Validity and reliability of the Indonesian version of COMDQ-26: A Pilot Study

by Carolina Damayanti Marpaung

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Validity and reliability of the Indonesian version of COMDQ-26: A Pilot Study

J.V. Winarto, I. Gunardi*, C.D. Marpaung, & R. Amtha
Faculty of Dentistry, Universitas Trisakti, Indonesia
W.M.N. Ghani
Oral Cancer Research & Coordinating Centre, Faculty of Dentistry, University of Malaya, Kuala Lumpur, Malaysia

*Correspondence: indrayadi@trisakti.ac.id

ABSTRACT: Oral mucosal diseases, such as acute and chronic oral lesions, may have an impact on an individual's quality of life. OHRQoL is a tool that can be used to determine whether an individual's quality of life is impaired by oral diseases. One of the OHRQoLs that has been utilized often for chronic oral mucosal diseases is the COMDQ-26. This study aims to analyze the Indonesian COMDQ-26 indices' validity and reliability in patients with both acute and chronic oral lesions. An analytic observational study using a cross-sectional design was conducted on subject with oral lesions. Indonesian version of COMDQ-26 was constructed and tested on 30 subjects. Rasch model was used to analyze data. Population was found predominantly female (76.6%) with age >30-40 years old (33.33%). Acute oral lesions were found to have a COMDQ-26 score of 31 (24–53), but chronic oral lesions was shown to have a score of 32 (13–73). The Cronbach alpha for the Indonesian version of the COMDQ-26 was 0.83 and the item reliability was 0.92 with separation of 3.35. Unidimensionality score was 4.3. The Indonesian version of the COMDQ-26 shown strong construct validity, despite the fact that it is still unable to distinguish between the impact of quality of life based on the type of oral lesion. The use of the Indonesian version of the COMDQ-26 has to be reconfirmed by additional investigation.

1 INTRODUCTION

Oral health problems remain a significant problem due to their prevalence and significance as indicators of health impairment (Tahun et al., 2019). The Global Burden of Disease Study in 2019 estimated that oral diseases affect nearly 3.5 billion people worldwide. The most frequent cases are caries, periodontal disease, oral cancer, oro-dental trauma, cleft lip and palate, and noma (Seattle: Institute of Health Metrics and Evaluation (IHME), 2020).

Oral mucosal lesions may range from mere discolouration, variation in surface characteristics, swelling, or loss of integrity of the oral mucosal. (Kesehatan, 2019)For the most part, these mucosal lesions are benign and require only symptomatic treatment, and some lesions may interfere with the quality of daily life in affected patients (Villanueva-Vilchis et al., 2016).

WHO recognizes OHRQoL as an essential segment of the Global Oral Health Program to provide an understanding of the impact of oral disease on daily life and quality of life (Bennadi & Reddy, 2013). Of the various types of OHRQoL, Chronic Oral Mucosal Diseases Questionnaire-26 (COMDQ-26) is a specific questionnaire developed in oral medicine (Ni Riordain et al., 2011). This questionnaire is a patient-centred approach and has demonstrated acceptable validity and reliability to support it's use (Li & He, 2013; Ni Riordain & Mccreary, 2012).

COMDQ-26 is an oral health-related QOL instrument that contains 26 items. The items are grouped into four domains: pain and functional limitations, medications and treatments, social and emotional status, and patient support. For each questionnaire, patients answer using a Likert-type response scale (Rajan et al., 2014) This questionnaire was created to determine the impact on quality of life

due to chronic oral lesions. This questionnaire has been validated in subjects with oral lesions such as oral lichen planus, pemphigus vulgaris, mucous membrane pemphigoid, recurrent aphthous stomatitis and oral granulomatosis. (Li & He, 2013; Ni Riordain et al., 2016; Ni Riordain & Mccreary, 2012) Previous studies comparing OHIP-14 and COMDQ-26, found that COMDQ-26 has discriminant and convergent validity and reliability qualities.(Ni Riordain & Mccreary, 2012)

The validity and reliability of the COMDQ-26 have been evaluated in the English version but have yet to be in the Indonesian version. Therefore, this pilot study aimed to validate the COMDQ-26 Indonesian version, thus beneficial to be applied in an Indonesian clinical setting. This questionnaire specifically determined the quality of life impact based on the oral lesion that may occur in the oral mucosa.

