial confirmatório arrojó buenos índices (RMSEA=0,08; CFI=0,91; TFI=0,89; CD=0,99), lo que demostró que el instrumento tenía buenas propiedades. El OMQoL fue traducido, adaptado y su versión brasileña reflejó adecuadamente el instrumento original. El OMQoL es válido para la población brasileña, así como su forma abreviada propuesta en este estudio.
Palabras clave: Estomatitis; Calidad de vida; Encuestas y cuestionarios; Estudios de validacíon; Neoplasias.

1. Introduction

The evolution of studies and discoveries in oncology has promoted improvements in cancer treatment, leading to an increase in the life expectancy of cancer patients. This led us to reflect more on how the disease and its treatment affect life and, more specifically, the quality of life (QoL) of these patients. The term QoL has been increasingly applied in the health domain to demonstrate and analyze the impact of various health conditions on human life (Bezinelli et al., 2016; Cecilio et al., 2020). While not being a well-defined concept, it is subjective and multidimensional (Seidl & Zannon, 2004), differs from individual to individual, and may be related to factors such as age, social class, lifestyle, preferences, and cultural and political aspects. QoL has been reported to refer to something broader than health, and it's one of the most important aspects, that are impacted by the side effects of the treatment (Locker, 1997; Calderon et al., 2022).

Oral mucositis (OM), which has been referred to as one of the three most important side effects of cancer treatment, affects patient health by causing pain; therefore, the approach adopted for its management is quite crucial (Villa, Vollemans, de Moraes & Sonis 2021). It is defined as mild or aggressive oral cavity inflammation (Cheng, 2007). OM is highly prevalent in patients undergoing head and neck radiotherapy and hematopoietic cell transplantation treatment. Severe OM can cause pain, dysgeusia, dysphagia, and other changes that hinder routine activities. There is a correlation between the trend of OM severity and the QoL scores in patients who have undergone hematopoietic cell transplantation (Oba et al., 2021; Guberti et al., 2022).

Therefore, it is essential to try to better understand the effects and sensations due to OM, prevent the disease, treat the effects, and minimize the late consequences. The changes associated with the diseases have been the target of analysis using quality-of-life instruments that can help individuals identify and report their problems (Aglarci et al., 2016; Silva et al., 2018; Faria et al., 2022).

The most significant difficulty in assessing the QoL in patients with OM is the lack of instruments that can encompass the relevant questions related to patients' symptoms (Cheng et al., 2007). Hence, the Oral Mucositis Quality of Life (OMQoL), a specific quality-of-life measure for OM, was developed (Cheng et al., 2007). Because it was created in another language (English) and for other populations (with different cultures and lifestyles), the OMQoL could not be used in Brazil before

being subjected to cross-cultural adaptation and strict validation. Thus, the adaptation and validation of the OMQoL for use in Brazil were proposed.

2. Methodology

The study was approved by the research ethics committees of the Faculdade de Odontologia da Universidade de São Paulo and Hospital Israelita Albert Einstein (HIAE) (São Paulo) (approval nos.: 1.664.785 and 1.851.775, respectively).

To validate the OMQoL, an addendum to the project was forwarded to the same research ethics committees (approvals 2,745,616 and 2,835,354), and authorization was obtained from Hospital Napoleão Laureano (João Pessoa, PB). The study was conducted according to the tenets of the Declaration of Helsinki. Terms of informed consent were explained to the participants before the start of the interview and clinical examination. After obtaining participant consent, data collection was performed using the OMQoL, European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC QLQ-C30), and a sociodemographic questionnaire.

Male and female participants older than 18 years of age who were able to understand the study proposal, undergoing any oncological treatment, and at risk of developing OM were invited to participate in the study. Participants younger than 18 years of age, who did not have the necessary cognitive ability to answer the questions, or who were very debilitated were not invited to participate in the study. This discernment of the possibility of participating in the study was performed by an entire team of professionals who accompanied the participants and adopted to avoid causing discomfort to the participants and reduce the margin of error in the answers.

