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Research Article
Determining Validity and Reliability of Oral Health-related Quality of Life Instrument for Clinical Consequences of Untreated Dental Caries in Children

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Abstract

Background and Objective: Many instruments have been developed to measure oral health-related quality of life for dental disease, however, no measurement available on clinical consequences of untreated dental caries, specifically for children. The aim of this study was to develop an instrument in this purpose derived from child oral health-related quality of life (COHRQoL) and determine its validity and reliability. **Methodology:** At first stage of the study, measuring of content validity of preliminary study was conducted on a sample of 34 students, between 6 and 12 years-of-age. All subjects completed the pilot COHRQoL-25 questionnaire, which measure five dimensions for clinical consequences of untreated caries included functional limitations, physical well-being, emotional well-being, social well-being and school. The second stage of this study was construct validity through principal components factor analysis on a sample of 400 students. Each component in the assessment instruments demonstrated internal consistency (alpha range = 0.847-0.940). **Results:** The validity coefficient for functional limitations was 0.847, physical well-being 0.877, emotional well-being 0.891, social well-being 0.845 and school 0.839 and the reliability coefficient (Cronbach's alpha) for functional limitations was 0.939, physical well-being 0.933, emotional well-being 0.931, social well-being 0.940 and school 0.940. Correlational analysis demonstrated a core of critical instrument items to be considered for future assessment of the quality of life. **Conclusion:** This study revealed, all items showed high coefficient, provided evidence that the developed instrument (OHRQoL-25) is valid and reliable for assessing oral health-related quality of life with the clinical consequences of untreated dental caries in children.

Key words: Child, indices/instrument, 5 dimensions, oral health, quality of life, untreated dental caries, validity, reliability

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Data Availability: All relevant data are within the paper and its supporting information files.

INTRODUCTION

Oral health is an essential part of general health and an important factor that impacts quality of life. The definition of quality of life by the World Health Organization (WHO) is "individual's perception of their position in life in the context of the culture and value system, where they live and in relation to their goals, expectations, standards and concerns[1]". Quality of life is influenced by numerous factors, one of which is health, defined by the WHO as "a state of complete physical, social and mental well-being and not merely the absence of disease or infirmity[1,2]".

Despite improvements in oral health in high-income countries during the last decades, dental caries is still a major global public health problem. For the last 70 years, data on caries have been collected worldwide using the DMFT/dmft index. This classical index provides information on caries and restorative and surgical treatment but fails to provide information on the clinical consequences of untreated dental caries, which may be more serious than the caries lesions themselves[3]. Untreated dental caries can lead to pulpal involvement, ulceration, fistula and/or abscess, which later can cause of tooth loss and affect children's growth and their general health.

In 2007, the WHO World Health Assembly recognized the growing burden of oral diseases worldwide and emphasized the need to scale up action based on comprehensive data collection systems. An index was developed, called PUFA/pufa index, used to assess the presence of clinical conditions resulting from untreated dental caries. The index was recorded separately from the DMFT/dmft and scored the presence of either a visible pulp, ulceration of the oral mucosa due to tooth fragments, a fistula or an abscess were secore. Lesions in the surrounding tissues which were not related to a carious tooth with pulpal involvement were not recorded.

Numerous measures have been developed in recent years to assess the effect of oral health problems on individual's physical, mental and social health and well-being[4,5]. Instrument development in the area of oral health-related quality of life (OHRQoL) initially focused on adult and geriatric populations. More recently, interest has centered on assessing the OHRQoL for children and adolescents[5]. A few studies have been conducted to verify the impact of different dental injuries on self-perception and quality of life in children and adolescents, considering their relationship with lifestyle and social environment.