2 METHODS

An observational analytic study was conducted with a cross-sectional design. A total of 32 subjects was obtained by consecutive sampling from August to December 2022. The inclusion criteria included subjects aged >18 with an oral mucosal lesion. All subjects signed informed consent before the questionnaire was filled out. One oral medicine specialist did oral lesion detection. Ethical clearance was obtained from the Ethical Commission Faculty of Dentistry Universitas Trisakti 022/S3/KEPK/FKG/7/2022.

The COMDQ-26 questionnaire contains 26 questions divided into four domains, namely pain and functional limitations (9 items), medications and treatments (6 items), social and emotional status (7 items), and patient support (4 items). The Likert scale was used for one single answer choice, such as very often (4), often (3), sometimes (2), very rarely (1), and never (0).

The COMDQ-26 questionnaire was translated from English to Indonesian by a certified translator. The validity and reliability of the questionnaires were then tested on 30 subjects with recurrent aphthous stomatitis whom an oral medicine specialist had diagnosed. The validity showed Cronbach alpha 0.83 item reliability 0.92 with separation 3.35. The unidimensional test showed an eigenvalue of 4.30 on the first contrast.

All data collected was analyzed by the Rasch model using the Winstep 4.3.4 program. The validity construct was deemed based on the score of Cronbach alpha (≥0.8), item and subject reliability (>0.8), and unidimensionality (eigenvalue >2.0).

3 RESULTS AND DISCUSSION

Out of 32 subjects, two were excluded based on incomplete data. Subjects were predominantly female (76.6%), aged >30-40 years old (33.33%), and had high school education (46.6%).

Table 1. Population characteristics

Variable	Male (n=7) n (%)	Female (n=23) n (%)
Age (year)		
20-30	-	4 (13.33)
>30-40	3 (10)	7 (23.33)
>40-50	1 (3.33)	6 (20)
>50-60	1 (3.33)	4 (13.33)
>60	2 (6.66)	2 (6.66)
Education		
Elementary school	1 (3.33)	6 (20)
Junior high school	-	-
High school	4 (13.33)	10 (33.33)
Diploma	-	3 (10)
Bachelor	1 (3.33)	4 (13.33)
Magister	1 (3.33)	-

Table 2. Summary of COMDQ-26 questionnaire statistics

Rasch model summary	Score	Reference
Cronbach alpha (KR-20)	0.83	≥0.8 (Excellent)
Probability	0.49	> 0.05
Mean	-0,05	Close to 0
SD	1.18	Close to 1
Chi-squared	1516.6170	-
Subject		
Infit MNSQ	0.96 logit	0.5 - 1.5
Infit ZSTD	-0.13 logit	-2 - 2
Outfit MNSQ	1.40 logit	0.5 - 1.5
Outfit ZSTD	0.31 logit	-2 - 2
Separation	1.99	Close to 2
Reliability	0.80	0.8-0.9 (Good)
Item		
Infit MNSQ	1.08 logit	0.5 - 1.5
Infit ZSTD	0.01 logit	-2 - 2
Outfit MNSQ	1.40 logit	0.5 - 1.5
Outfit ZSTD	0.19 logit	-2 - 2
Separation	3.35	Close to 3
Reliability	0.92	>0.9 (Excellent)

SD standard deviation; MNSQ mean square; ZSTD Z standard;

Table 2 shows that the COMDQ-26 questionnaire has a Cronbach alpha value of 0.83 which is in the excellent category. This is supported by the probability value above 0.05, the mean is close to 0, and the SD is close to 1. In addition, the MNSQ values for both infit and outfit are within the range of 0.5 to 1.5; the standard Z value for both infit and outfit is within the range of -2 to +2. Subject reliability was 0.80 in the Good category with a separation of 1.99, while item reliability was 0.92 in the Good category with a separation of 3.35.