For cross-cultural adaptation, a method whereby six stages were proposed was employed from February to November 2017 (Beaton, Bombardier, Guillemin & Ferraz, 2000). The steps consisted of translations and back-translations performed by professionals whose native language was English but who were fluent in Portuguese and vice-versa, resulting in different versions of the instrument. These versions were synthesized into a single one by a committee of experts and administered to the participants to determine the difficulties experienced in reading/answering the questions. The participants were encouraged to offer suggestions for improvement.

The validation stage was performed by applying the instruments to patients from different hospitals and at different times; the entire period extended from February 2019 to May 2021. The participants were separated based on health services and forms of treatment. They were subdivided into four large groups: Einstein QT (patients on chemotherapy, n = 32), Einstein RT (patients on radiotherapy, n = 29), Einstein TMO (bone marrow transplant patients, n = 18), and Laureano (patients at Hospital Napoleão Laureano on chemotherapy or radiotherapy of the head and neck, n = 23).

The EORTC QLQ-C30 was used to later compare with the OMQoL as well as in the study of the English version (Cheng et al., 2010). It has already been validated for use in Brazil, demonstrating adequate psychometric properties (Paiva et al., 2014), and has 30 questions divided into five functional scales and a scale of general health status and QoL. The OMQoL is composed of 31 questions divided into four subscales. The scores are computed from response options ranging from 1 to 4. In addition, the participants were also asked personal questions for sample characterization, and a clinical examination was performed to assess the degree of OM according to the grading of the World Health Organization (WHO, 1979).

Data analysis was performed using a database developed in EXCEL, which contained the interview responses from the three instruments used (sociodemographic questionnaire, OMQoL, and EORTC-QLQ-C30). R version 4.0.5 and R Studio 1.4.1717 software were used for data analysis, and the packages used were Dplyr, Tidyr, Gplot2, Likert, Lavaan, mirt, EGAnet, psychTools, and qgraph. Descriptive statistics were used to characterize the sample, and the participants were divided into four large groups according to the hospital and type of treatment.

A confirmatory factor analysis was performed by structural equation modeling using the Lavaan package for the initial analysis. Two analyses were performed, one considering the four domains of the OMQoL and another without. The following indexes were used to test the fit of the proposed model: $\chi 2$, comparative fit index (CFI), root mean square error of approximation (RMSEA), Tucker-Lewis index (TLI), and coefficient of determination (CD). For a satisfactory model fit to the data, the criteria used had these index values as references: CFI > 0.90, RMSEA close to or less than 0.08, TLI > 0.90, and CD > 0.90 (Pilati & Abad, 2005).

Using two analysis parameters, the item response theory (IRT) and the generalized partial credit model, the possibility of item reduction in the instruments was verified (Li & Baser, 2012). The analysis approach network was used to investigate the dimensionality of the instrument, in which the edges represented the partial correlations between two items, after controlling for the other items of the network. This generated network represented all the statistical relationships between the instrument's items. The structural consistency of the identified communities was assessed using Bootstrap Exploratory Graph Analysis (Baek et al., 2021).

