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EVIDENCE OF PSYCHOMETRIC VALIDATION OF ORAL HEALTH RELATED QUALITY OF LIFE MEASURES: A SYSTEMATIC REVIEW

Dissertação apresentada como requisito parcial para a obtenção do título de Mestre em Saúde Bucal Coletiva ao Programa de Pós-Graduação em Odontologia da Faculdade de Odontologia da Universidade Federal do Rio Grande do Sul.

Orientador: Prof. Dr. Roger Keller Celeste

Porto Alegre

2019

CIP - Catalogação na Publicação

Riva Romano, Federico
Evidence of psychometric validation of oral health related quality of life measures: a systematic review / Federico Riva Romano. -- 2019.
97 f.
Orientador: Roger Keller Celeste.

Dissertação (Mestrado) -- Universidade Federal do Rio Grande do Sul, Faculdade de Odontologia, Programa de Pós-Graduação em Odontologia, Porto Alegre, BR-RS, 2019.

1. Qualidade de vida relacionada à saúde bucal. 2. Instrumentos de qualidade de vida associados à saúde oral. 3. Evidência de validação psicométrica. I. Celeste, Roger Keller, orient. II. Título.

Elaborada pelo Sistema de Geração Automática de Ficha Catalográfica da UFRGS com os dados fornecidos pelo(a) autor(a).

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Dissertação aprovada para obtenção do título de Mestre no Programa de Pós-Graduação em Odontologia da Universidade Federal do Rio Grande do Sul pela banca examinadora formada por:

Porto Alegre, 08 de Março de 2019.

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(suplente)

To Z, my parents and my siblings
Your support is the main reason
of any achievement I may have
accomplished in this process

ACKNOWLEDGMENTS

To Prof. Roger Keller Celeste and Profª. Mariana Seoane Campomar, this work would not have been possible without their patience, help, and constant support.

To both institutions, UFRGS and UDELAR, for their teachings and assistance during this time.

To the librarians of the faculty of dentistry of UDELAR for their help in retrieving articles for this review.

Finally, to my co-workers, classmates, family, and friends, who in one way or another had been there at some point of this process, if you feel identify with this statement, then thanks!!

ABSTRACT

Riva Romano, Federico. **Evidence of psychometric validation of oral health related quality of life measures: a systematic review**. 2019. 95f. Dissertação (Mestrado em Saúde Bucal Coletiva) – Faculdade de Odontologia, Universidade Federal do Rio Grande do Sul, Porto Alegre.

Purpose: To systematically review the process of validation of oral health related quality of life (OHRQoL) measures for adults. Methods: A literature search was made following Cosmin's protocol. Original articles were included if they presented any statistical indicator of validation over OHRQoL instruments in adults. Data were collected about the type of validation: face/content/associations (construct); Exploratory Factor Analysis/Principal Components Analysis (EFA/PCA); Confirmatory Factor Analysis/Item Response Theory/Structural Equation Modelling (CFA/IRT/SEM) and if there was evidence of cross-cultural adaptation. Results: 262 references were included. 39 original instruments were found among 66 different versions, 42 generic and 24 condition-specific. The Oral Health Impact Profile (OHIP) presented 16 versions. OHIP-14 was the most frequently (30.92%) validated instrument, followed by the Geriatric Oral Assessment Index (GOHAI) (17.56%), OHIP-49 (16.8%) and Oral Impacts on Daily Performances (OIDP-8) (6.9%). There was a predominance of different forms of construct validation (70.23%) over EFA/PCA (21.37%) and CFA/IRT/SEM (8.40%). For OHIP-14, 9.9% (n=8) of the studies reported CFA/IRT/SEM and 13.6% (n=11) reported EFA/PCA. For GOHAI-12, 8.7% (n=4) of the studies reported CFA/IRT/SEM and 45.6% (n=21) reported EFA/PCA. Most CFA/IRT/SEM studies were for Portuguese speaking versions (n=8), followed by English (n=7). Presence of cross-cultural adaptation was 12.6% (n=33) among all studies, mostly performed on OHIP-49 (n=9). Conclusions: Few instruments have gone through a rigorous validation process neither have documented cross-cultural adaptation, making difficult for researchers to choose based on best psychometric properties. OHIP-14 seems to be the most widely validated instrument. Future studies should assess its psychometrics properties and factorial structure.

Key words: Oral Health Related Quality of Life, Factor Analysis, Validity, Patient Reported Outcome Measures.

RESUMO

Riva Romano, Federico. **Evidência de validação psicométrica de medidas de qualidade de vida relacionada à saúde bucal: uma revisão sistemática**. 2019. 95f. Dissertação (Mestrado em Saúde Bucal Coletiva) - Faculdade de Odontologia, Universidade Federal do Rio Grande do Sul, Porto Alegre.

Objetivo: Revisar sistematicamente o processo de validação de medidas de qualidade de vida relacionada à saúde bucal (OHRQoL) para adultos. Métodos: Uma pesquisa bibliográfica foi feita seguindo o protocolo de Cosmin. Artigos originais foram incluídos se apresentassem algum indicador estatístico de validação sobre instrumentos de OHRQoL em adultos. Foram coletados dados sobre o tipo de validação: face/conteúdo/associações (construto); Análise Fatorial Exploratória/Análise de Componentes Principais (EFA/PCA); Análise Fatorial Confirmatória/Teoria de Resposta ao Item/Modelagem de Equações Estruturais (CFA/IRT/SEM) e se houve evidência de adaptação transcultural. Resultados: 262 referências foram incluídas. 39 instrumentos originais foram encontrados entre 66 versões diferentes, 42 genéricas e 24 específicas para uma condição. O Oral Health Impact Profile (OHIP) apresentou 16 versões. O OHIP-14 foi o instrumento validado com maior frequência (30,92%), seguido pelo Geriatric Oral Assessment Index (GOHAI) (17,56%), OHIP-49 (16,8%) e Oral Impacts on Daily Performances (OIDP-8) (6,9%). Houve predomínio de diferentes formas de validação de construto (70,23%) sobre EFA/PCA (21,37%) e CFA/IRT/SEM (8,40%). Para o OHIP-14, 9,9% (n = 8) dos estudos relataram CFA/IRT/SEM e 13,6% (n=11) relataram EFA/PCA. Para o GOHAI-12, 8,7% (n=4) dos estudos relataram CFA/IRT/SEM e 45,6% (n=21) relataram EFA/PCA. A maioria dos estudos com CFA/IRT/SEM foi para as versões em português (n=8), seguida por inglês (n=7). A presença de adaptação transcultural foi de 12,6% (n=33) entre todos os estudos, a maioria realizada no OHIP-49 (n=9). Conclusões: Poucos instrumentos passaram por um processo de validação rigoroso e não documentaram a adaptação transcultural, dificultando a escolha dos pesquisadores com base nas melhores propriedades psicométricas. OHIP-14 parece ser o instrumento mais validado. Estudos futuros devem avaliar suas propriedades psicométricas e estrutura fatorial.

LIST OF ABBREVIATIONS AND ACRONYMS

CFA	Confirmatory Factor Analysis
COMDQ	Chronic Oral Mucosal Diseases Questionnaire
DHEQ	Dentine Hypersensitivity Experience Questionnaire
DIDL	Dental Impact on Daily Living
DIP	Dental Impact Profile
EFA	Exploratory Factor Analysis
EORTC QLQ-OH17	European Organization for Research and Treatment of Cancer QoL Questionnaire Oral supplement module
EORTC QLQ-OH30	European Organization for Research and Treatment of Cancer QoL Questionnaire
FA	Factor Analysis
FIS	Family Impact Scale
GOHAI	Geriatric Oral Health Assessment Index
HRQoL	Health Related Quality of Life
ICSII-OHRQOL	2nd International Collaborative Study on Oral Health Care Systems
IRT	Item Response Theory
LDF-TMDQ	Limitations of Daily Function - Temporo mandibular disorders questionnaire
LORQ	Liverpool Oral Rehabilitation Questionnaire
MHISS	Mouth Handicap is Systemic Sclerosis scale
MIQ	Malocclusion Impact Questionnaire
OES	Oral Esthetic Scale
OHIDL	Oral Health Impacts on Daily Living
OHIP	Oral Health Impact Profile
OHQOL	Oral Health Related Quality of Life Instrument
OH-QoL	Oral Health Quality of Life Inventory
OHQoL-UK	Oral Health Quality of Life – United Kingdom
OHRQoL	Oral Health Related Quality of Life
OIDP	Oral Impact on Daily Performances
OQLQ	Orthognathic Quality of Life Questionnaire

OQOL	Oral Quality Of Life
PCA	Principal Components Analysis
PIDAQ	Psychosocial Impact of Dental Aesthetics Questionnaire
POHW	Positive Oral Health and Wellbeing
PQL	Prosthetic Quality of Life
QLQ-OH	Quality of Life Questionnaire Oral Health
QoL	Quality of Life
QoLDAS	Quality of Life associated with Dental Aesthetics Satisfaction
QoLIP	Quality of Life with Implant-Prostheses
RAQoL	Rheumatoid Arthritis Quality of Life
SIDD	Social Impacts of Dental Disease
SOHSI	Subjective Oral Health Status Indicators
SOOQ	Surgical Orthodontic Outcome Questionnaire
SEM	Structural Equation Modelling
TMD	Temporo-Mandibular Disorders
TOQOL	Teen Oral Health Quality of Life
WHO	World Health Organization
WHOQoL	World Health Organization Quality of Life

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1 INTRODUCTION

The study of Oral Health Related Quality of Life (OHRQoL) is not a new subject of research, and it has been growing since its beginnings in the early 80's. In a broader sense, the World Health Organization (WHO) defines Quality of Life (QoL) as "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns". It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment (WHOQOL GROUP, 1998).

The compartmentalization of studding the mouth separately of the rest of the body is a misconception, since it affects the rest of the body, not only by its effect over chronic diseases (PETERSEN, 2003), which by itself is a major reason, but also because of the effect that oral health has in general health by causing considerable pain and suffering, and by changing what people eat, their speech, and their QoL and well-being (SHEIHAM, 2005).

Over the last 40 years many instruments have been developed, studied and adapted with the intention of assessing the different degrees of impact that oral health has over QoL, and understanding the role it plays. The use of these instruments should not only be intended for health surveys and clinical trials (which are of great importance), but also to reorient health policies, to incorporate patient centered approaches, to assess treatment needs, and for their use in clinical practice (PETERSEN, 2003; SHEIHAM; WATT, 2000).

1.1 JUSTIFICATION

Among the vast pool of measurement instruments, some of them are more widely use than others. They assess different aspects of QoL and how is oral health affecting it by measuring latent variables indirectly throw observable variables (smiling is not OHRQoL but an indirect measure of a dimension of it). For such use a process of validation is needed.

The psychometric proprieties of the instruments should be assessed, but

also the different variations as well as their translated versions. We have to consider: a) if a transcultural adaptation was made; b) in case it was, which was the protocol used; and c) in case it hasn't, if it's needed according to its psychometric proprieties.

Not all validation articles incorporate the same instruments or analysis, not all had a cultural adaptation and those that have usually follow different protocols. There is no single standardized procedure for the validation of measurement instruments, which makes it difficult to choose one over the others, generally leading to the shortest or the easiest to implement in surveys.

There is limited or non-existent evidence that systematically collects the psychometric properties of the "validated" measurement instruments. Obtaining results from a systematized study could guide researchers in a selection based on scientific evidence, or in the incorporation of what they consider best in a process of cross-cultural adaptation. Considering the dimensional facets of instruments, there are some known publications using Factor Analysis (FA) as an instrument to validate measures, but they have not been summed up (MELLO DOS SANTOS et al., 2013a; MONTERO et al., 2010; MONTERO; BRAVO; LOPEZ-VALVERDE, 2011; NAIK et al., 2016; PILOTTO et al., 2016). They show different results regarding the number of factors; fit indices; and they also spotted items that may not work properly in some situations. Although not clearly defined, the most widely used scales have been practice to measure the same latent construct (OHRQoL) and there should be fair agreement, at least in their factorial structure.

As they have been used in different countries, it has been assumed they kept the same good basic psychometric properties across very different cultures. Comparing item functioning in different versions may help improving them. Sometimes, changes have to be made to cross-culturally adapt them, but it is unknown if it's still equivalent to the original one.

A systematic review is a useful tool to get a comprehensive overview of the process of validation of the instruments, and is the most valid tool to determine if an instrument is fulfilling its purpose in the analyzed circumstances.

2 LITERATURE REVIEW

As it has been stated, the concept of QoL has been growing interest over the last four decades, not only in the bio-medical field, but also in other areas such as sociology, psychology, economics, politics, environment, sports, etc. For a clearer understanding of the concept and its variants first we should explore the concept of QoL itself, and analyze its similarities and differences with concepts such as Health Related Quality of Life (HRQoL) and OHRQoL.

2.1 QUALITY OF LIFE

A clear definition of QoL with a consensus among researchers is hard to find, given de multidimensional aspect of the concept, the logical tendency to study one or some of these dimensions at a time (for practical reasons), and the "popularity" that the study of QoL has taken among different fields over the last decades.