Among the instruments used in dentistry, the Oral Health Impact Profile (OHIP) is considered a consistent tool to identify the OHRQoL dimensions and is widely used in cross-sectional and longitudinal studies[2]. Broder and Wilson-Genderson[3] developed an adapted version of the OHIP for children and namely Child Oral Health Impact Profile (COHIP). This questionnaire consists of two parallel inquiries, one for children and one for parents[2]. Both inquiries comprise the 34 items of the COHIP divided over 5 domains. The parent's questionnaire contained an extra scale: "Family impact" comprising 9 items. The Child Perceptions Questionnaire (CPQ) developed by Jokovic measures the extent of the oral health impact on quality of life reported by children[6]. It is composed of 3 items distributed among 4 domains: Oral symptoms, functional limitation, emotional well-being and social well-being. However, to facilitate its use in population-based studies, some versions were developed with only 16 and 8 items[2,3,7]. Pahel *et al.*[7] has developed the Early Childhood Oral Health Impact Scale (ECOHIS) to measure the parental perceptions regarding the impact of their children's oral health condition on their daily lives. The ECOHIS consists of 13 questions divided into 6 domains, which are child symptoms domain, child function domain, child psychological domain, child self-image per social interaction domain, parent distress domain and family function domain[7]. The results obtained by using these instruments are usually reported as a score system, which indicates the severity of the outcome measures or oral diseases.

Information on quality of life allows the evaluation of feeling and perceptions in the individual level, increasing the possibility of effective communication between professionals and patients, better understanding of the impact of oral health on the lives of the subject and family and measuring the clinical results of services provided. In public health, quality of life measurement in a useful tool to plan welfare policies because it is possible to determine the population needs, priority of care and evaluation of adopted treatment strategies, thus helping in the decision making process. Regarding study, these measurement tools help to assess the outcomes of treatments or actions and further develop guidelines for evidence-based clinical practice.

Most methods to measure self-perceived oral health were developed in english-speaking countries and the health outcome measures can be influenced by cultural and conceptual differences[2]. Ikebe *et al.*[8] stated that if researchers have no appropriate OHRQoL measure in their own language, they have two options: to develop a new measure or to modify one previously validated in another language, which is known as cross-cultural adaptation[7].

A direct translation of existing instruments is inadequate because it keeps the disadvantages of the original questionnaire and does not permit modifications, which reflect differences in culture and values. Even when a translation is done with great care, cultural factors may not be accurately conveyed[8]. The aim of this study is to develop an instrument suitable for the usage in Indonesia, which has multiple tribes and varied cultural beliefs and determine its validity and reliability.

MATERIALS AND METHODS

Study participants were children ages 6-12 years old who did not have systemic and/or mental development disorders. The subjects and their parents were informed about their participation in this study and stated their willingness to participate in the study through an informed consent prior to administration of the questionnaire and dental exam. This study was conducted in two stages, which are qualitative explorative and quantitative confirmatory.

Development of the instrument

Step 1: Qualitative explorative: The instrument was developed from the COHIP, CPQ 11-14 and ECOHIS. The basic theories of child development and consultations of some experts provided the basis for this development. There were 7 experts participating in the development process of questionnaire; those experts were 5 experts in dental public health and 2 experts of public health. The experts also helped choose the recall period and response options, write instructions and construct the grammar and language for the questions.

The questionnaire was then assessed for readability, comprehension, ease of administration and its face validity and reliability in a study that involved a convenience sample of 34 subjects from populations attending government and private primary schools in the Medan city. Following self-administration of the questionnaire, a qualitative interview was conducted concerning each child's understanding of instructions, wording of items, recall period and response options.

Step 2: Quantitative confirmatory: The second stage of this study was conducted at 4 primary schools in Medan; two of which were government primary schools and the other two were private primary schools in inner and outer Medan city. The samples for this stage were 400 subjects, divided into 100 subjects per schools. The schools and subjects participating were picked randomly using multistage cluster random sampling. This study was approved by the Bioethics Research Committee, Faculty of Medicine at University of Sumatera Utara in Medan, Indonesia.