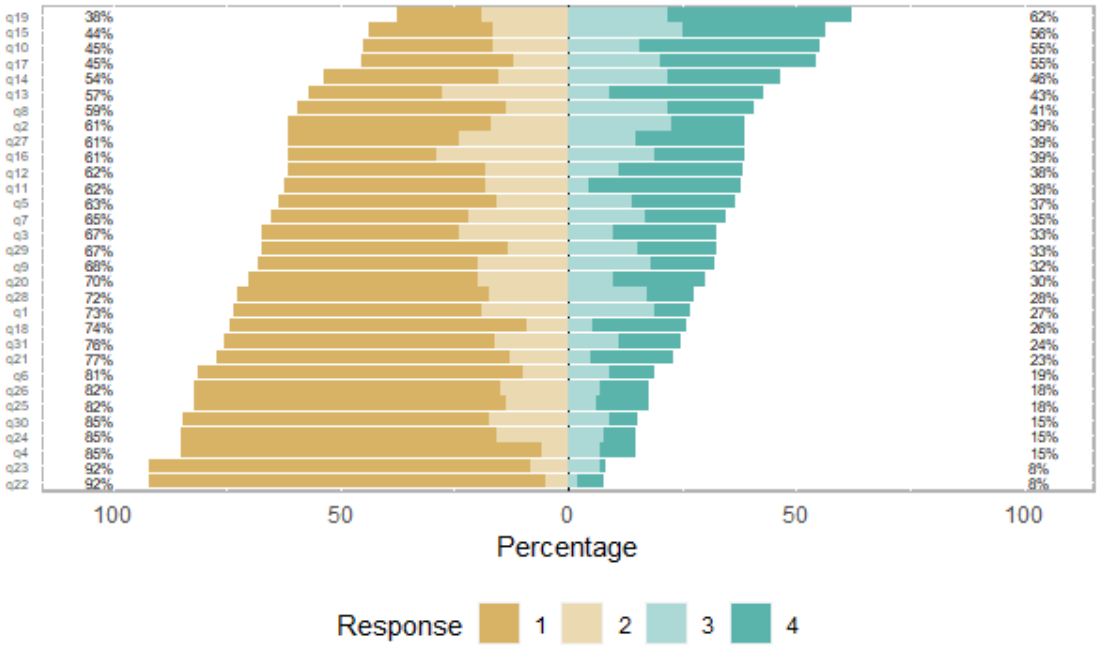
3. Results

Forty participants (20 men and 20 women) were interviewed in the cross-cultural adaptation phase. The mean participant age was 54.8 ± 13.2 years (range: 27 to 79 years). Most participants (77.5%) were married, and 72.5% had completed a college education. OM was detected in 60% of the patients, and 25% had grade 2 OM. During the application of the instrument, it was noticed that most participants (60%) had no difficulty in answering the questions, with some of the responses being "I have no doubts," "questions are easy to answer," "I have no suggestions to make," "the questions are clear," and "I had no difficulty answering the questions." Most of the comments received were for items 18 ("I avoid eating soft/solid foods") and 29 ("I have difficulty swallowing soft/solid foods"), which necessitated the following revisions "I avoid eating soft solid foods (e.g., noodles)" and "I have difficulty swallowing soft solid foods (e.g., noodles)," respectively. The item that reflected the least impact on QoL was item 22, "I need to use other means (e.g., paper/pencil, body language) to communicate with other people." The highest number of questions with high scores were from the diet subscale.

In the validation phase, the participants were divided into 4 main groups according to healthcare services and treatment methods: Einstein QT (patients undergoing chemotherapy, n=32), Einstein RT (patients undergoing radiotherapy, n =29), Einstein TMO (patients undergoing Hematopoietic Cell Transplantation, n= 18), and Laureano (patients at the Napoleão Laureano Hospital undergoing chemotherapy pr radiotherapy for head an neck, n=23).

No statistically significant differences were identified among the groups in terms of age and sex. Furthermore, no differences were found between age and mucositis grade distribution and between mucositis grade and sex in the groups. The chi-square test revealed intergroup differences in the degree of OM ($p < 0.001$). The Einstein QT and Laureano groups had participants with more severe degrees of OM. Figure 1 shows all the participants' answers to the OMQoL items. The items that had the least impact on QoL were Q4 (*I have oozing/bleeding on my lips, or inside my mouth*), Q22 *(I need to use other means (e.g. paper/pen, body language) to communicate with others*), and Q23 (*I feel embarrassed at mealtimes with my family/friends*) (85%, 92%, and 92%, respectively) and those with the greatest impact were Q19 (*I worry my inadequate nutritional intake*), Q15 (*I use longer time to drink/eat*), and Q10 (*I am unable to enjoy food*) (62%, 56%, and 55%, respectively).

Figure 1 - Distribution to participants' responses to OMQoL (1: not at all; 2: a little bit; 3: quite a bit; 4: very much).



Source: Own elaboration.

It's important to observe the items that had the most impact on quality of life (q19, q15, q10), all of them from the diet domain.

Chart 1 presents the 31 items of the OMQoL divided into the four domains of symptoms, diet, social function, and swallowing.

Chart 1 - Items of OMQoL instrument in Brazilian Portuguese and English.