This wide use of the term QoL is the main reason why it is ambiguous and elusive, the importance of subjectivity in its definition is a key aspect, understanding the multidimensional aspect of the concept, in which a standardized set of valid, reliable and evidence-based measures of all those dimensions (psychological, spiritual, health, etc.) are encompassed in the person's QoL evaluation. Only a minority of studies provide an original conceptualization of QoL, while others rely on other authors' formulations, some do not even attempt a theoretical conceptualization, some are more concerned about reliably measure QoL without defining it theoretically, while many others consider QoL as a determinant or an indicator of something else (BARCACCIA et al., 2013).

This vague definition of the concept results in a problem applying it; sometimes it is considered as the measure of subjective well-being, in other cases it is used as an indicator of physical health, etc. Gasper explains the existence of many different conceptualizations of QoL arguing that this concept "refers to an evaluation (an evaluative judgment) about selected aspects or the entirety of a life situation and that it doesn't refer to one unitary or objective entity". The problem with this is that a lot of confusion has ensued as a

consequence, since the term “quality of life” lends itself to more than one interpretation and when used, it is not always meaning the same, but is affected by the context in which the QoL consideration takes place. The multidimensional nature of the concept should always be taken into account, knowing in which context is the concept being use (GASPER, 2010).

Overall, QoL appears as an ambiguous and elusive concept, widely used in all fields of knowledge. Therefore, it would be of great importance to improve its understanding; however, the importance of subjectivity in the definition of what QoL really is seems to be a key aspect. The assessment of psychological, spiritual, and social variables, as well as other variables not strictly related to physical health, should be an important part of how QoL is evaluated.

Considering all the aspects that had been mention, it could be attempt to define QoL as an evaluation (an evaluative judgement) about major aspects, or the entirety, of a life or a society under a given circumstance (MCGILLIVRAY, 2007).

The situation is quite different when we focus upon just one feature of QoL, as HRQoL, which is a concept that involves those aspects that are influenced by health status, and is based on dimensions that can be assessed (i.e., physical, psychological, and social aspects) although such aspects may not be easy to measure (BENITO-LEÓN et al., 2011),.

2.1.1 HEALTH RELATED QUALITY OF LIFE

QoL is conceived as a complex construct due to its subjective and dynamic nature. In this regard, variations in the conception that a subject or groups of subjects have of their QoL over time can be expected, due to the relative importance that they assign to their health and the impact this has on their general well-being. Similarly, it is possible to consider that different age or population groups may present different concepts about the QoL (ALLISON et al., 1999).

Traditionally, the investigation that the impact of health conditions has over the QoL of the subjects is carried out through measurement instruments. In

the years before and during the Second World War, these tools conceived QoL as a construct associated mainly with material goods. It was widely used in psychiatry and provided a conceptual basis for obtaining other questionnaires that asses symptoms (FARQUHAR, 1995).

Subsequently, the use of questionnaires was consolidated, finding a place in surveys as well as in longitudinal studies. Gradually, the subjective nature of the indicators was generating new types of instruments. Such is the case of "Activities on Daily Living" that incorporated the notion of "distal symptoms", those not directly related to the disease but that, associated with them, affect the daily life of people generating functional disabilities, repercussions on their jobs, etc. The notion of QoL synthesizes the possible distal symptoms to be experienced by the patient. Most of the QoL instruments included the question “how would you rate your current QoL?” In 1976, the "Sickness Impact Profile" and the Kaplan Wellness Index emerge, which incorporate the dimensions of mobility, physical and social activity (ARMSTRONG et al., 2007).

In 1980, WHO presents the International Classification of Impairments, Disabilities, and Handicaps, incorporating the social dimension as an aspect linked to diseases (WHO, 1980). Later, it defines QoL as “individuals’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” (WHOQOL GROUP, 1998). It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment. From this the World Health Organization Quality of Life (WHOQoL) is established as a QoL assessment tool (W. KUYKEN, 1995).

In this way, HRQoL measurements have given the symptoms a new and extended meaning and have consolidated the patient's report as a central component in the definition of health and disease (ARMSTRONG et al., 2007).

The conceptualization of HRQoL requires a cultural perspective, as well

as economic and political aspects. The perspectives and definitions that are granted to this construct are varied, from the most global to the most detailed. Some highlight its subjective nature, others the multi-dimensionality and others offer a more integrative vision (ARDILA, 2003; URZÚA, 2012).

The most global visions take on objective and subjective aspects, their multidimensional and dynamic nature, concepts of satisfaction and well-being as well as the impact of the social, community and political environment (ARDILA, 2003; URZÚA, 2012; W. KUYKEN, 1995).

As stated by Guyatt et al, HRQoL can be summed up as a construct that ranges from negatively valued aspects of life, including death, to the more positively valued aspects such as role function or happiness. The boundaries of the definition usually depend on the reason why health is being assessed, as well as the particular concerns of patients, clinicians, and researchers. There are aspects of life are not generally considered as "health", but may have an impact on it, including income, freedom, and quality of the environment. Although low or unstable income, the lack of freedom, or a low-quality environment may adversely affect health, these problems are often distant from a health or medical concern. Clinicians focus on HRQoL, but when a patient is ill or diseased, almost all aspects of life can become health related (GUYATT; FEENY; PATRICK, 1993).

2.1.2 ORAL HEALTH RELATED QUALITY OF LIFE

In the dental field, measures that draw on the patient’s perspective were originally referred to as socio-dental indicators or measures of oral health status, subjective oral health or the social impacts of oral disease. Subsequently, these terms were replaced with the term OHRQoL, with measures being characterized as such irrespective of their content (LOCKER; ALLEN, 2007).

When focusing specifically on oral health, Locker states that the definition of QoL is relatively loose, changing among researchers, but in simple terms OHRQoL can be defined as the extent to which oral disorders affect functioning and psychosocial well-being, and the symptoms and functional and

psychosocial impacts that emanate from oral diseases and disorders (LOCKER; CLARKE; PAYNE, 2000).

The mechanisms of measurement of oral health had traditionally focused their attention on the disease, based on the biomedical model. A somewhat more encompassing perspective conceives oral health as "a functional and comfortable dentition that allows individuals to continue with their social roles". Currently oral health is considered a dynamic and fluctuating concept according to the perception of the individual and their experiences (BRONDANI; MACENTEE, 2014).

Population studies of oral health conditions can uncover vulnerable social sectors, thus allowing reorientation of public health social policies. Oral health can impact on the general health of individuals in the physical but also in the psychological aspect, either by its possible effect on social relationships or in the consequences that certain symptoms such as oral pain cause in the general well-being of the subjects (COULTER; MARCUS; ATCHISON, 1994).

It is not certain that the conditions in oral health generate the same consequences in different groups of subjects. It is possible that the conception presented by the subjects about their oral health, about their relationship with general health and about its impact on QoL varies in relation to oral conditions in a given time. But it can also vary in relation to other factors such as the age of the subjects, since although certain conditions are more frequent at an advanced age, they can also be more tolerated (MACENTEE; HOLE; STOLAR, 1997).

While the link between oral health and QoL is clear, they are not synonymous. Brondani and MacEntee make reference to "oral health" supported by theoretical models and "quality of life associated with oral health" referring to the potential application of these models, assessing the results of treatments, allocating public resources and developing socio-dental indicators (BRONDANI; MACENTEE, 2014), measuring the extent of the harm that oral diseases give to the social roles exercised by individuals in society, causing behavioral changes, such as inability to go to work or school, or to perform

domestic tasks related to social interactions (LOCKER, 1998).

2.2 ORAL HEALTH MODELS

The use of OHRQoL measuring instruments has a wide acceptance in the scientific field. Its application is increasingly broad in population surveys, in order to determine the impact of various variables on the QoL of a population by directing public health policies, as well as at the clinical level, when verifying the results of treatments and guiding the professional in the assessment of the best therapeutic options.

Established oral health models have evolved along with the change from the biomedical to the biopsychosocial model (BRONDANI; MACENTEE, 2014; COULTER; MARCUS; ATCHISON, 1994). The theoretical model of Locker stands out (LOCKER, 1988), product of the adaptation of the WHO classification on Impairment, Disability and Handicap (WHO, 1980). This model incorporates the perspective centered on the patient and contemplates the following six dimensions of QoL: physical; psychological; independence; social relationships; environment and; spiritual, religious and personal beliefs (BAKER; GIBSON; LOCKER, 2008; LOCKER, 1997; W. KUYKEN, 1995).

Locker's model establishes the link between the aforementioned dimensions, modulated by other variables such as pain (BRONDANI; MACENTEE, 2014; LOCKER, 1997). Considering the dental loss, it could be assumed that from this, a functional limitation is generated which causes an incapacity, which then provokes a social disadvantage. It begins in the disease through unidirectional links and portrays the consequences at a physical, psychological and social level. The measurement instruments Oral Health Impact Profile (OHIP) and Oral Impact on Daily Performances (OIDP) are partially or totally supported in this theoretical model (LOCKER, 1997; VELÁZQUEZ-OLMEDO et al., 2014).

The model of Williams et al incorporates the dynamic notion, graphed by bidirectional arrows, understanding that each dimension affects others and vice versa. It tries to demonstrate a continuous circular movement between the concepts of symptomatic, functional state, and perception. Other outstanding

models are Gilbert et al, Locker & Gibson, Nuttall et al, ICF (BRONDANI; MACENTEE, 2014).

A common denominator in the theoretical models is that they arise from visions coming from professionals, who usually have an external view of the problem. The concept of 'normal mouth' and 'diseased mouth' lies in the opinion of the professional, as well as the concept of the impact that oral conditions has over QoL. From these concepts various measurement instruments are established, and therefore, do not always fit the feelings of the subjects (BRONDANI; MACENTEE, 2014).

Another model to highlight, developed by MacEntee, emerges as a result of interviews with relatively healthy older adults. Thought in a three-dimensional way, it is represented by a series of concentric spheres, each of equal hierarchy, delimited by arrows in both directions, where the environment is located in the most peripheral part, and hygiene, comfort and general health, closest to oral health. In 2007, through discussions in focus groups, it was modified. Among the modifications mentioned is the incorporation of: diet, economic priorities, personal expectations and beliefs and health values. Even the discussion in focus groups led to the change of spheres by ellipses since they would better describe the dynamics and superposition of the components of the model (BRONDANI; MACENTEE, 2014).

This brief summary shows how the models aim to portray or explain oral health and the dimensions that should be considered when it is affected. Despite the variety of health models and the conceptual network that interprets how its presence or its absence affects QoL, a fundamentally negative perspective is presented, with little or no attention to psychosocial aspects and perspective from the patients.

In 2007, a review by Locker & Allen verified at least 16 OHRQoL questionnaires (LOCKER; ALLEN, 2007). Among the most used instruments were OHIP (SLADE; SPENCER, 1994), OIDP (ADULYANON; VOURAPUKJARU; SHEIHAM, 1996), and the Geriatric Oral Health Assessment Index (GOHAI) (ATCHISON; DOLAN, 1990), all of them are

generic measures that assess oral health in a broad sense (Appendix E Table 1) .

On the other hand, there are also condition-specific instruments that aim to measure the effect of a particular oral condition over HRQoL. Such questionnaires had been around for over two decades (e.g. OHIP-30 for Temporo-Mandibular Disorders (TMD) (MURRAY et al., 1996)), but it is was not until recently that many new specific measures had arisen, like the Quality of Life with Implant-Prostheses questionnaire (QoLIP-10) (PRECIADO et al., 2013) for implant-assisted treatments, the Quality of Life associated with Dental Aesthetics (QoLDAS-9) (PEREA et al., 2015), or the European Organization for Research and Treatment of Cancer QoL Questionnaire Oral supplement module (EORTC QLQ-OH17) (HJERMSTAD et al., 2012) for oral cancer, among others (Appendix E Table 2).

The division between general and disease-specific measures is not exclusive of OHRQoL measures (GARRATT, 2002), the same categorization can be found if we think about OHRQoL as a specific measure of HRQoL, and the latter can be thought as a specific aspect of QoL itself, as shown in fig. 1.

Many conditions are encompass by condition-specific instruments, and some authors suggest to supplement generic with specific measures to address clinically important changes (GUYATT; FEENY; PATRICK, 1993). This broad spectrum of measures can be useful (generic instruments are more applicable for the general population, as is the case of surveys, and specific instruments are for limited samples with a specific aspect of study), but can also represent an inconvenience with the misusage and poor validation of the instruments, when there are numerous measures and little standardization, as it happens in HRQoL (GARRATT, 2002). OHIP is a clear example of this, with numerous derivations of its original version, both into generic and condition-specific measures, but not always with a thorough process of validation.