The criteria for the PUFA/pufa index were applied on the examination. The PUFA index records the presence of severely decayed teeth with visible pulpal involvement (P/p), ulceration caused by dislocated tooth fragments (U/u), fistula (F/f) and abscess (A/a)[9]. Only one score is assigned per tooth. In case of doubt concerning the extent of odontogenic infection, the basic score (P/p for pulp involvement) is given. If the primary tooth and its permanent successor tooth are present and both present stages of odontogenic infection, both teeth will be scored. Uppercase letters (PUFA) are used for the permanent dentition and lowercase letters (pufa) used for the primary dentition. They are reported separately, the score of an individual person can range from 0-20 for the primary dentition and 0-32 for the permanent dentition[9].

To ensure consistent clinical judgement, 10 examiners participated in the study and underwent 2 days of theoretical and clinical training in PUFA/pufa diagnosis. The questionnaire was then administered following the dental examination. Filling the questionnaire happened both individually and assisted on children who were still not very good in reading and writing.

Data from the dental examinations and paper questionnaires were entered into a computer. Validity of the questionnaire was tested again using the Pearson's correlation test and the reliability was tested using the Cronbach's alpha. The socio-demographic variables available for this study were sex, age, parent's age, educational level and employment status, PUFA/pufa status and the quality of life of the children (Table 1). Univariate analysis were conducted for all variables. Bi-variable associations of socio-demographic status and PUFA/pufa status, PUFA/pufa status and quality of life and socio-demographic status and quality of life were analyzed using linear regressions and *post hoc* test. Statistical significance was inferred at $p < 0.05$.

RESULTS

Step 1: Description of the developed instrument: Item statements were derived from a review of the literature concerning to quality of life index such as COHIP, CPQ 11-14 and ECOHIS. The questionnaire resulted consists of 25 questions organized into 5 health dimensions (Table 2): (1) Functional limitations, (2) Physical well-being, (3) Emotional well-being, (4) Social well-being and (5) School.

Table 1: Socio-demographic characteristics of 400 children and their parents

Variables	n	(%)
Children		
Age (years)		
6	43	10.75
7	73	18.25
8	59	14.75
9	55	13.75
10	72	18.00
11	62	15.50
Sex		
Boy	118	47
Girl	212	53
Parental education and occupation		
Age (years)		
21-30	20	5
31-40	204	51
41-50	154	38.50
>50	22	5.05
Education level		
No school/elementary school	30	7.50
Junior high school	44	11
High school	184	46
College/bachelor's degree	142	35.50
Occupation		
Not working	198	49.50
Labor	15	3.75
Government employee/PNS	42	10.50
Private employee	57	14.25
Businessman	88	22

Table 2: Questions included in the 5 dimensions of the developed instrument

Dimension	No. of questions	Question
Funtional limitation	5	Difficulty chewing or biting food
		Difficulty eating foods you like
		Had food caught between teeth
		Difficulty pronouncing any words (espesially f, s, t)
		Avoided brushing the teeth
Physical well-being	5	Teeth, gums sensitive to hot/cold things
		Had pain in your teeth
		Had bad breath
		Had headache
		Had fever
Emotional well-being	5	Felt irritable per frustrated
		Felt embarrassed
		Less confident
		Avoided smiling per laughing
		Trouble in sleeping
Social well-being	5	Avoided speaking with friends
		Avoided meeting per playing with friends
		Been teased, bullied by other children
		Avoided usual activity of daily living (room clean up)
		Avoided outside the home
School	5	Difficulty of paying attention in school
		Avoided doing homework
		Avoided speaking per reading out loud in class
		Avoided doing extra-curricular activity (gym, art)
		Avoided going to school

Each dimension consists of five questions asking about the frequency of events in the previous one month in relation to the clinical consequences or impact of untreated caries. The response options are: "never" = 1; "sometimes (once or twice a month)" = 2 and "often (almost every week)" = 3.