Oral Mucositis Quality of Life.
Sintomas (*Symptoms*)
1 Tenho inchaço dentro da minha boca *I have swelling inside my mouth*
2 Tenho feridas / úlceras na boca *I have mouth ulcer*
3 Dores na boca me deixam angustiado *Mouth pain makes me distressed*
4 Tenho secreção / sangramento em meus lábios, ou dentro da minha boca *I have oozing/bleeding on my lips, or iside my mouth*
5 Sinto desconforto quando escovo os dentes / enxaguo minha boca *I feel discomfort while tooth brushing/mouth rinsing*
6 Dores na boca me fazem ter dificuldade para dormir *Mouth pain makes me have trouble sleep*
7 Tenho dores na boca *I have mouth pain*
8 Eu tenho sensação de queimação / ardência dentro da boca *I have burning sensation inside my mouth*
9 Tenho dificuldades para abrir a boca *I have difficulty in opening my mouth*
Dieta *(Diet)*

10 Não consigo apreciar a comida *I am unable to enjoy food*
11 Saio menos para jantar devido ao desconforto na boca *I reduce outside social dining due to mucosal discomfort*
12 Minha saliva torna-se espessa/pegajosa e eu preciso cuspir com frequência *My saliva becomes thick/sticky and I need to spit out frequently*
13 Tenho mudanças de paladar *I have taste changes*
14 A dificuldade para comer me deixa angustiado (a) *Eating difficulty makes me distressed*
15 Demoro mais tempo para beber / comer *I use longer time to drink/eat*
16 Tenho perda de peso *I have weight loss*
17 Eu modifico minha dieta (por ex. tipo de comida, textura e tamanho) *I modify my diet (e.g. food type, texture and size)*
18 Evito a ingestão de alimentos macios, como o macarrão *I reduce my soft/solid food intake*
19 Eu me preocupo com minha alimentação inadequada *I worry my inadequate nutritional intake*
Função social (Social function)
20 A qualidade da minha voz piorou *I spaeak with lower quality/voice*
21 Tenho dificuldades para falar *I have difficulty in talking*
22 Preciso usar outros meios (ex. papel/caneta, linguagem corporal) para me comunicar com outras pessoas *I need to use other means (e.g. paper/pen, body language) to communicate with others*
23 Sinto-me envergonhado (a) durante as refeições com a minha família/amigos *I feel embarrassed at mealtimes with my family/friends*
24 A dificuldade em falar me deixa angustiado (a) *Speaking difficulty makes me distressed*
25 Eu não quero conversar com outras pessoas (incluindo falar ao telefone) devido ao desconforto na boca *I do not want to talk to others (including talking on phone) due to mouth discomfort*
26 Minhas expressões (incluindo sorrir para os outros) e comunicação foram afetadas *I have my expression (including smiling to others) and communication affected*
Deglutição (Swallowing)
27 Tenho desconforto na garganta *I have throat discomfort*
28 Tenho dificuldade para engolir líquidos (por exemplo, água, suco, sopa) *I have difficulty in swallowing liquids (e.g. water, juice, soup)*
29 Tenho dificuldade para engolir alimentos macios, como o macarrão *I have difficulty in swallowing soft/solid food*
30 Engasgo facilmente ao engolir *I feel easily choked while swallowing*
31 Tenho dificuldade para engolir a saliva *I have difficulty in swalloing saliva*

Source: Own elaboration.