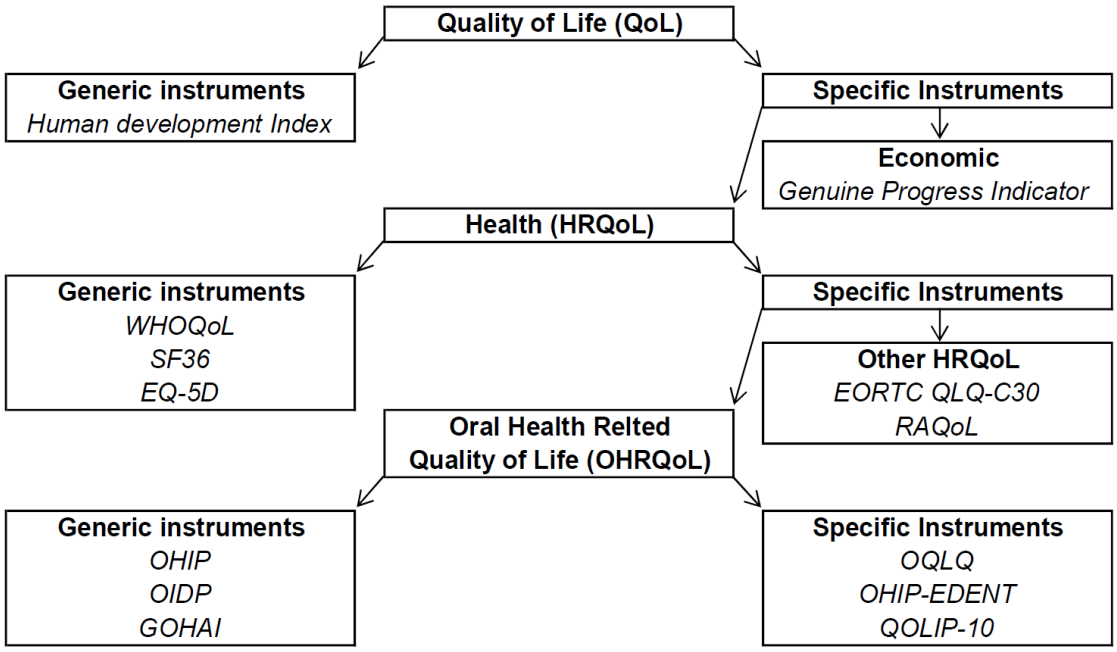

Fig. 1 Measures may be categorized according to their scope in generic and specific instruments. Such division can be made at: a) a QoL instruments level, where HRQoL questionnaires are specific measures of it, b) at a HRQoL instruments level, where OHRQoL questionnaires are specific measures of it, and c) at an OHRQoL instruments level, where there are generic questionnaires and condition-specific instruments as well. The specificity of the instruments aims to a particular oral condition that may affect HRQoL.

2.2.1 THE ORAL HEALTH IMPACT PROFILE

The use of OHIP has been very widespread. Created in 1994 (SLADE; SPENCER, 1994), its original version consists of 49 items linked to seven dimensions based on Locker's model, where the impact of the conditions are categorized in a hierarchical way from the internal symptoms, apparently primary, going through the individual represented in the dimension of functional limitation, and reaching the handicap dimension that affects social roles such as going to work (LOCKER, 1988; SLADE, 1997a; SLADE; SPENCER, 1994; W. KUYKEN, 1995).

The OHIP was developed with the aim of providing a comprehensive measure of self-reported dysfunction, discomfort and disability attributed to oral conditions. These impacts were intended to complement traditional oral epidemiological indicators of clinical disease, thereby providing information about the "burden of illness" within populations and the effectiveness of health services in reducing that burden of illness. The OHIP is concerned with impairment and three functional status dimensions (social, psychological and

physical) which represent four of the seven QoL dimensions proposed by Patrick and Bergner. Hence, it excludes perceptions of satisfaction with oral health, changes in oral health, and prognosis or self-reported diagnoses. Furthermore, the OHIP aims to capture impacts that are related to oral conditions in general, rather than impacts that may be attributed to specific oral disorders or syndromes. All impacts in the OHIP are conceptualized as adverse outcomes, and therefore the instrument does not measure any positive aspects of oral health (ADULYANON; VOURAPUKJARU; SHEIHAM, 1996; PATRICK; BERGNER, 1990; SLADE, 1997a).

Several versions of OHIP are described, being OHIP-14 the most common, possibly because it is a reduced version that demands less application time (ABUZAR; KAHWAGI; YAMAKAWA, 2012; DALY et al., 2010; IKEBE et al., 2012; MCKENNA et al., 2015; PEREA et al., 2013). There are also specific versions like the OHIP-EDENT, that aims to be specific for fully edentulous patients (ALLEN; LOCKER, 2002).

There are adaptations of the different versions for Germany (JOHN; PATRICK; SLADE, 2002), Switzerland (LARSSON et al., 2004), Mexico (CASTREJÓN-PÉREZ et al., 2010), Korea(BAE et al., 2007), Japan (YAMAZAKI et al., 2007), China (WONG; LO; MCMILLAN, 2002), Holland (VAN DER MEULEN et al., 2008), Israel (KUSHNIR; ZUSMAN; ROBINSON, 2004), Spain (MONTERO et al., 2012), Brazil (PIRES; FERRAZ; DE ABREU, 2006) and Chile (LEÓN et al., 2014), among others.

2.2.2 THE ORAL IMPACT ON DAILY PERFORMANCES

Developed by Adulyanon and Sheiham in 1996, the OIDP is a flexible, rapid application instrument consisting of 8 items. It is based on three dimensions, physical, psychological and social (ADULYANON; SHEIHAM, 1997).

The OIDP aims to provide an alternative socio-dental indicator which focuses on measuring the serious oral impacts on the person's ability to perform daily activities. This approach should provide advantages, not only in terms of being easier to measure the behavioral impact on performances of the feeling-

state dimensions, but also in being short. That will be achieved by measuring the serious consequences of outcomes (ADULYANON; SHEIHAM, 1997). Its theoretical framework was modified from the WHO International Classification of Impairments, Disabilities and Handicaps amended for dentistry (LOCKER, 1988).

Same as in OHIP, the OIDP is used in cross-sectional studies in diverse populations, associated both with co-variables, or the results of other measurement instruments. The results of its administration confirms the impact of oral conditions on the performance of daily activities (MOHEBBI et al., 2014). Its use is described to assess the impact of prosthodontic treatments (PRADO et al., 2015), as well as in survey studies (ABEGG et al., 2015).

The OIDP has been adapted for the population of India (PUROHIT et al., 2012), Israel (KUSHNIR et al., 2013), Bosnia (ERIĆ et al., 2012), Nigeria (LAWAL; TAIWO; AROWOJOLU, 2013), and Brazil (ABEGG et al., 2015), among others. It has also been validated in Spain (MONTERO; BRAVO; ALBALADEJO, 2008), and in relation to OHIP-14 it demonstrates good psychometric properties (construct and content validity) (MONTERO et al., 2011).

2.2.3 THE GERIATRIC ORAL HEALTH ASSESSMENT INDEX

Created in the year 1990 by Atchison and Dolan, the GOHAI measures patient-reported oral functional problems in a simple to administer manner. It is also designed to estimate the degree of psychosocial impacts associated with oral diseases. The measure, based on a patient-centered definition of oral health for older adults, includes items regarding freedom from pain and infection, and the patient's ability to continue in his or her desired social roles. This patient-centered definition of health diverges from disease-centered epidemiological measures of health (presence or absence of disease) traditionally used in dentistry (ATCHISON, 1997; ATCHISON; DOLAN, 1990).

The index contains twelve questions on the functional and psychosocial aspects of treatment with removable dentures, and relates the subjective perception of dental health with the resulting quality of life. In contrast to the

short version of OHIP (OHIP-14, more widely used), GOHAI includes more questions about functional aspects such as chewing, swallowing, biting and pain. Within the psychological part of the questionnaire, there is more attention to socio-psychological aspects with questions, for example, about restrictions on chewing due to the prosthesis, while the OHIP emphasizes the psychological condition of the patients (PISTORIUS et al., 2013).

GOHAI has been adapted for the population of China (WANG et al., 2011), Serbia (PETROVIĆ et al., 2017), Netherlands (NIESTEN et al., 2016), Arabia (ATIEH, 2008), Brazil (PINTO, 2000), and Spain (PINZÓN-PULIDO; GIL-MONTOYA, 1999), among others.

2.3 PSYCHOMETRY OF THE OHRQOL INSTRUMENTS

Instruments that intend to measure the association between oral conditions and QoL must present a series of attributes that makes them applicable, either in population surveys or in the dental practice. The particular difficulty in this type of measurements lies both in the nature of the construct to be measured (QoL) and in achieving that the instrument meets the dimensions of this construct and not others (such as happiness, self-esteem, depression). QoL questionnaires are generally designed in relation to underlying dimensions or models, and there must be an appreciable correlation. Likewise, their items should be correlated with each other in relation to the dimensions they represent (FAYERS et al., 1997). Despite this, some variability given by the application of the instruments in different cultural contexts is to be expected (STREINER; NORMAN; CAIRNEY, 2015).

An example of validation that brings together different contexts and participants constitutes the instrument designed by the WHO group that addresses QoL (WHOQoL). In it, work was foreseen in discussion groups (with professionals), translation and adaptation in different cultures and psychometric assessment. A conceptual clarification was made from which six dimensions of the QoL construct were established, namely: physical, psychological, independence, social relations, environment and, spiritual, religious and personal beliefs (W. KUYKEN, 1995).

It is expected that the instrument presents: validity, reliability, and sensitivity. It is considered a minimum requirement that all instruments meet the dimensions of the construct and present an acceptable design. This process is usually carried out thanks to the participation of experts in the construction of the contents and the design of the questionnaire. It is also necessary to establish how valuable its use will be, through a validation process as well as the degree of reliability (STREINER; NORMAN; CAIRNEY, 2015).

Reliability is the property of an instrument by which its results are reproducible under different circumstances. The first step is to know if the results of the application of the instrument will be similar in different individuals, gathered by different observers and by parallel tests. Reliability reports that the test is somehow reproducible (STREINER; NORMAN; CAIRNEY, 2015).

Validity on the other hand, allows determining if it is possible to assume precise conclusions on the presence and the degree in which an attribute is pronounced on an individual. The psychometric factors and the characteristics of the individuals are elements to consider when interpreting the validity of the measurement instruments. Streiner et al citing Landi (1986) allude to the three 'C' of validity: content, criterion and construct (STREINER; NORMAN; CAIRNEY, 2015).

The content validity shows if the content of the instrument really represents the construct that is being evaluated. Criterion validity is established through the correlation of an instrument with another measurement of the construct in question, accepted in the field of research or 'gold standard'. In turn, it is possible to refer to the validation of the construct, which refers to the network of hypotheses that supports it. Faced with a concrete theory and a valid questionnaire, the answers will be oriented as expected (STREINER; NORMAN; CAIRNEY, 2015).

Statistical tests of varying degrees of complexity are not the only means of validating questionnaires that measure subjective aspects. Understanding the subjective and dynamic nature of the construct, the validation of its measurement mechanism is possible partially through quantitative analysis, the

perception of the subjects involved is the means that in a complementary way will allow verifying the validity of the instrument.

2.3.1 FACTOR ANALYSIS

It is possible to use statistical methods such as FA to verify the validity of measurement instruments. This method is based on the exploration of the underlying dimensions of the items included in a questionnaire aiming to associate latent variables with the observed variables. It is a way to determine if a questionnaire supports the dimensions of the conceptual model on which it is based (FAYERS; HAND, 1997).

FA uses mathematical procedures for the simplification of interrelated measures to discover patterns in a set of variables. It has its origins in the early 1900's with Charles Spearman's development of the Two-Factor Theory. The two main FA techniques are Exploratory Factor Analysis (EFA) and Confirmatory Factor Analysis (CFA). CFA attempts to confirm hypotheses and uses path analysis diagrams to represent variables and factors, whereas EFA tries to uncover complex patterns by exploring the dataset and testing predictions (CHILD, 1975).

FA operates on the notion that measurable and observable variables can be reduced to fewer latent variables that share a common variance and are unobservable, they are not directly measured but are essentially hypothetical constructs that are used to represent variables. Among them, EFA is used when a researcher wants to discover the number of factors influencing variables and to analyze which variables 'go together' (SUHR, 2006)..

A basic hypothesis of EFA is that there are *n* common 'latent' factors to be discovered in the dataset, and the goal is to find the smallest number of common factors that will account for the correlations. Common factors are those that affect more than one of the surface attributes, and specific factors are those which only affect a particular variable (YONG; PEARCE, 2013). In essence, EFA is used to explore the possible underlying factor structure of a set of observed variables without imposing a preconceived structure on the outcome (CHILD, 1975), it explains the maximum amount of variance.

CFA is a statistical technique used to verify the factor structure of a set of observed variables. It allows the researcher to test the hypothesis that a relationship between observed variables and their underlying latent constructs exists, the researcher uses knowledge of the theory, empirical research, or both, postulates the relationship pattern a priori and then tests the hypothesis statistically. Unlike EFA, CFA requires specification of a model a priori, the number of factors, which items load on each factor, a model supported by theory or previous research, and error explicitly (SUHR, 2006).

Goals of FA are: 1) to help an investigator determine the number of latent constructs underlying a set of items (variables), 2) to provide means of explaining variation among variables (items) using a few newly created variables (factors), condensing information, and 3) to define the content or meaning of factors (latent constructs) (SUHR, 2006).

2.3.2 CULTURAL EQUIVALENCE

Most of the QoL measurement instruments have been originated in English speaking countries, and the single translation does not seem to give reliable results in other cultures (BERKANOVIC, 1980; GUILLEMIN; BOMBARDIER; BEATON, 1993). Instruments designed to measure OHRQoL have been translated into several languages and, as established by Streiner et al, validation must consider the population in which a measurement instrument will be applied. Generally, the instruments are translated in two senses and after their application they are confronted with psychometric analysis, without rescuing the particularities of the target culture(STREINER; NORMAN; CAIRNEY, 2015).