Table 3: Validity and reliability coefficient of quality of life dimension

Dimension	Corrected item-total correlation	Cronbach's alpha if item deleted
Functional limitation		
Difficulty chewing or biting food	0.773	0.785
Difficulty eating foods you like	0.748	0.793
Had food caught between teeth	0.681	0.813
Difficulty pronouncing any words (especially f, s, t)	0.461	0.813
Avoided brushing the teeth	0.639	0.822
Physical well-being		
Sensitive to hot/cold things	0.689	0.790
Had pain in your teeth	0.678	0.793
Had bad breath	0.619	0.811
Had headache	0.615	0.812
Had fever	0.606	0.814
Emotional well-being		
Felt irritable per frustrated	0.704	0.838
Felt embarrassed	0.709	0.837
Less confident	0.711	0.837
Avoided smiling per laughing	0.697	0.840
Trouble in sleeping	0.644	0.853
Social well-being		
Avoided speaking with friends	0.717	0.783
Avoided meeting per playing with friends	0.709	0.786
Been teased, bullied or called names by other children	0.613	0.814
Avoided usual activity of daily living (room clean up)	0.573	0.823
Avoided outside the home	0.596	0.817
School		
Difficulty of paying attention in school	0.776	0.860
Avoided doing homework	0.764	0.863
Avoided speaking per reading out loud in class	0.754	0.863
Avoided doing extra-curricular activity (gym, art)	0.752	0.866
Avoided going to school	0.640	0.890

Table 4: Analysis of linear correlation between item to quality of life dimension

Quality of life dimension	Corrected item-total correlation	Cronbach's alpha if item deleted
Functional limitation	0.847	0.939
Physical well-being	0.877	0.933
Emotional well-being	0.891	0.931
Social well-being	0.845	0.940
School	0.839	0.940

Using the domains identified by Jokovic *et al.*[6] as a guide we identified four descriptive domains for items included in the child impact section (symptoms, function, psychological, self-image per social interaction) and two domains for the family impact section (parent distress, family function).

Step 2: Validity and reliability of the developed instrument: Validity and internal consistency reliability of the OHRQol-25 was assessed among samples (n = 400) and they also underwent an examination for dental caries and treatment experience by trained and standardized dental examiners. Table 3 shows the validity and reliability of the five dimensions. The item-to-total correlation coefficient range was 0.613-0.866. Cronbach's alpha coefficients on each of components demonstrated high value, the coefficient range was 0.783-0.890. Cronbach's alphas were computed for each of the five defined components. Almost all the items reflected similar Cronbach's alpha scores to those from the previous study by Jokovic *et al.*[6] some being higher and others slightly lower. The reliability was determined by an analysis of inter-item correlation matrix: An examination of corrected average inter-item and item-to-total correlation coefficients. The elimination of items in an instrument based on low correlations increases the homogeneity and coefficient alpha. A factor analysis determined that the components and their items created in the first study adequately supported those initially identified from first trial in convenience samples of 34 subjects, with somewhat different assessment items under each component. In order to continue with instrument refinement using item reduction, while also maintaining high levels of reliability.