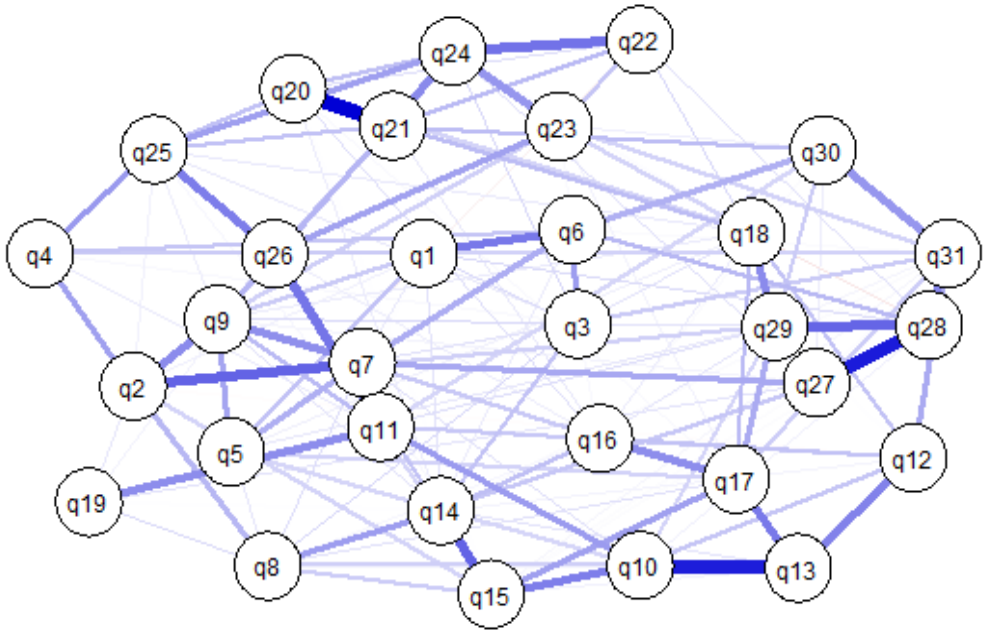
This chart shows the OMQoL in both Portuguese and English, and is important to have an overview of the instrument.

An IRT analysis was performed to verify the amount of information generated by the items; question 11 (*I reduce outside social dining due to mucosal discomfort*) resulted in a very low degree of information and was removed from the analyses.

A confirmatory factor analysis was performed to check the consistency of the model with the exclusion of question 11. The indicators of the factor analysis for the OMQoL model with 30 questions, divided into four domains had results close to the recommended values (RMSEA = 0.09; CIF = 0.80; TFI = 0.78; CD = 0.99).

Figure 2 presents the network relationships of all variables, with which the dimensionality of the instrument could be assessed. The nodes visually present the items in the network, and edges represent partial correlations. This network represents all the statistical relationships between the items of the instrument.

Figure 2 - Network analysis of all instrument items.

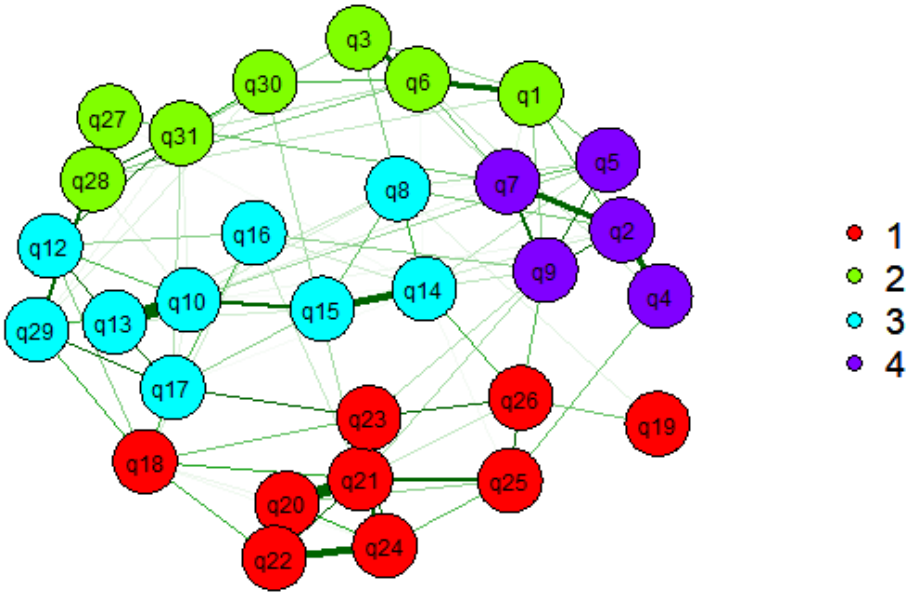


Source: Own elaboration.

It's important to note the largest edges like q20 and q21, q10 and q13, q27 and q28, showing strong relationships between these questions.

Network analysis was also performed to verify a new proposed use of the instrument (Figure 3), with an aim to obtain better responses from the indicators. Figure 4 shows the stability of the items in these new dimensions.