Psychometric analysis can validate a questionnaire in their culture of origin. But this is not necessarily true for another cultural field, much less if there is a language barrier. In addition to considering translations and psychometric analysis, cultural equivalence should be considered (STREINER; NORMAN; CAIRNEY, 2015). Although the use of QoL instruments is growing, its conception has not been thought (in most cases) to be administered in different cultures. It is necessary to establish a transcultural adaptation of the

instruments in a way that the results obtained from them can be considered valid, showing equivalence between their different language versions (HERDMAN; FOX-RUSHBY; BADIA, 1998).

Guillemin et al propose a guide for cultural adaptation that incorporates translation to and from the target culture; a pre-test of equivalence and the possible psychometric tests. When considering cultural equivalence, they establish a typology that includes different types of equivalence: semantic, idiomatic, experience, and concept (GUILLEMIN; BOMBARDIER; BEATON, 1993).

Herdman et al in 1997 conducted a review of the literature in order to investigate the different types of cross-cultural equivalence used in relation to health measurement instruments associated with QoL. They found 19 different types of equivalence and definitions of authors in relation to translations and adaptations of the generic health questionnaires associated with QoL. In order of frequency they found: conceptual, semantic, functional, metric, scale, technical and operational equivalence (HERDMAN; FOX-RUSHBY; BADIA, 1997). In 1998, this group of authors, in line with the Guillermin protocol (1993), proposed the following models of cross-cultural equivalence: conceptual, semantic, item, operational and of measurement (HERDMAN; FOX-RUSHBY; BADIA, 1998).

Obtaining conceptual equivalence implies, through search for information, to establish the conceptualization of the construct in both cultures (the origin and the objective). The equivalence of items exists when in both cultures the same parameters are estimated on the latent traits that are being measured and when they are equally relevant and accepted by both cultures (HERDMAN; FOX-RUSHBY; BADIA, 1998).

The transfer of meanings and being able to generate similar responses between cultures is semantic equivalence. In this sense it is necessary to consider the connotation that certain statements can have in different cultures. It is possible to carry out a semantic translation by consulting other translators, a linguistic translation and finally a poll in a population sample of the target

community (HERDMAN; FOX-RUSHBY; BADIA, 1998).

The use of a questionnaire in similar format, instructions, method of administration and measurement methods without affecting the results, allows an operational equivalence. The implementation of pilot studies is a good resource for it. If an instrument applied in two different cultures has similar psychometric properties, then it presents measurement equivalence. Following the model proposed by Herdman et al, psychometric measurements constitute the last step of cultural adaptation of a measurement instrument. All aspects of adaptation must be considered whenever it is intended to obtain valid and reliable results (HERDMAN; FOX-RUSHBY; BADIA, 1998).

3 HYPOTHESIS

There is a wide variety of instruments created for OHRQoL assess. The psychometric properties of these instruments are those that in fact reflect that they measure what they claim to do. The present work is based on the hypothesis that there are few instruments that have gone through a rigorous validation process that includes EFA, and even less with CFA.

4 OBJECTIVES

4.1 GENERAL OBJECTIVE

- To assess the methods of validation of the existing versions of the OHRQoL instruments for adults.

4.2 SPECIFIC OBJECTIVES

- To have an overview of published instruments for adults and which types of validation processes are being use for them.

- To find if there is a reasonable degree of homogeneity among the versions of the instruments most commonly assessed (number of items).

- To evaluate the use of FA for validation of the current instruments.

- To evaluate the frequency of construct validation performed for current instruments.

5 METHODS

Following the ten steps protocol recommended by Cosmin (TERWEE et al., 2011), a research question was stated: "*Are oral health related quality of life measurement instruments measuring what they say they do in the adult population? Are they properly validated according to this?*" A PROSPERO protocol was subscribed and accepted on October 17th, 2018, Reg. N° CRD42018110341 (RIVA; SEOANE; CELESTE, 2018)

It is recommended a search strategy consisting of collections of search terms for the following characteristics: 1) target population, 2) construct of interest, and 3) measurement properties. According to this, a strategy was developed combining a target population (adults, over 18 years old), names of the more common scales (appendix A), and a high sensitivity strategy to retrieve validation studies proposed by Cosmin (TERWEE et al., 2009). This strategy was first developed for PubMed (appendix B), and adapted to Scopus (appendix C). A Google scholar search strategy was developed to rescue gray literature that may be of interest (appendix D), together with consultation of key books and articles and contact with relevant authors of the subject.

5.1 INCLUSION CRITERIA

The inclusion criteria were original articles assessing psychometric properties of OHRQoL instruments in the adult population without limitations of language or location.

Often, much indirect evidence on measurement properties of instruments can be obtained, e.g. from studies in which the instrument of interest is used in the validation process of another instrument, or in an RCT or other longitudinal study in which indirect evidence for responsiveness might be found. It is recommended excluding these kinds of studies from reviews for two reasons; first, it is very difficult to find all of these articles in a manageable and structured way; and second, it is often difficult to interpret the psychometric evidence provided in these studies, because no hypotheses about the validity or responsiveness of the instruments of interest are formulated and tested in them (TERWEE et al., 2011). Despite this, as the aim of the study was to retrieve

most of the existing measures and perform a descriptive analysis, the aforementioned studies were included at this stage.

5.2 EXCLUSION CRITERIA

Samples under 18 years old, not psychometric analysis or validation, not OHRQoL, review, animals, or laboratory studies were excluded. Instrument with less than 3 items were drop, following the criteria by Marsh et al (MARSH et al., 1998).

5.3 DATA COLLECTION

The manual selection of articles assessing psychometric properties was made by two researchers, first by the titles and abstracts, and then by analyzing the full text of the remaining articles. In case of dispute, a third researcher was involved in the process. Since some articles validated more than one instrument in more than one target population, the study units were instruments used and groups to which they were applied

Data was retrieved using a previously designed form, the following information was sought: (i) first author; (ii) journal of publication; (iii) year of publication; (iv) country of the study; (v) if validation of an OHRQoL instrument was one of the objectives; (vi) instrument name; (vii) number of items; (viii) aim of the instrument when developed; (ix) type of validation performed; and (x) data of the process of cross-cultural adaptation.

5.4 OUTCOME

The outcome variables were: (i) the development of the measure; (ii) the scope of the instrument; (iii) the psychometric properties assessed by any type of validation (FA or construct validation) and; (iv) the presence of cross-cultural adaptation in the study.

According to its development, measures were categorized regarding their original conception in; (i) original instrument, and (ii) derived version. When not clear in the methodology, the reference of the used measure was consulted.

The scope of the instrument was categorized according to its aim regarding the object of measure, being: (i) generic, when the measure was developed to assess OHRQoL in a broad sense; and (ii) specific, when the effect of a particular oral condition over HRQoL was measured.

For the assessment of the psychometric properties three mutually exclusive categories were created: (i) articles with CFA, Item Response Theory (ITR), or Structural Equation Modelling (SEM) (CFA/IRT/SEM); (ii) articles with EFA or Principal Components Analysis (PCA) (EFA/PCA); and (iii) articles with any other type of validation (content validity, face validity, associations) (construct). In case more than one type of validation was present, it was categorized as CFA/IRT/SEM in the first place, since it is regarded as the highest value of validation, EFA/PCA in second place, and as other types of construct validation in third place.

The last variable was categorized as: (i) with cross-cultural adaptation; and (ii) without cross-cultural adaptation. The criteria for inclusion were the specific mention of cross-cultural adaptation, and the use of a pre-established guideline or basic steps for a back-forward translation.

5.5 CO-VARIABLES OF EXPOSURE AND INTERES

To perform a descriptive analysis, the variables of exposure were the instrument name and number of items, year of publication, journal of publication (then grouped by area), country of the study (then grouped by language), and presence of validation as an objective of study.

5.6 ETHICAL ASPECTS

No ethical approval was required.

5.7 STATISTICAL ANALYSIS

STATA software version 13.1 was used for data analysis. Descriptive analysis is presented in frequency tables (Appendix E – Tables 3 to 13). Bivariate associations were tested using chi-square test for independence, Fisher’s exact test when assumptions were violated.

6 RESULTS

EVIDENCE OF PSYCHOMETRIC VALIDATION OF ORAL HEALTH RELATED QUALITY OF LIFE MEASURES: A SYSTEMATIC REVIEW

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COUNTER

Abstract: 250/250

Figures/Tables: 4/No limits established

Main Text: 2926/4000

References: 72/No limits established

ABSTRACT

Purpose: To systematically review the process of validation of oral health related quality of life (OHRQoL) measures for adults. Methods: A literature search was made following Cosmin's protocol. Original articles were included if they presented any statistical indicator of validation over OHRQoL instruments in adults. Data were collected about the type of validation: face/content/associations (construct); Exploratory Factor Analysis/Principal Components Analysis (EFA/PCA); Confirmatory Factor Analysis/Item Response Theory/Structural Equation Modelling (CFA/IRT/SEM) and if there was evidence of cross-cultural adaptation. Results: 262 references were included. 39 original instruments were found among 66 different versions, 42 generic and 24 specific. The Oral Health Impact Profile (OHIP) presented 16 versions. OHIP-14 was the most frequently (30.92%) validated instrument, followed by the Geriatric Oral Assessment Index (GOHAI) (17.56%), OHIP-49 (16.8%) and Oral Impacts on Daily Performances (OIDP-8) (6.9%). There was a predominance of different forms of construct validation (70.23%) over EFA/PCA (21.37%) and CFA/IRT/SEM (8.40%). For OHIP-14, 9.9% (n=8) of the studies reported CFA/IRT/SEM and 13.6% (n=11) reported EFA/PCA. For GOHAI-12, 8.7% (n=4) of the studies reported CFA/IRT/SEM and 45.6% (n=21) reported EFA/PCA. Most CFA/IRT/SEM studies were for Portuguese speaking versions (n=8), followed by English (n=7). Presence of cross-cultural adaptation was 12.6% (n=33) among all studies, mostly performed on OHIP-49 (n=9). Conclusions: Few instruments have gone through a rigorous validation process neither have documented cross-cultural adaptation, making difficult for researchers to choose based on best psychometric properties. OHIP-14 seems to be the most widely validated instrument. Future studies should assess its psychometrics properties and factorial structure.

Key words: Oral Health Related Quality of Life, Factor Analysis, Validity, Patient Reported Outcome Measures.

INTRODUCTION

The study of Oral Health Related Quality of Life (OHRQoL) is not a new subject of research; it started with Locker's conceptual model and has been growing since the mid 90's [1]. In a broader sense, the World Health Organization (WHO) defines Health Related Quality of Life (HRQoL) as "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns". It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment (WHOQL) [2]. Following this concept, Locker et al. defines OHRQoL as the extent to which oral disorders affect functioning and psychosocial well-being [3].

Many instruments have been developed, validated and adapted with the intention of assessing the different degrees of impact that oral health has over QoL, and understanding the role of oral health. The use of these instruments should not only be intended for health surveys and clinical trials, but also to reorient health policies, incorporate patient centered approaches, and assess treatment needs [4, 5].

Instruments intended to measure the association between oral conditions and HRQoL must present a series of attributes that makes them applicable, either in populational surveys or in the dental practice. The particular difficulty lays both in the nature of the construct to be measured, and in achieving that the instrument meets the dimensions of this construct and not others (such as happiness, self-esteem, or depression) [6].

The questionnaires can be developed for a specific age range, where two major groups are mostly found, child and adults, the latter can also be categorized in adults and elders. For either of them measures may be categorized according to their scope in generic and specific questionnaires. Such division can be made at: a) a QoL level, where HRQoL questionnaires are specific measures of it, b) at a HRQoL level, where OHRQoL questionnaires are specific measures of

it, and c) at a OHRQoL level, where there are generic and condition-specific instruments as well. The specificity of the instruments aims to different oral conditions that may affect HRQoL.

Measures are generally designed in relation to underlying dimensions or models, and there must be an appreciable correlation. Factor Analysis (FA) does this based on the exploration of the underlying dimensions of the items included in a questionnaire. It aims to associate latent variables with the observed items and determine if a questionnaire supports the dimensions of the conceptual model on which it is based [7]. Considering the dimensional facets of instruments, there are some known publications using FA as an instrument to validate measures, but they have not been summed up. They show different results regarding the number of factors; fit indices; and they also spotted items that may not work properly in some situations [8–12].

Regarding the target population of the instruments, psychometric analysis can validate a questionnaire in their culture of origin, but this is not necessarily true for another cultural field, much less if there is a language barrier. In addition to considering translations and psychometric analysis, cultural equivalence should be taken into account [13]. In any case items should be correlated with each other in relation to the dimensions they represent [7]. Despite this, some variability given by the application of the instruments in different cultural contexts is to be expected [13].

Among the measurement instruments, some are more widely use than others, assessing different aspects of OHRQoL. For such use, a process of validation is needed, not only by analyzing the psychometric proprieties of their original versions, but also of their different variations as well as their adapted versions. So far there is no systematic review, and obtaining results from a systematized study could eventually guide researchers in the selection of one over the others based on scientific evidence.