Table 4 shows overall Cronbach alpha of common composite quality of life in children is larger than 0.6, which means having good reliability. The dimensions of emotions had the highest value (0.891), followed by physical dimension (0.877), functional limitation dimension (0.847), social well-being (0.845) and the lowest is school dimension (0.839).
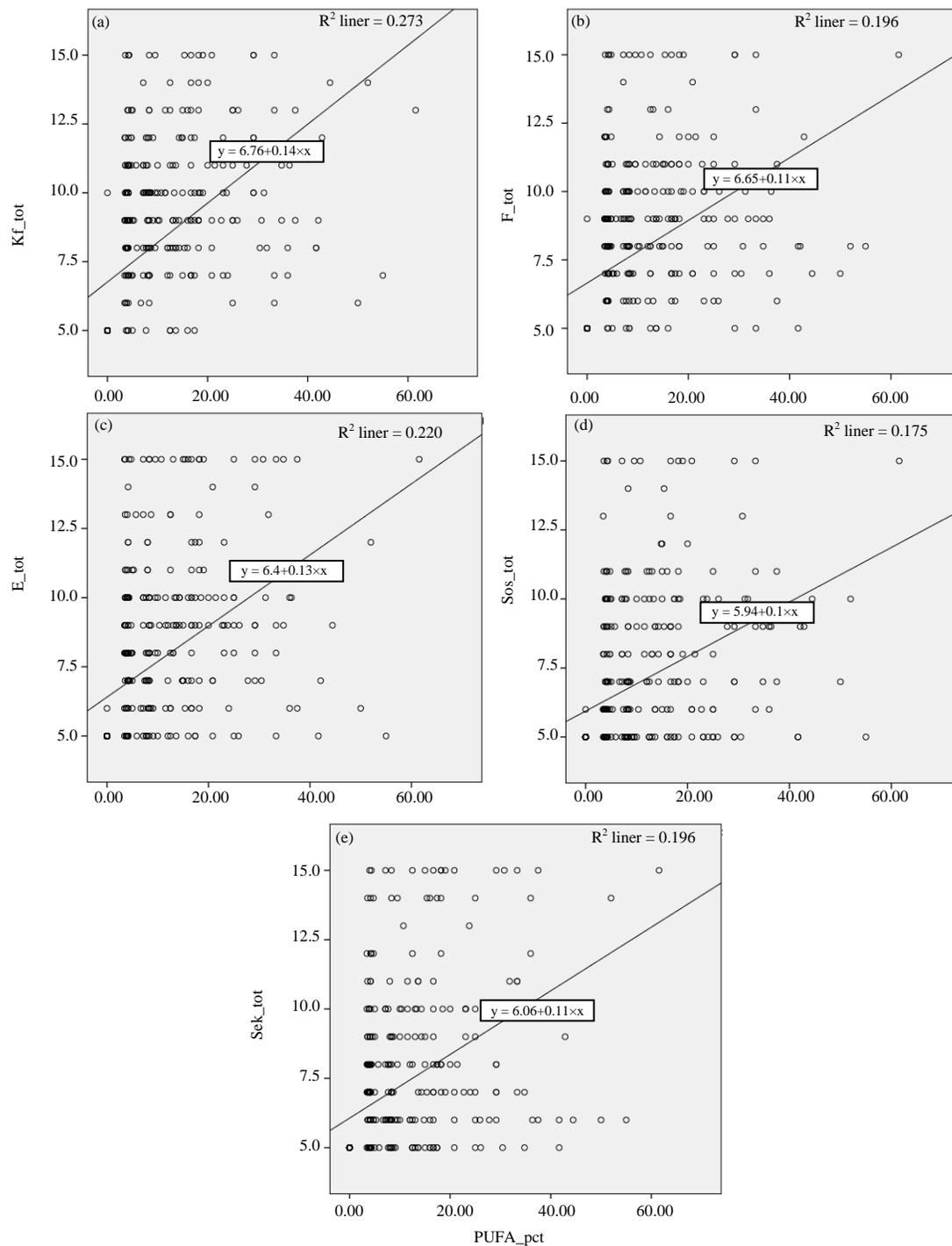
Fig. 1(a-e): Linear equations for relation between PUFA index and quality of life, (a) Functional limitation, (b) Physical well-being, (c) Emotional well-being, (d) Social well-being and (e) School dimensions

All dimensions have value an item-to-total correlation coefficient more than 9.2, which means all dimensions have good validity against common composite of the quality of life in children (Table 4).

Figure 1 shows the linear equation for relation between the quality of life dimensions with PUFA index. The coefficient determinant for functional limitation dimension is $R^2 = 0.27$ (Fig. 1a), physical well-being $R^2 = 0.20$ (Fig. 1b), emotional

well-being R^2 = 0.22 (Fig. 1c), social well-being R^2 = 0.18 (Fig. 1d) and school dimension R^2 = 0.20 (Fig. 1e), respectively. The equation regression line explained that relation of all dimensions to PUFA index was good and patterned positive, which means that the higher PUFA index, the higher the dimensions quality of life.