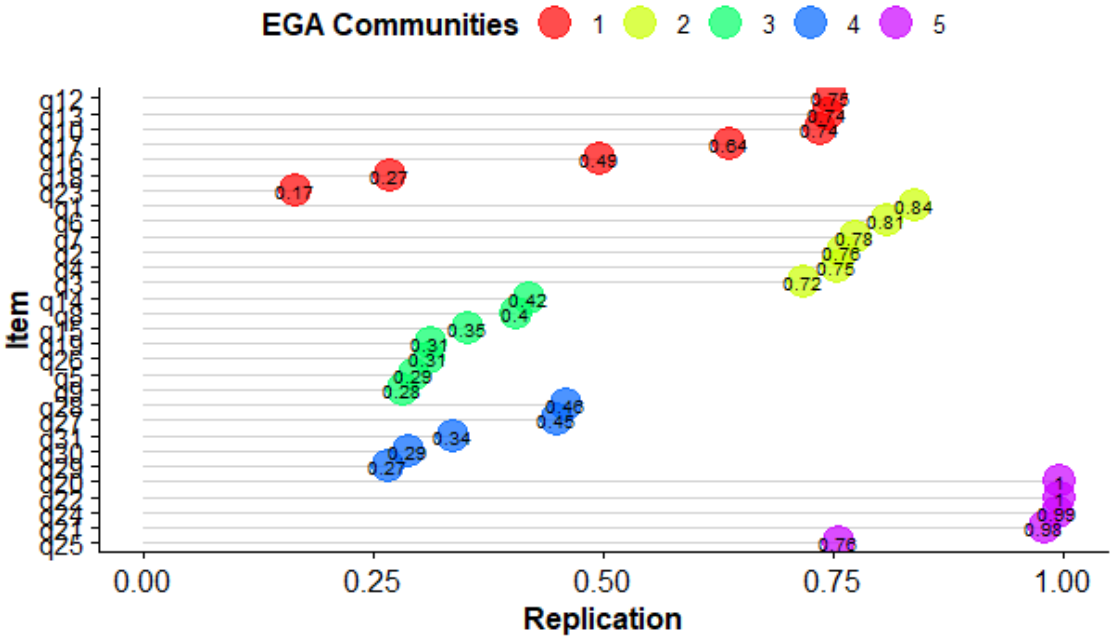
Figure 3 – Study of the new dimensions of the instrument. (1: social function; 2: swallowing; 3: diet; 4: symptoms).



Source: Own elaboration.

The organization of the dimensions was a little bit different from the original instrument.

Figure 4 - Stability of the items after reduction. (1: diet; 2: symptoms; 3: excluded questions; 4: swallowing; 5: social function).



Source: Own elaboration.

The questions with less stability like q16, q18, q23, q29, q25 were all excluded from the final short form.

Based on these analyses and the decision of a specialist committee, a new instrument model with fewer questions but still divided into four domains was proposed. Chart 2 shows the excluded questions, and Chart 3 presents the final short form of the OMQoL for the Brazilian population.

Chart 2 - Excluded items from the OMQoL original instrument.

Sintomas (*Symptoms*)
5 *I feel discomfort while tooth brushing/mouth rinsing*
6 *Mouth pain makes me have trouble sleep*
8 *I have burning sensation inside my mouth*
9 *I have difficulty in opening my mouth*
Dieta *(Diet)*
11 *I reduce outside social dining due to mucosal discomfort*
14 *Eating difficulty makes me distressed*
15 *I use longer time to drink/eat*
16 *I have weight loss*
18 *I reduce my soft/solid food intake*
19 *I worry my inadequate nutritional intake*
Função social (Social function)
23 *I feel embarrassed at mealtimes with my family/friends*
25 *I do not want to talk to others (including talking on phone) due to mouth discomfort*
26 *I have my expression (including smiling to others) and communication affected*
Deglutição (Swallowing)
29 *I have difficulty in swallowing soft/solid food*

Source: Own elaboration.

Overview of the questions excluded, it should be observed that all domains had at least one item excluded.

Chart 3 - Final short form of OMQoL Brazilian version.