The present work was based on the hypothesis that despite the large number of existing instruments, there are few that have gone through a rigorous validation process that includes Confirmatory Factor Analysis (CFA). The aim of this study

was to perform a comprehensive scrutinizing of the existing OHRQoL instruments for adults, with a descriptive analysis of their scope (generic or specific), methods of validation regarding factor analysis and cross-cultural adaptation, and their bibliometric characteristics.

METHOD

Search strategy

Following the protocol recommended by Cosmin [14], a research question was stated: "*Are oral health related quality of life measurement instruments measuring what they say they do in the adult population? Are they properly validated according to this?*" A strategy was developed combining a target population (ages between 18 and 70), and a high sensitivity filter to retrieve validation studies proposed by Cosmin [15]. This strategy was developed for PubMed and then adapted for Scopus. To rescue gray literature, a Google scholar search strategy, a scope of references in books and key articles, and contact with relevant authors of the subject was performed.

Selection criteria

The inclusion criteria were original articles assessing psychometric properties of OHRQoL instruments in the adult population without limitations of language or location. Much indirect evidence on measurement properties of instruments can be obtained, e.g. from studies in which the instrument of interest is used in the validation process of another instrument, or in an RCT or other longitudinal study in which indirect evidence for responsiveness might be found. It is recommended excluding these kinds of studies from reviews for two reasons; first, it is very difficult to find all of these articles in a manageable and structured way; and second, it is often difficult to interpret the psychometric evidence provided in these studies, because no hypotheses about the validity or responsiveness of the instruments of interest are formulated and tested in them [14]. Despite this, as the aim of the study was to retrieve most of the existing measures and perform a descriptive analysis, the aforementioned studies were included at this stage. Samples under 18 years old, not psychometric analysis

or validation, not OHRQoL, review, animals, or laboratory studies were excluded. Instrument with less than 3 items were drop, following the criteria by Marsh et al [16].

Articles classification and variables of study

After the initial search, a manual selection of articles assessing any psychometric properties was made by two researchers, first by titles and abstracts, and then by full text analysis of the remaining articles. The outcome variables were: (i) the development of the measure; (ii) the scope of the instrument; (iii) the psychometric properties assessed by any type of validation (FA or construct validation) and; (iv) the presence of cross-cultural adaptation in the study.

According to its development, measures were categorized regarding their original conception in; (i) original instrument, and (ii) derived version. When the origin of the instrument was not clear in the methodology, the reference of the used measure was consulted.

The scope of the instrument was categorized according to its aim regarding the object of measure, being: (i) generic, when the measure was developed to assess OHRQoL in a broad sense; and (ii) specific, when the effect of a particular oral condition over HRQoL was measured.

For the assessment of the psychometric properties three mutually exclusive categories were created: (i) articles with CFA, Item Response Theory, or Structural Equation Modelling (CFA/IRT/SEM); (ii) articles with EFA or Principal Components Analysis (EFA/PCA); and (iii) articles with any other type of validation (content validity, face validity, associations) (construct). In case more than one type of validation was present, it was categorized as CFA/IRT/SEM in the first place, since it is regarded as the highest value of validation, EFA/PCA in second place, and as other types of construct validation in third place [7].

The last variable was categorized as: (i) with cross-cultural adaptation; and (ii) without cross-cultural adaptation. The criteria for inclusion were the specific mention of cross-cultural adaptation, and the use of a pre-established guideline

or basic steps for a back-forward translation.

Data extraction

Data was retrieved using a previously designed form, the following information was sought: (i) first author; (ii) journal of publication; (iii) year of publication; (iv) country of the study; (v) if validation of an OHRQoL instrument was one of the objectives; (vi) instrument name; (vii) number of items; (viii) aim of the instrument when developed; (ix) type of validation performed; and (x) data of the process of cross-cultural adaptation.

Data analysis

STATA v13.1 software was used for data analysis. Descriptive analysis was presented in a frequency table. Bivariate associations were tested using chi-square test for independence, Fisher's exact test when assumptions were violated.

RESULTS

The initial search identified 2959 references. After reading titles and abstracts, 2662 had to be excluded since they did not fulfill the eligibility criteria. A total of 297 articles were selected for full text review, which ended up excluding another 53 articles, resulting in 244 studies. Since the aim of the study was to describe how the instruments were validated, and many articles did that to more than one instrument in more than one population, the study units were instruments used and groups to which they were applied, resulting in n=262 (Fig. 1).

In function of the obtained data, categories were created by: (i) instrument (name and number of items); (ii) period of publication (1990-2000, 2001-2005, 2006-2010, and 2011-2017); (iii) group of journals (Dental public health, Dental, and Quality of life); (iv) language of the country of the publication (English, Portuguese, Germany/Netherlands, Spanish, and others); and (v) validation as an objective (yes or no).

Characteristics of the studies and the retrieved instruments

A total of 66 OHRQoL measurement instruments were found, all derived from 39 original versions. The aims of the measures were recovered from their development articles, 42 of them were generic OHRQoL questionnaires and the remaining 24 were condition-specific instruments, the most frequents being esthetic, prosthetic and surgical related measures (table 1).

The Oral Health Impact Profile (OHIP) presented the highest number of variants (16 in total). OHIP was also the most frequent instrument with 58.78% among all versions; its original version (OHIP-49) had a 16.79% rate, while the most validated instrument both among OHIP versions and all of the measures was OHIP-14, with 30.92%. The second most frequent instrument was the Geriatric Oral Health Assessment Index (GOHAI) with 17.56%, followed by The Oral Impact on Daily Performances (OIDP) with 13,74 (table 2).

The journals with the highest score were the dental public health group (Community Dentistry & Oral Epidemiology, Public Health Dentistry, and Community Dental Health) with 24.43% (table 2). The number of publications over time has been increasing since the beginning, peaking in the period 2011-2017, with 50.38% of the cases, and the majority of the samples were from English speaking countries with 25.57%, followed by Portuguese (10.69%) (table 2).

Type of validation

There was a predominance of construct validation (70.23%) over both EFA/PCA (21.37%) and CFA/IRT/SEM (8.40%) combined (p=0.001). GOHAI was the only one that had the same number of EFA/PCA and construct validation (n=21), resulting in more FA than construct validation when CFA/IRT/SEM is added (n=4). Only OHIP-49 showed a higher value of CFA/IRT/SEM than EFA/PCA (11.36% vs. 4.55%) (table 3).

The CFA/IRT/SEM studies began to be published in the period 2006-2010 with 9.59% of the sample, increasing to 11.36% in the period 2011-2017, but they had the lowest ratio in each period, being construct validity the predominant in

all periods (p=0.03) (Table 3). Although without a statistical difference, a similar situation can be assume with the journals, where all groups presented some form of construct validation as the most common method, ranging between 70.00% and 72.59%. Quality of life journals presented the highest ratio of CFA/IRT/SEM studies (15%), while for EFA/PCA dental journals published the most (30.23%) (p=0.24) (table 3).

Statistically significant differences were found regarding the cultural background of the target populations, where the validation of OHRQoL instruments in samples of Portuguese language presented most of the CFA/IRT/SEM studies (n=8), representing 28.57% of all Portuguese validations. EFA/PCA presented the best ratio in the Spanish speaking samples (39.13%) (p=0.00) (table 3).

Cross-cultural adaptation

Cross-cultural adaptation was mostly accomplished when the objective of the study was validation of an OHRQoL instrument (15.17%) (p=0.011). When considering all the measures, 12.60% presented some kind of cross-cultural adaptation; the only instruments with rates over 20% were OHIP-49 (20.45%) and OIDP-8 (22.22%) (p=0.068) (Table 3).

Cross-cultural adaptation studies presented a rate of 6.67% in 1990-2000 and rates ranging between 12.12% and 14.29% in the post-2001 periods (p=0.90), being published the most in Quality of Life journals (10.00%) (p=0.078). Statistically significant differences were found regarding the language of the country where the data was obtained. Spanish speaking countries had the highest proportion with 21.74% of the samples. Germany/Netherlands and Portuguese had a ratio of 19.05% and 14.29% respectively. English speaking countries represented 1.49% of the cases (p=0.005) (Table 3). In only 2 studies the subjects of the new culture were included at the initial stages of the adaptation process through a qualitative approach for conceptualization of the construct.

DISCUSSION

In the present study 66 OHRQoL instruments where retrieved among 39 original versions, with 24 condition-specific measures. Validation was performed with EFA/PCA in 21,3% and CFA/IRT/SEM in 8,4%. Only 12,6% performed cross-cultural adaptation. The first validation with CFA/IRT/SEM was not found until 2006, showing a delay in the use of the technique similar to the late incorporation of the concept of OHRQoL years after HRQoL concept were already being studied [17–19]. Most of the adaptations were performed for Portuguese and Spanish languages, being Portuguese the one with the highest number of CFA.

This was a descriptive review, so the results of the validity studies are not present, further research should explore item loadings, dimensional structure, and goodness of fit of the models. It is also unknown if instruments perform equally well when adapted to other cultures. Although it was a systematic search, a few studies and/or instruments may have not been retrieved. The review aimed to recover all instruments with any type of validation, focusing on FA studies, cultural adaptation, and scope of the instruments, presenting a comprehensive view of the current state of OHRQoL measures.

The number of original instruments found (39 measures) were different from the results from Locker and Allen in 2007 (14 measures) [20], probably responding to an arising need of using condition-specific measures, where we found most of the instruments in the last decade, together with the demand of shorter and easily applicable versions [21], which also explains the large number of derived instruments found (OHIP alone presented 16 versions). Many conditions are encompassed by them and some authors suggest supplementing generic with specific measures to address clinically important changes [19]. Nevertheless, similarly to HRQoL where there are numerous measures and little standardization [22], this heterogeneity represents a difficulty in the selection of an instrument and when comparing results of different condition-specific measures. It also complicates the systematization of data for validation purposes.

CFA validates an instrument by testing a postulated model to see whether it is adequate to explain the observed data [7]. The present study reflected a low percentage in the use of FA and even less when we focus exclusively on CFA as a validation process, most studies relayed on construct validity, probably due to its relative simplicity. Even thou FA is not a new method [23] EFA studies presented a low frequency in the first analyzed periods, and it is not until 2006 that the firsts CFAs appeared regarding validation of OHRQoL instruments. This late implementation, together with the low rate found, suggests that its application may be somehow more complex. The aforementioned heterogeneity of measures makes it difficult to synthesize the CFA data for most instruments because, in addition to the low number of studies with CFA, they are wildly distributed among the different version. Important conclusions of FA studies [8, 10, 12, 24, 25] may benefit from more research with CFA to compare results in similar populations and in different cultures.

OHRQoL should be consider a culturally and dynamic defined concept [26], so more cross-cultural adaptations are desirable not only in different populations, but also in different time periods considering the change in individuals' perceptions over time, as showed by Slade and Sanders [27]. The low number of cross-cultural adaptations assessing psychometric properties is not exclusive of OHRQoL, but is a problem for many health assessment measures [28]. The target population is an important aspect regarding the validity of the instrument and when comparing results from different studies. A cross-cultural adaptation of the instruments should be performed in these regards, including an early qualitative approach and FA in the process. This may contribute to a conceptual and dimensional adaptation, as well as the incorporation of cultural features of the items content.

In conclusion, the present study was intended as a first step toward a more comprehensive analysis of the validity of instruments. The high heterogeneity of generic and condition-specific measures represents both a benefit, offering a wide broad of possibilities to policy makers and clinicians, and a difficulty to researchers when trying to synthetize the information about the psychometric properties scattered among all measures, with no standardized procedure for

their validation. A higher number of CFA studies would be desirable for a better understanding of the factorial structure of widely use instruments.

ACKNOWLEDGEMENTS

There is no conflict of interest. The authors would like to thank the librarians of the faculty of dentistry of UDELAR for their help in retrieving articles for this review.