DISCUSSION

Oral health could affect general health by causing considerable pain and suffering and finally by changing the quality of life. Oral health affects people physically and psychologically and influences how they grow, speak, chew, taste food and socialize as well as their feelings of social well-being. Severe caries detracts from children's quality of life: they experience pain, discomfort, disfigurement, acute and chronic infections and eating and sleep disruption as well as higher risk of hospitalization, high treatment costs and loss of school days with the consequently diminished ability to learn. Caries affects nutrition, growth and weight gain. Children under 5 years of age with nursing caries weighed about 1 kg less than control children because toothache and infection alter eating and sleeping habits, dietary intake and metabolic processes[10].

A million of children suffer from toothache and poor quality of life and end up with few teeth. Toothache leads to school absence, which is an indicator of children's health. Many children with untreated caries have pulpal involvement, ulceration, fistula and suppuration per abscess, therefore, the program planners continue to overlook oral diseases, despite their significant impact on cost and quality of life.

Contemporary concepts of health suggest that oral health should be defined in general physical, psychological and social well-being terms in relation to oral status. Disruptions in physical, psychological and social functioning are therefore, important in assessing oral health. Traditional measures use mainly clinical indices, though there are alternatives using measures of oral health-related quality of life in socio-dental approaches to assessing need.

Chronic diseases included caries are increasing in developing countries, with the implication that quality of life related to oral healthas well as general quality of life might be deteriorated. Therefore, when measuring the impact of dental disease, it is important to assess not only the clinical changes in the mouth but also the effects of the disease on quality of life. Oral health-related quality of life is measured in relation not only to know how the mouth and teeth affect physical, emotional and social well-being but also to functional activities such as eating, chewing, swallowing and speaking. Measures of quality of life are useful in identifying a wide range of the impacts of childhood illnesses[3].

A number of valid and reliable instruments for measuring children's oral health quality of life are available including child oral impact daily performance (child-OIDP), Child Perception Questionnaire (CPQ) for different ages, parent-CPQ and Early Childhood Oral Health Impact Scale (ECOHIS) for preschool children and child oral health impact profile (COHIP)[3,6,7]. The OHRQol-25 was developed recently for this purpose. Cohen and Jago consider the greatest contribution of dentistry is to improve quality of life[10].

The present study evaluated the properties of the Indonesian version of modified OHRQol by determining its validity and reliability using construct validity, internal consistency and test reliability. Internal consistency was satisfactory with Cronbach's alpha coefficient (>0.60) for all dimensions. As shown in Fig. 1, the logistic regression analysis between quality of life dimensions and PUFA index have a good relation with moderately correlated (r>0.4). This finding shows that almost all the variation of quality of life dimension The item-to-total correlation coefficient range was 0.613-0.866 (Table 3). Based on these findings, it was concluded that most items in each component fit within the parameters of being acceptable, thus providing the component with a high level of reliability. These results support continuing with all items for future study purpose.

CONCLUSION

The new instrument demonstrated adequate outcomes in terms of validity and reliability, therefore this finding suggests that OHRQoL-25 questionnaire was able to detect the impact of clinical consequences of untreated dental caries in school children. The OHRQoL-25 might be valuable as quality of life instrument for assessing clinical consequences of untreated dental caries in children. Information gathered from the instruments will contribute to their further theory development and practice not only in the increasing study of oral health but also more globally for general health care. By integrating oral health into strategies for promoting general health, health care practitioners can also greatly enhance both general and oral health.

ACKNOWLEDGMENT

SIGNIFICANCE STATEMENTS

To date, there is no literature describing a validated instrument suitable for Indonesian, which has multiple tribes and varied cultural beliefs. The quality of life related to oral health assessment is needed to evaluate health programs to improve oral and general health. The question is whether government programs improved the quality of life of Indonesian. The Indonesian government implemented universal health coverage in 2014, to bear in mind that measuring quality of life related to oral health plays a big role in the success of this policy. This manuscript is a previously unpublished study and no other submission or publication will be made. All of the authors participated in the study agreed to the content of the manuscript.

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