	1 - De modo algum *Not at all*	**2 – Um pouco** *A little bit*	**3 - Razoável** *Quite a bit*	**4 - Muito** *Very much*
Sintomas				
1 Tenho inchaço dentro da minha boca				
2 Tenho feridas / úlceras na boca				
3 Dores na boca me deixam angustiado				
4 Tenho secreção / sangramento em meus lábios, ou dentro da minha boca				
5 Tenho dores na boca				
Dieta				
6 Não consigo apreciar a comida				
7 Minha saliva torna-se espessa/pegajosa e eu preciso cuspir com frequência				
8 Tenho mudanças de paladar				
9 Eu modifico minha dieta (por ex. tipo de comida, textura e tamanho)				
Função social				

10 A qualidade da minha voz piorou				
11 Tenho dificuldades para falar				
12 Preciso usar outros meios (ex. papel/caneta, linguagem corporal) para me comunicar com outras pessoas				
13 A dificuldade em falar me deixa angustiado (a)				
Deglutição				
14 Tenho desconforto na garganta				
15 Tenho dificuldade para engolir líquidos (por exemplo, água, suco, sopa)				
16 Engasgo facilmente ao engolir				
17 Tenho dificuldade para engolir a saliva				

Source: Own elaboration.

The short form presents a more direct instrument, all the domains have a similar number of questions and these are the most relevant items based on our analyses.

A new confirmatory factor analysis was performed with this model (with 17 questions divided into four domains); it resulted in adequate values of the indicators (x^2 = 118.7; RMSEA = 0.08; CFI = 0.91; TFI = 0.89; CD = 0.99).

4. Discussion

Most participants (65%) had no doubts in the cross-cultural adaptation phase, and any doubts that the remaining patients had were limited mainly to two questions (18 and 29). This finding shows a good understanding of the instrument. The cross-cultural adaptation followed the guidelines of a specific protocol (Beaton et al., 2000), which provided greater standardization and allowed the adaptation of the same scale for other countries through a single methodology. New studies are using the same protocol (Cruz et al., 2022; Perazzo et al., 2022).

In the evaluation phase of the psychometric properties, significant differences in the degree of OM were observed among the four large groups. Most patients had grade 2 OM; this finding was in agreement with that of a previous study (Cheng, 2007). Another population investigated by the same group of researchers had a higher percentage of patients with grade 3 OM (32%) (Cheng et al., 2010). A study performed in patients who underwent hematopoietic cell transplantation at HIAE showed a higher frequency of mild mucositis (grades 1 and 2, 64.9%), with only 15.6% of the patients with mucositis of grades 3 and 4 (Bezinelli et al., 2021). The questions with the highest impact on the participants' QoL were all from the diet domain (Q19, Q15, and Q10). The lowest impact was observed for items Q4, Q23, and Q22, the first being related to the symptom domain and the latter two to a social function, which was also observed in the instrument development study in which Q22 presented a high ceiling effect (>70% of the participants choosing the lowest possible score) (Cheng et al., 2007).

In a study using the OMQoL with free translation in Brazil, an increase in the total score was observed as the degree of OM increased. In this study, 82 patients were analyzed, and the highest OMQoL score achieved was 113 points in a patient with grade 4 OM. The highest score that could be achieved for the OMQoL is 124. The mean scores for patients with OM of grades 1, 2, and 3 were 52.42, 63.15, and 94.58, respectively (Pereira et al., 2018). During our analysis, it was observed that the total OMQoL score is not the ideal way to assess the instrument and that the scores of the domains should be considered separately.

In this study, we used IRT, a method focused on highlighting the extent to which individual items contribute to the scores of the scales, i.e., how relevant and informative that item is (Eichenbaum, Marcus & French, 2019). We noticed that question 11 (I go out less for dinner due to discomfort in the mouth) did not have significance, mainly because many patients were hospitalized and part of the survey was conducted during the pandemic. Therefore, many patients had stopped going out,

were quarantined for treatment, or had stopped going out because of the effects of chemotherapy. Thus, we excluded question 11 from the analysis since it reduced the instrument's performance.