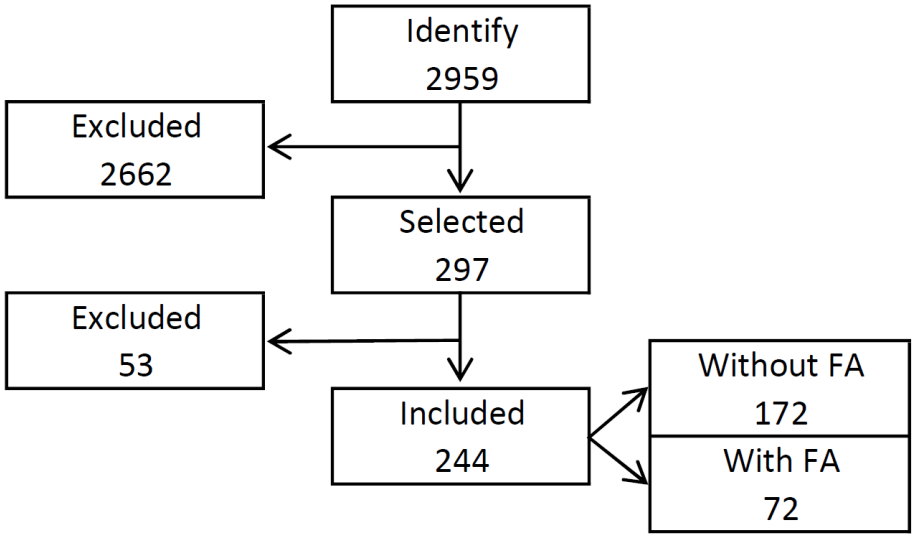

Figure 1 – Fluxogram of the selection process of articles
Some articles validated more than one instrument in more than one target population, the study units were instruments used and groups to which they were applied, resulting in n=262

Table 1 – Retrieved OHRQoL instruments and aim

	ID	Name or description	Authors and year	n	T
GENERIC	SIDD	Social Impacts of Dental Disease	1986 CUSHING et al. [29]	1	42
	GOHAI	Geriatric Oral Health Assessment Index	1990 ATCHISON; DOLAN., [30]	1	
	DIP	Dental Impact Profile	1993 STRAUSS et al., [31]	1	
	OHIP	Oral Health Impact Profile – Items: 49 (original), 14, 55, 54, 46, 45, 22, 7, 7 (NHANES), and 5	1994 SLADE; SPENCER [32]	10	
	SOHSI	Subjective Oral Health Status Indicators	1994 LOCKER; MILLER [33]	1	
	DIDL	Dental Impact on Daily Living – Items: 49 (original), 36, and 33	1996 LEAO; SHEIHAM [34]	3	
	OHQOL	Oral Health Related Quality of Life Measure – Items: 3 (final) and 8	1996 KRESSIN et al., [35]	2	
	OIDP	Oral Impact on Daily Performances – Items: 8 (original), 3, 7, 9, 10, 11, and 12	1996 ADULYANON et al., [36]	7	
	OH-QoL	Oral Health Quality of Life Inventory	1997 CORNELL, et al., [37]	1	
	ICSII-OHRQOL	International Collaborative Study on Oral Health Care Systems	1997 CHEN et al., [38]	1	
	Rand Health Insurance St.	Dental health questions from the Rand Health Insurance Study	1997DOLAN, GOOCH [39]	1	
	Gift1997	Oral clinically assessed impairment and self-reported acute symptoms affecting QoL	1997 GIFT et al., [40]	1	
	OHQoL-UK	Oral Health Quality of Life – United Kingdom	2001 MCGRATH; BEDI, [41]	1	
	FIS	Family Impact Scale – Items: 14 (original), 19, and 8	2002 LOCKER et al., [42]	3	
	Chavers 2003	Incidence of oral disadvantages. Two years and chronical	2003 CHAVERS et al., [43]	1	
	LORQ (v1-v3)	The Liverpool Oral Rehabilitation Questionnaire	2004 PACE-BALZAN et al., [44]	1	
	Bagewitz 2005	Questions derived from literature analysis on conditions for oral health	2005 BAGEWITZ et al., [45]	1	
	OQOL	Oral Quality Of Life – Items: 6 (short form), and 12 (long form)	2008 KRESSIN et al., [46]	2	
	Daneshvar 2015	Young Adults age-specific self-perception issues and physical and social impediments	2015 DANESHVAR et al., [47]	1	
	John 2016	Four-dimensional model	2016 JOHN et al., [48]	1	
	POHW	Positive Oral Health and Wellbeing	2016 ZINI et al., [49]	1	
SPECIFIC	OHIP-30 TMD	OHIP for Temporo-mandibular disorders	1996 MURRAY et al., [50]	1	24
	Gadbury-Amyot 1999	OHRQOL for Dental Hygiene	1999 GADBURY-AMYOT et al., [51]	1	
	OQLQ	Orthognathic Quality of Life Questionnaire	2000 CUNNINGHAM et al., [53]	1	
	Sonoyama 2002	QoL in patients with fixed prosthesis	2002 SONOYAMA et al., [53]	1	
	OHIP-19 EDENT	OHIP for edentulous patients	2002 ALLEN; LOCKER [54]	1	
	LDF-TMDQ	Limitations of daily function-Temporo mandibular disorders questionnaire	2005 SUGISAKI et al., [55]	1	
	PIDAQ	Psychosocial Impact of Dental Aesthetics Questionnaire	2006 KLAGES et al., [56]	1	
	MHISS	Mouth Handicap is Systemic Sclerosis scale	2007 MOUTHON et al., [57]	1	
	SOOQ	Surgical Orthodontic Outcome Questionnaire	2007 LOCKER et al., [58]	1	
	OES	Oral Esthetic Scale	2010 LARSSON et al., [59]	1	
	DHEQ	Dentine Hypersensitivity Experience Questionnaire	2010 BOIKO et al., [60]	1	
	PQL	Prosthetic quality of life	2011 MONTERO et al., [11]	1	
	OHIP-22 TMD	OHIP for Temporo-mandibular disorders	2011 DURHAM et al., [61]	1	
	COMDQ	Chronic Oral Mucosal Diseases Questionnaire	2011 NI RIORDAIN; MCCREARY, [62]	1	
	Musurlieva 2012	Impact of Periodontal diseases on QOL	2012 MUSURLIEVA et al., [63]	1	
	OHIP-20 EDENT	OHIP for Spanish edentulous patients	2012 MONTERO et al., [64]	1	
	EORTC QLQ-OH17	European Organization for Research and Treatment of Cancer Quality of life Quest. Oral supplementary module	2012 HJERMSTAD et al., [65]	1	
	QoLIP-10	Quality of Life with Implant-Prostheses	2013 PRECIADO et al., [66]	1	
	Matijević2014	QoL after removing of impacted lower wisdom	2014 MATIJEVIĆ et al., [67]	1	
	OHIP-22 EDENT	OHIP for Chinese edentulous patients	2015 HE; WANG, [68]	1	
	OHIP-7	OHIP for Masticatory efficiency	2015 CUSSON et al., [69]	1	
	QoLDAS-9	Quality of Life associated with Dental Aesthetics Satisfaction	2015 PEREA et al., [70]	1	
	TOQOL	Teen Oral Health Quality of Life	2017 WRIGHT et al., [71]	1	
	OHIDL	Oral health impacts on Daily Living	2017 LIU et al., [72]	1	

Table 2 - Frequency and percentage of the studied variables

		n	%
OHRQoL Instrument and number of items	OHIP-14	81	30.92
	OHIP-49	44	16.79
	Other OHIP	29	11.07
	GOHAI-12	46	17.56
	OIDP-8	18	6.87
	Other OIDP	18	6.87
	Other OHRQoL	26	9.92
	Total	262	100.00
Year of publication by period	1990-2000	15	5.73
	2001-2005	42	16.03
	2006-2010	73	27.86
	2011-2017	132	50.38
	Total	262	100.00
Journal of publication by group of journals	Dental Public Health	64	24.43
	Dental	43	16.41
	Quality of life	20	7.63
	Others	135	51.53
	Total	262	100.00
Country of publication	English Speaking	67	25.57
	Portuguese speaking	28	10.69
	Germany/Netherlands	21	8.02
	Spanish Speaking	23	8.78
	Others	123	46.95
	Total	262	100.00
Validation as objective	yes	211	80.53
	no	51	19.47
	Total	262	100.00

Table 3 – Frequency and percentages by Type of validation and Cross-cultural adaptation

		Type of validation – n (%)				Cross-cultural adaptation – n (%)		
		Construct	EFA/PCA	CFA/TRI	Total	No	Yes	Total
Instrument Name-items	OHIP-14	62	11	8	81	74	7	81
		(76.54)	(13.58)	(9.88)	(100.00)	(91.36)	(8.64)	(100.00)
	OHIP-49	37	2	5	44	35	9	44
		(84.09)	(4.55)	(11.36)	(100.00)	(79.55)	(20.45)	(100.00)
	Other OHIP	18	8	3	29	28	1	29
		(62.07)	(27.59)	(10.34)	(100.00)	(96.55)	(3.45)	(100.00)
	GOHAI-12	21	21	4	46	43	3	46
		(45.65)	(45.65)	(8.70)	(100.00)	(93.48)	(6.52)	(100.00)
	OIDP-8	13	4	1	18	14	4	18
		(72.22)	(22.22)	(5.56)	(100.00)	(77.78)	(22.22)	(100.00)
	Other OIDP	15	2	1	18	15	3	18
		(83.33)	(11.11)	(5.56)	(100.00)	(83.33)	(16.67)	(100.00)
	Other	18	8	0	26	20	6	26
	OHRQoL	(69.23)	(30.77)	(0.00)	(100.00)	(76.92)	(23.08)	(100.00)
	Total	184	56	22	262	229	33	262
		(70.23)	(21.37)	(8.40)	(100.00)	(87.40)	(12.60)	(100.00)
			Pr = 0.001				Pr = 0.068	
Year of publication	1990-2000	10	5	0	15	14	1	15
		(66.67)	(33.33)	(0.00)	(100.00)	(93.33)	(6.67)	(100.00)
	2001-2005	36	6	0	42	36	6	42
		(85.71)	(14.29)	(0.00)	(100.00)	(85.71)	(14.29)	(100.00)
	2006-2010	45	21	7	73	63	10	73
		(61.64)	(28.77)	(9.59)	(100.00)	(86.30)	(13.70)	(100.00)
	2011-2017	93	24	15	132	116	16	132
		(70.45)	(18.18)	(11.36)	(100.00)	(87.88)	(12.12)	(100.00)
	Total	184	56	22	262	229	33	262
		(70.23)	(21.37)	(8.40)	(100.00)	(87.40)	(12.60)	(100.00)
			Fisher = 0.033				Fisher = 0.906	
Group of Journals	Dent. Pub. Health	46	16	2	64	60	4	64
		(71.88)	(25.00)	(3.13)	(100.00)	(93.75)	(6.25)	(100.00)
	Dental	26	13	4	43	40	3	43
		(60.47)	(30.23)	(9.30)	(100.00)	(93.02)	(6.98)	(100.00)
	Quality of Life	14	3	3	20	18	2	20
		(70.00)	(15.00)	(15.00)	(100.00)	(90.00)	(10.00)	(100.00)
	Others	98	24	13	135	111	24	135
		(72.59)	(17.78)	(9.63)	(100.00)	(82.22)	(17.78)	(100.00)
	Total	184	56	22	262	229	33	262
		(70.23)	(21.37)	(8.40)	(100.00)	(87.40)	(12.60)	(100.00)
			Fisher = 0.243				Fisher = 0.078	
Language	English	51	9	7	67	66	1	67
		(76.12)	(13.43)	(10.45)	(100.00)	(98.51)	(1.49)	(100.00)
	Portuguese	17	3	8	28	24	4	28
		(60.71)	(10.71)	(28.57)	(100.00)	(85.71)	(14.29)	(100.00)
	Germany/Netherlands	16	3	2	21	17	4	21
		(76.19)	(14.29)	(9.52)	(100.00)	(80.95)	(19.05)	(100.00)
	Spanish	12	9	2	23	18	5	23
		(52.17)	(39.13)	(8.70)	(100.00)	(78.26)	(21.74)	(100.00)
	Others	88	32	3	123	104	19	123
		(71.54)	(26.02)	(2.44)	(100.00)	(84.55)	(15.45)	(100.00)
	Total	184	56	22	262	229	33	262
		(70.23)	(21.37)	(8.40)	(100.00)	(87.40)	(12.60)	(100.00)
			Fisher = 0.000				Fisher = 0.005	
Validation as an objective	yes	149	46	16	211	179	32	211
		(70.62)	(21.80)	(7.58)	(100.00)	(84.83)	(15.17)	(100.00)
	no	35	10	6	51	50	1	51
		(68.63)	(19.61)	(11.76)	(100.00)	(98.04)	(1.96)	(100.00)
	Total	184	56	22	262	229	33	262
		(70.23)	(21.37)	(8.40)	(100.00)	(87.40)	(12.60)	(100.00)
			Pr = 0.615				Pr = 0.011	

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7 FINAL CONSIDERATIONS

More than three decades had pass since the publication of Locker's conceptual framework (LOCKER, 1988). During this period, most efforts had been focused toward the development of instruments and their use seeking the association of different oral health situations with HRQoL. Also, many variations of the aforementioned measures had emerged with or without a proper process of validation. In the present study, within the limitations of a descriptive review, an assessment was performed regarding these aspects, 66 OHRQoL instruments where retrieved among 39 original versions, with 24 condition-specific measures (Appendix E – Tables 1 and 2). Validation was performed with EFA/PCA in 21,3% and CFA/IRT/SEM in 8,4%. Only 12,6% performed cross-cultural adaptation. The first validation with CFA/IRT/SEM was not found until 2006, showing a delay in the use of the technique similar to the late incorporation of the concept of OHRQoL years after HRQoL concept were already being studied (BRODER; MCGRATH; CISNEROS, 2007; FARQUHAR, 1995; GUYATT; FEENY; PATRICK, 1993). Most of the adaptations were performed for Portuguese and Spanish languages, being Portuguese the one with the highest number of CFA (Appendix E – Tables 3 to 13).

This review aimed to recover all instruments with any type of validation, focusing on FA studies, cultural adaptation, and scope of the instruments, presenting a comprehensive view of the current state of OHRQoL measures. The 39 original measures found were different from the results obtained by Locker and Allen (14 measures) (LOCKER; ALLEN, 2007), probably responding to an arising need of using condition-specific measures, where we found most of the instruments in the last decade, together with the demand of shorter and easily applicable versions (SLADE, 1997b), which also explains the large number of derived instruments found (OHIP alone presented 16 versions).