Confirmatory factor analysis is a method used to explore instrument scales, through which it is possible to analyze correlations between items. However, before its use, it is essential that authors define the type of criterion to assess consistency (Ondé & Alvarado, 2020). In this study, we used RMSEA, the CFI, the TLI, the CD, and the chi-square test to evaluate the fit of a model derived from a sample of the actual population. Unlike the chi-square, RMSEA shows sensitivity to model complexity rather than sample size (Hoofs et al., 2018). Confirmatory factor analysis was used elsewhere to achieve the psychometric properties of an instrument that evaluates positive oral health (Perazzo et al., 2022), and to evaluate construct validation of a quality of life instrument, in a specific population (pacients rehabilited from head and neck cancer) (Ferreira et al., 2022).

We present a short version of the instrument, which was developed to obtain greater consistency among the domains and, consequently, an instrument more faithful to its purpose. We recommend that the instrument be applied in the Brazilian population by using the questions presented in Chart 2 since they afford a better performance. Instruments are created with specific objectives, with each having its peculiarities. Hence, it is difficult to reach a consensus on the ideal number of items required. Nevertheless, it is known that the application of long instruments can decrease the response quality and increase the number of items lost. On the other hand, the more the questions, the more complete is the study of the concept (Skevington, Rowland, Panagioti, Bower & Krägeloh, 2021). Changing the instrument is a common part of the validation process and can occur due to many reasons. These changes are always aiming to improve the instrument to fit the specific population, and sometimes authors have to do minimal changes in the subscales or items (Pimentel et al., 2022).

QoL instruments can be generic or specific and both could have similar dimensions, including health, physical and social aspects, but assess them from different perspectives. The right way to choose your instrument is the one that best fits the aims of the research. Researchers showed that using a specific instrument to access oral health related quality of life was better to find out discomfort and functional issues related to oral cavity (Gondivkar et al., 2019).

The limitations of this study are characteristic of research in cancer patients, which is the low prevalence of the disease. In addition, daily follow-up with the Odontology team at HIAE helped control OM, reducing the number of patients with this condition. To expand the sample, the following two hospitals from different cities and administrations were included: HIAE in São Paulo (predominantly for people from higher socioeconomic classes), and Hospital Napoleão Laureano in João Pessoa (which is a public service that caters through the Unified Health System (SUS). These two hospitals were included to reflect the reality of the Brazilian population since it is a country of much diversity. The participants responded to the questionnaires through an interview, which facilitated the response process for those with difficulty in reading and understanding. The interview approach was compatible with a higher total return rate because it decreased the possibility of missing data and did not depend on literacy (Leelataweewud et al., 2021).

Understanding QoL is important for several aspects, such as helping to relieve symptoms, choose better treatment, and modify behaviors. The information revealed by the instruments can help to communicate to future patients about possible problems that could be overlooked without the assessment of QoL. A systematic review showed that QoL research is truly international, and uses many types of measures, different study designs, target and groups; many of the included studies were not intended to increase QoL, and therefore it appears as a secondary outcome (Haraldstad et al., 2019).

It is important to remember that the interpretation of the difficulties experienced by each individual may vary according to several factors, and the instrument used may not reveal the magnitude of these experiences. The validation of an instrument that seeks the understanding of experienced sensations is exclusively an attempt to understand and improve these aspects. Thus, the adaptation of instruments is vital so that Brazilian patients with OM can contribute to the understanding of

their needs and so that QoL can be observed to emphasize the view of the individual as a whole. In addition, it seeks to provide effective data collection and a better understanding of patients' limitations. The findings achieved with this instrument may benefit Brazilians with this morbidity, facilitating the implementation of modifications in daily care.

5. Conclusion

The cross-cultural adaptation of the OMQoL was adequately performed, and the validity of the instrument was proven for use in a Brazilian population with OM. We recommend using the instrument in the short form, with only 17 questions, because it is more directed and faster which can fit better into the routine of hospitals.

For future research, it is suggested to utilize the short form of the OMQoL in a larger sample size of patients to evaluate the oral health quality of life within this specific population. This will help to demonstrate the applicability of this instrument in hospitals' routines, leading to enhanced self-reported data and improved health care for these patients.

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