The conditions encompass by the different questionnaires are wide, some authors suggest to supplement generic with specific measures to address clinically important changes (GUYATT; FEENY; PATRICK, 1993). Nevertheless, similarly to HRQoL where there are numerous measures and little standardization (GARRATT, 2002), the heterogeneity in OHRQoL instruments represent a difficulty in the selection of an instrument and when comparing results of different condition-specific measures. It also complicates the

systematization of data for validation purposes.

When an instrument is used its validation must be present, either by a previous work that validates it in the same population or in a relatable one, or as a previous step in the methodology, showing validity for the situation where it will be applied. CFA does this by testing a postulated model to see whether it is adequate to explain the observed data (FAYERS; HAND, 1997). The present work reflected that most studies relayed on construct validity, probably due to its relative simplicity. Even thou FA is not a new method (CHILD, 1975) it's late implementation, together with the low rate found, suggests that its application may be somehow more complex.

The aforementioned heterogeneity of measures makes it difficult to synthesize the CFA data for most instruments because, in addition to the low number of studies with CFA, they are wildly distributed among the different version. Important conclusions of FA studies (CAMPOS et al., 2015; MELLO DOS SANTOS et al., 2013b; MONTERO et al., 2010; NAIK et al., 2016; PILOTTO et al., 2016) may benefit from more research with CFA to compare results in similar populations and in different cultures. The high rate of other forms of construct validation found may be due to the simplicity of those methods in contrast to FA, but to really find an association between an instrument and its underlying model, a CFA is necessary since it is the only way to verify the factor structure of a set of observed variables, allowing to test the hypothesis that a relationship between them and their underlying latent constructs exists.

OHRQoL is a culturally defined concept (ALLISON; LOCKER; FEINE, 1997), so more cross-cultural adaptations are desirable in this regard. But it is also defined as a dynamic concept, as showed by Slade and Sanders (SLADE; SANDERS, 2011), so different adaptations in different time periods, considering the changes in individuals perceptions over time, will also be desirable. In the present study, a scope of the presence of cross-cultural validation was performed searching for references of guidelines and/or basic steps for a back-forward translation (BEATON et al., 2000; GUILLEMIN; BOMBARDIER; BEATON, 1993), but no deep analysis of the process of validation itself was performed, as the intention was only to see which instruments where presented as validated for the different populations. This may result in an over dimension

of the presence of cross-cultural validation.

The present study found that most of the cross-cultural validations were performed for Spanish and Portuguese languages, it was expected that the English language presented a low number of cross-cultural validations, since most instruments were developed in that language. Nevertheless, OHRQoL should be consider as a culturally and dynamic defined concept (ALLISON; LOCKER; FEINE, 1997), so more cross-cultural adaptations should be performed in the English speaking populations and in different periods of time. Also, the changes in the individuals perceptions over time may be considered, as showed by Slade and Sanders (SLADE; SANDERS, 2011). The inclusion of an early qualitative approach and FA in the adaptation process would be desirable. This may contribute to a conceptual and dimensional adaptation, as well as the incorporation of cultural features of the items content.

In conclusion, the present study was intended as a first step toward a more comprehensive analysis of the validity of instruments. The high heterogeneity of generic and condition-specific measures represents both a benefit, offering a wide broad of possibilities to policy makers and clinicians, and a difficulty to researchers when trying to synthetize the information about the psychometric properties scattered among all measures. A higher number of CFA studies would be desirable for a better understanding of the factorial structure of widely use instruments.

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APENDIXES

APPENDIX A - INSTRUMENTS INCLUDED IN SEARCH STRATEGY

- Oral Health Impact Profile (ohip and its variations)
- Oral Impact on Daily Performance (oidp)
- Geriatric Oral Health Assessment Index (gohai)
- Dental Impact on Daily Living (didl)
- Dental Impact Profile (dip)
- Social Impacts of Dental Disease (sidd)
- Oral Health Quality of Life – United Kingdom (ohqoluk)
- Positive Oral Health and Wellbeing (pohw)
- Orthognathic Quality of Life Questionnaire (oqlq)
- Malocclusion Impact Questionnaire (miq)
- Family Impact Scale (fis)
- Quality of Life with Implant-Prostheses (qolip 10)

APPENDIX B - PUBMED SEARCH FILTER

((aged[All fields] OR Age[Text word] OR adult[Mesh Terms] OR "Middle aged"[MeSH Terms] OR "of age"[Text word]) NOT (adolescen*[All fields] OR child*[All fields] OR "child, preschool"[MeSH Terms] OR infant*[All fields] OR gestation[All fields] OR neonatal[All fields])) AND ("oral health related quality of life"[tiab] OR "ohip*"[tiab] OR "oral health impact profile"[tiab] OR "oidp*"[tiab] OR "oral impact on daily performance"[tiab] OR "oral impact on daily performances"[tiab] OR "oral impacts on daily performance index"[tiab] OR "oral impacts on daily performances"[tiab] OR "gohai*"[tiab] OR "general oral health assessment index"[tiab] OR "geriatric oral health assessment"[tiab] OR "didl"[tiab] OR "dental impact on daily living"[tiab] OR "sidd"[tiab] OR "ohqoluk"[tiab] OR "dip"[tiab] OR "pohw"[tiab] OR "oqlq"[tiab] OR "miq"[tiab] OR "fis"[tiab] OR "family impact scale"[tiab] OR "qolip 10"[tiab] OR cosmin[tiab] OR "quality of life with implant prostheses qolip 10"[tiab]) AND (((instrumentation[sh] OR methods[sh] OR Validation Studies[pt] OR Comparative Study[pt] OR "psychometrics"[MeSH] OR psychometr*[tiab] OR clinimetr*[tw] OR clinometr*[tw] OR "outcome assessment (health care)"[MeSH] OR outcome assessment[tiab] OR outcome measure*[tw] OR "observer variation"[MeSH] OR observer variation[tiab] OR "Health Status Indicators"[Mesh] OR "reproducibility of results"[MeSH] OR reproducib*[tiab] OR "discriminant analysis"[MeSH] OR reliab*[tiab] OR unreliab*[tiab] OR valid*[tiab] OR coefficient[tiab] OR homogeneity[tiab] OR homogeneous[tiab] OR "internal consistency"[tiab] OR (cronbach*[tiab] AND (alpha[tiab] OR alphas[tiab])) OR (item[tiab] AND (correlation*[tiab] OR selection*[tiab] OR reduction*[tiab])) OR agreement[tiab] OR precision[tiab] OR imprecision[tiab] OR "precise values"[tiab] OR test-retest[tiab] OR (test[tiab] AND retest[tiab]) OR (reliab*[tiab] AND (test[tiab] OR retest[tiab])) OR stability[tiab] OR interrater[tiab] OR inter-rater[tiab] OR intrarater[tiab] OR intra-rater[tiab] OR intertester[tiab] OR inter-tester[tiab] OR intratester[tiab] OR intra-tester[tiab] OR interobserver[tiab] OR inter-observer[tiab] OR intraobserver[tiab] OR intra-observer[tiab] OR intertechnician[tiab] OR inter-technician[tiab] OR intratechnician[tiab] OR intra-technician[tiab] OR interexaminer[tiab] OR inter-examiner[tiab] OR intraexaminer[tiab] OR intra-examiner[tiab] OR interassay[tiab] OR inter-assay[tiab] OR intraassay[tiab] OR intra-assay[tiab] OR interindividual[tiab] OR inter-individual[tiab] OR intraindividual[tiab] OR intra-individual[tiab] OR

interparticipant[tiab] OR inter-participant[tiab] OR intraparticipant[tiab] OR intra-participant[tiab] OR kappa[tiab] OR kappa's[tiab] OR kappas[tiab] OR repeatab*[tiab] OR ((replicab*[tiab] OR repeated[tiab]) AND (measure[tiab] OR measures[tiab] OR findings[tiab] OR result[tiab] OR results[tiab] OR test[tiab] OR tests[tiab])) OR generaliza*[tiab] OR generalisa*[tiab] OR concordance[tiab] OR (intraclass[tiab] AND correlation*[tiab]) OR discriminative[tiab] OR "known group"[tiab] OR factor analysis[tiab] OR factor analyses[tiab] OR dimension*[tiab] OR subscale*[tiab] OR (multitrait[tiab] AND scaling[tiab] AND (analysis[tiab] OR analyses[tiab])) OR item discriminant[tiab] OR inter scale correlation*[tiab] OR error[tiab] OR errors[tiab] OR "individual variability"[tiab] OR (variability[tiab] AND (analysis[tiab] OR values[tiab])) OR (uncertainty[tiab] AND (measurement[tiab] OR measuring[tiab])) OR "standard error of measurement"[tiab] OR sensitiv*[tiab] OR responsive*[tiab] OR ((minimal[tiab] OR minimally[tiab] OR clinical[tiab] OR clinically[tiab]) AND (important[tiab] OR significant[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR (small*[tiab] AND (real[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR meaningful change[tiab] OR "ceiling effect"[tiab] OR "floor effect"[tiab] OR "Item response model"[tiab] OR IRT[tiab] OR Rasch[tiab] OR "Differential item functioning"[tiab] OR DIF[tiab] OR "computer adaptive testing"[tiab] OR "item bank"[tiab] OR "cross-cultural equivalence"[tiab] OR cosmin[tiab] OR ("Oral Health"[MeSH Major Topic] AND "Psychometrics/instrumentation"[MeSH Major Topic] AND "Quality of Life"[MeSH Major Topic])))

APPENDIX C - SCOPUS SEARCH FILTER

(TITLE-ABS-KEY (aged OR age OR adult OR "Middle aged" OR "of age"))

AND (TITLE-ABS-KEY ("oral health related quality of life" OR "ohip*" OR "oral health impact profile" OR "oidp*" OR "oral impact on daily performance" OR "oral impact on daily performances" OR "oral impacts on daily performance index" OR "oral impacts on daily performances" OR "gohai*" OR "general oral health assessment index" OR "geriatric oral health assessment" OR "didl" OR "dental impact on daily living" OR "sidd" OR "ohqoluk" OR "dip" OR "pohw" OR "oqlq" OR "miq" OR "fis" OR "family impact scale" OR "qolip 10" OR "quality of life with implant prostheses qolip 10"))

AND (TITLE-ABS-KEY (instrumentation OR "Validation Studies" OR "reproducibility of results" OR reproducib* OR "psychometrics" OR psychometr* OR clinimetr* OR clinometr* OR "observer variation" OR "discriminant analysis" OR reliab* OR valid* OR coefficient OR "internal consistency" OR (cronbach* AND (alpha OR alphas)) OR "item correlation" OR "item correlations" OR "item selection" OR "item selections" OR "item reduction" OR "item reductions" OR agreement OR precision OR imprecision OR "precise values" OR test-retest OR (test AND retest) OR (reliab* AND (test OR retest)) OR stability OR interrater OR inter-rater OR intrarater OR intra-rater OR intertester OR inter-tester OR intratester OR intra-tester OR interobserver OR inter-observer OR intraobserver OR intra-observer OR intertechnician OR inter-technician OR intratechnician OR intra-technician OR interexaminer OR inter-examiner OR intraexaminer OR intra-examiner OR interassay OR inter-assay OR intraassay OR intra-assay OR interindividual OR inter-individual OR intraindividual OR intra-individual OR interparticipant OR inter-participant OR intraparticipant OR intra-participant OR kappa OR kappa's OR kappas OR "coefficient of variation" OR repeatab* OR ((replicab* OR repeated) AND (measure OR measures OR findings OR result OR results OR test OR tests)) OR generaliza* OR generalisa* OR concordance OR (intraclass AND correlation*) OR discriminative OR "known group" OR "factor analysis" OR "factor analyses" OR "factor structure" OR "factor structures" OR

dimensionality OR subscale* OR "multitrait scaling analysis" OR "multitrait scaling analyses" OR "item discriminant" OR "interscale correlation" OR "interscale correlations" OR ((error OR errors) AND (measure* OR correlat*or AND evaluat*or AND accuracy OR accurate OR precision OR mean) OR "individual variability" OR "interval variability" OR "rate variability" OR "variability analysis") OR (uncertainty AND (measurement OR measuring)) OR "standard error of measurement" OR sensitiv* OR responsive* OR (limit AND detection) OR "minimal detectable concentration" OR interpretab* OR ((small* AND (real OR detectable) AND (change OR difference)) OR "meaningful change" OR "minimal important change" OR "minimal important difference" OR "minimally important change" OR "minimally important difference" OR "minimal detectable change" OR "minimal detectable difference" OR "minimally detectable change" OR "minimally detectable difference" OR "minimal real change" OR "minimal real difference" OR "minimally real change" OR "minimally real difference" OR "ceiling effect" OR "floor effect" OR "Item response model" OR irt OR rasch OR "Differential item functioning" OR dif OR "computer adaptive testing" OR "item bank" OR "cross-cultural equivalence")))

APPENDIX D - GOOGLE SCHOLAR SEARCH FILTER

("(cuestionario|questionnaire)" "("Malocclusion Impact Questionnaire"|"Family Impact Scale"|FIS|Qlip|"Dental Impact on Daily Living"|DIDL|"Geriatric Oral Health Assessment Index"|GOHAI|"Social Impacts of Dental Disease"|"Oral Health Quality of Life"-United Kindom|OHQOL-UK|"Dental Impact Profile"|"Positive Oral Health and Wellbeing"|POHW|"oral health impact profile"|OHIP|"Oral impacts on daily performance"|OIDP|"Orthognatic Quality of Life Questionarie"|OQLQ|)" ("(systematic|sistemática)"|"(adult)")

APPENDIX E - TABLES

Table 1 - Retrieved Generic OHRQoL instruments

GENERIC INSTRUMENTS			
ID	**Name or description**	**Authors and year**	**n**
SIDD	Social Impacts of Dental Disease	(CUSHING; SHEIHAM; MAIZELS, 1986)	1
GOHAI	Geriatric Oral Health Assessment Index	(ATCHISON; DOLAN, 1990)	1
DIP	Dental Impact Profile	(STRAUSS; HUNT, 1993)	1
OHIP	Oral Health Impact Profile – Items: 49 (original), 14, 55, 54, 46, 45, 22, 7, 7 (NHANES), and 5	(SLADE; SPENCER, 1994)	10
SOHSI	Subjective Oral Health Status Indicators	(LOCKER; MILLER, 1994)	1
DIDL	Dental Impact on Daily Living – Items: 49 (original), 36, and 33	(LEAO; SHEIHAM, 1996)	3
OHQOL	Oral Health Related Quality of Life Measure – Items: 3 (final) and 8	(KRESSIN et al., 1996)	2
OIDP	Oral Impact on Daily Performances Items: 8 (original), 3, 7, 9, 10, 11, and 12	(ADULYANON; VOURAPUKJARU; SHEIHAM, 1996)	7
OH-QoL	Oral Health Quality of Life Inventory	(CORNELL et al., 1997)	1
ICSII-OHRQOL	International Collaborative Study on Oral Health Care Systems	(CHEN; ANDERSEN; BARMES, 1997)	1
Rand Health Insurance Study.	Dental health questions from the Rand Health Insurance Study	(DOLAN; GOOCH, 1997)	1
Gift1997	Oral clinically assessed impairment and self-reported acute symptoms affecting QoL	(GIFT; ATCHISON; DAYTON, 1997)	1
OHQoL-UK	Oral Health Quality of Life – United Kingdom	(MCGRATH; BEDI, 2001)	1
FIS	Family Impact Scale – Items: 14 (original), 19, and 8	(LOCKER et al., 2002)	3
Chavers 2003	Incidence of oral disadvantages. Two years and chronical	(CHAVERS; GILBERT; SHELTON, 2003)	1
LORQ (v1-v3)	The Liverpool Oral Rehabilitation Questionnaire	(PACE-BALZAN et al., 2006)	1
Bagewitz 2005	Questions derived from literature analysis on conditions for oral health	(BAGEWITZ et al., 2005)	1
OQOL	Oral Quality Of Life – Items: 6 (short form), and 12 (long form)	(KRESSIN et al., 2008)	2
Daneshvar 2015	Young Adults age-specific self-perception issues and physical and social impediments	(DANESHVAR et al., 2015)	1
John 2016	Four-dimensional model	(JOHN et al., 2016)	1
POHW	Positive Oral Health and Wellbeing	(ZINI et al., 2016)	1
n = number of retrieved versions		**TOTAL:**	**42**

Table 2 - Retrieved Specific OHRQoL instruments

SPECIFIC INSTRUMENTS			
ID	**Name or description**	**Reference**	**n**
OHIP-30 TMD	OHIP for TMD	(MURRAY et al., 1996)	1
Gadbury-Amyot1999	OHRQOL for Dental Hygiene	(GADBURY-AMYOT et al., 1999)	1
OQLQ	Orthognathic Quality of Life Questionnaire	(CUNNINGHAM; GARRATT; HUNT, 2000)	1
Sonoyama 2002	QoL in patients with fixed prosthesis	(SONOYAMA et al., 2002)	1
OHIP-19 EDENT	OHIP for edentulous patients	(ALLEN; LOCKER, 2002)	1
LDF-TMDQ	Limitations of daily function-TMD questionnaire	(SUGISAKI et al., 2005)	1
PIDAQ	Psychosocial Impact of Dental Aesthetics Questionnaire	(KLAGES et al., 2006)	1
MHISS	Mouth Handicap is Systemic Sclerosis scale	(MOUTHON et al., 2007)	1
SOOQ	Surgical Orthodontic Outcome Questionnaire	(LOCKER et al., 2007)	1
OES	Oral Esthetic Scale	(LARSSON P., JOHN M T, NILNER K, BONDEMARK L, 2010)	1
DHEQ	Dentine Hypersensitivity Experience Questionnaire	(BOIKO et al., 2010)	1
PQL	Prosthetic quality of life	(MONTERO; BRAVO; LOPEZ-VALVERDE, 2011)	1
OHIP-22 TMD	OHIP for TMD	(DURHAM et al., 2011)	1
COMDQ	Chronic Oral Mucosal Diseases Questionnaire	(NI RIORDAIN; MCCREARY, 2011)	1
Musurlieva 2012	Impact of Periodontal diseases on QOL	(MUSURLIEVA; STOYKOVA; BOYADJIEV, 2012)	1
OHIP-20 EDENT	OHIP for Spanish edentulous patients	(MONTERO et al., 2012)	1
EORTC QLQ-OH17	European Organization for Research and Treatment of Cancer QoL Quest. Oral sup. module	(HJERMSTAD et al., 2012)	1
QoLIP-10	Quality of Life Implant-Prostheses	(PRECIADO et al., 2013)	1
Matijević2014	QoL after removing of impacted lower wisdom	(MATIJEVIĆ et al., 2014)	1
OHIP-22 EDENT	OHIP for Chinese edentulous patients	(HE; WANG, 2015)	1
OHIP-7	OHIP for Masticatory efficiency	(CUSSON et al., 2015)	1
QoLDAS-9	Quality of Life associated with Dental Aesthetics Satisfaction	(PEREA et al., 2015)	1
TOQOL	Teen Oral Health Quality of Life	(WRIGHT et al., 2017)	1
OHIDL	Oral health impacts on Daily Living	(LIU; WONG; LO, 2017)	1
n = number of retrieved versions		**TOTAL:**	**24**

Table 3 - Frequency and percentage of the studied variables

Instrument	Freq.	Percent
OHIP-14	81	30.92
OHIP-49	44	16.79
Other OHIP	29	11.07
GOHAI-12	46	17.56
OIDP-8	18	6.87
Other OIDP	18	6.87
Other OHRQoL	26	9.92
Total	**262**	**100.00**

Year	Freq.	Percent
1990-2000	15	5.73
2001-2005	42	16.03
2006-2010	73	27.86
2011-2017	132	50.38
Total	**262**	**100.00**

Journal	Freq.	Percent
Dental Public Health	64	24.43
Dental	43	16.41
Quality of life	20	7.63
Others	135	51.53
Total	**262**	**100.00**

Country of data	Freq.	Percent
English Speaking	67	25.57
Portuguese speaking	28	10.69
Germany/Netherlands	21	8.02
Spanish Speaking	23	8.78
Others	123	46.95
Total	**262**	**100.00**

Is valid. an objective?	Freq.	Percent
yes	211	80.53
no	51	19.47
Total	**262**	**100.00**

Table 4 - Type of validation by instrument

Instrument Name-items	Type of validation			
	Construct	EFA/PCA	CFA/TRI	Total
OHIP-14	62	11	8	81
	76.54	13.58	9.88	100.00
OHIP-49	37	2	5	44
	84.09	4.55	11.36	100.00
Other OHIP	18	8	3	29
	62.07	27.59	10.34	100.00
GOHAI-12	21	21	4	46
	45.65	45.65	8.70	100.00
OIDP-8	13	4	1	18
	72.22	22.22	5.56	100.00
Other OIDP	15	2	1	18
	83.33	11.11	5.56	100.00
Other OHRQoL	18	8	0	26
	69.23	30.77	0.00	100.00
Total	184	56	22	262
	70.23	21.37	8.40	100.00
Pearson chi2(12) = 32.9942 Pr = 0.001				

Table 5 - Type of validation by year of publication

Publication Year	Type of validation			
	Construct	EFA/PCA	CFA/TRI	Total
1990-2000	10	5	0	15
	66.67	33.33	0.00	100.00
2001-2005	36	6	0	42
	85.71	14.29	0.00	100.00
2006-2010	45	21	7	73
	61.64	28.77	9.59	100.00
2011-2017	93	24	15	132
	70.45	18.18	11.36	100.00
Total	184	56	22	262
	70.23	21.37	8.40	100.00
Pearson chi2(6) = 13.0087 Pr = 0.043 Fisher's exact = 0.033				

Table 6 - Type of validation by journal of publication

Journal	Type of validation			
	Construct	EFA/PCA	CFA/TRI	Total
Dental Public Health	46	16	2	64
	71.88	25.00	3.13	100.00
Dental	26	13	4	43
	60.47	30.23	9.30	100.00
Quality of life	14	3	3	20
	70.00	15.00	15.00	100.00
Others	98	24	13	135
	72.59	17.78	9.63	100.00
Total	184	56	22	262
	70.23	21.37	8.40	100.00
Pearson chi2(6) = 7.3285 Pr = 0.292 Fisher's exact = 0.243				

Table 7 - Type of validation by language

Language of Country of data	Type of validation			
	Construct	EFA/PCA	CFA/TRI	Total
English	51	9	7	67
	76.12	13.43	10.45	100.00
Portuguese	17	3	8	28
	60.71	10.71	28.57	100.00
Germany/Netherlands	16	3	2	21
	76.19	14.29	9.52	100.00
Spanish Speaking	12	9	2	23
	52.17	39.13	8.70	100.00
Others	88	32	3	123
	71.54	26.02	2.44	100.00
Total	184	56	22	262
	70.23	21.37	8.40	100.00
Pearson chi2(8) = 29.6294 Pr = 0.000 Fisher's exact = 0.000				

Table 8 - Type of validation by objective of the study

Is validation an objective?	Type of validation			
	Construct	EFA/PCA	CFA/TRI	Total
yes	149	46	16	211
	70.62	21.80	7.58	100.00
no	35	10	6	51
	68.63	19.61	11.76	100.00
Total	184	56	22	262
	70.23	21.37	8.40	100.00
Pearson chi2(2) = 0.9709 Pr = 0.615				

Table 9 - Cross-cultural adaptation by instrument

Instrument Name-items	Cross-cultural adaptation		
	No	Yes	Total
OHIP-14	74	7	81
	91.36	8.64	100.00
OHIP-49	35	9	44
	79.55	20.45	100.00
Other OHIP	28	1	29
	96.55	3.45	100.00
GOHAI-12	43	3	46
	93.48	6.52	100.00
OIDP-8	14	4	18
	77.78	22.22	100.00
Other OIDP	15	3	18
	83.33	16.67	100.00
Other OHRQoL	20	6	26
	76.92	23.08	100.00
Total	229	33	262
	87.40	12.60	100.00
Pearson chi2(6) = 11.7449 Pr = 0.068			

Table 10 - Cross-cultural adaptation by year of publication

Publication Year	Cross-cultural adaptation		
	No	Yes	Total
1990-2000	14	1	15
	93.33	6.67	100.00
2001-2005	36	6	42
	85.71	14.29	100.00
2006-2010	63	10	73
	86.30	13.70	100.00
2011-2017	116	16	132
	87.88	12.12	100.00
Total	229	33	262
	87.40	12.60	100.00
Pearson chi2(3) = 0.6956 Pr = 0.874 Fisher's exact = 0.906			

Table 11 - Cross-cultural adaptation by journal of publication

Journal	Cross-cultural adaptation		
	No	Yes	Total
Dental Public Health	60	4	64
	93.75	6.25	100.00
Dental	40	3	43
	93.02	6.98	100.00
Quality of life	18	2	20
	90.00	10.00	100.00
Others	111	24	135
	82.22	17.78	100.00
Total	229	33	262
	87.40	12.60	100.00
Pearson chi2(3) = 6.9896 Pr = 0.072 Fisher's exact = 0.078			

Table 12 - Cross-cultural adaptation by country

Language of Country of data	Cross-cultural adaptation		
	No	Yes	Total
English Speaking	66	1	67
	98.51	1.49	100.00
Portuguese speaking	24	4	28
	85.71	14.29	100.00
Germany/Netherlands	17	4	21
	80.95	19.05	100.00
Spanish Speaking	18	5	23
	78.26	21.74	100.00
Others	104	19	123
	84.55	15.45	100.00
Total	229	33	262
	87.40	12.60	100.00
Pearson chi2(4) = 11.0245 Pr = 0.026 Fisher's exact = 0.005			

Table 13 - Cross-cultural adaptation by objective of the study

Is validation an objective?	Cross-cultural adaptation		
	No	Yes	Total
yes	179	32	211
	84.83	15.17	100.00
no	50	1	51
	98.04	1.96	100.00
Total	229	33	262
	87.40	12.60	100.00
Pearson chi2(1) = 6.5056 Pr = 0.011			