Table 2 showed the chi-square value of 1516.6170 with a degree of freedom (df) 1,517 with a probability value of 0.49. The probability value indicates that the data has conformity with the Rasch model and the level of item difficulty is well distributed, as seen from the probability value of p, which is greater than 0.05, and the data is invariant. The mean value of -0.05 with SD 1.18 indicated that the data has a normal distribution where the mean value is close to 0 with an SD close to 1.

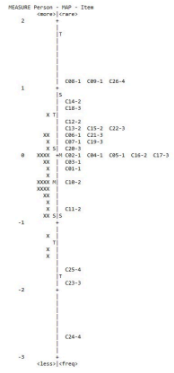
It appears from the results of the analysis in the person table that the MNSQ infit and outfit values have a value of 0.96 and 1.40 and are under the MNSQ value tolerance limit of 0.5-1.5; these results indicate that the response given by the subject as a whole is of good value. The outfit and infit ZSTD values are -0.13 and 0.31. This shows that the overall pattern of the subject's answers fit with the Rasch model with a limit that is between -2 to 2.113.

The subject reliability score reached 0.80, which is a good category. This shows that the overall pattern of the subject's answers fits well with the model.

Table 2 shows the summary results for items with an infit MNSQ value of 1.08 and an outfit MNSQ of 1.40 and under a tolerance limit of 0.5 - 1.5. This is supported by the infit ZSTD and outfit ZSTD values of 0.01 and 0.19 with tolerance limits on a scale between -2 and 2. This shows that the overall instrument is good and has an excellent reliability value of 0.92.

The Cronbach alpha (KR-20) value, which measures the interaction between subjects and items, shows a good reliability value of 0.83 and is included in the excellent category. This study result showed that the data obtained in the study was good and according to the requirements of the Rasch model.

Figure 1A showed the distribution of response patterns given by the subjects denoted in the form (#) and (.) on the left and the difficulty level of items on the right according to the item code. The subject's response pattern shows that the average logit value reaches 0.612 logit, indicating that all subjects tend to have oral disorders due to oral lesions, as indicated by the lower logit value compared to the average item/question item (Figure 1A).



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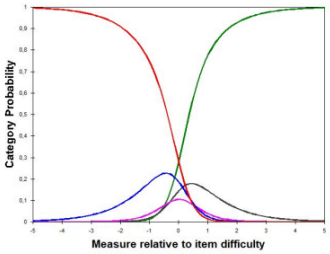

Category label	Observed count	Andrich threshold
0	391	NONE
1	122	0.40
2	44	0.58
3	54	-0.31
4	168	-0.67

B

Figure 1. A. Item map showed distribution of subjects (left) and item of COMDQ-26 (right). B. Andrich threshold analysis.

As shown in Figure 1A, it can be seen that the distribution of items is good, as can be seen from the even distribution of the difficulty level of the items. However, some items exceed 2SD (C23-3 and C24-4), but overall the questionnaire can measure respondents well and group respondents into three categories.

Figure 1B explains the questionnaire items' rank validity and the questionnaire's unidimensionality test so that the questionnaire can measure what should be measured.

The validity of the rating scale is used to determine the grouping of the responses to the questionnaire with a Likert scale. With Rasch model analysis, a verification process can be carried out to determine the ranking grouping in the instrument. In this questionnaire used. Likert scale type grouping with five categories.

Respondents provide answers to each item, and the answers given by respondents will be grouped to whether respondents tend to answer in the left column (always) or the far right (never) to questions related to the effect of oral disorders on quality of life.

The figure shows the mean value of the observations is -6.96 for option 1 (Always) and increases until it reaches +4.18 for option 5 (Never). The increase in each choice needs to be more consistent in Figure 6.

AVRGE and Andrich thresholds, so it is necessary to modify the Likert scale from 5 categories to 4 categories because option three is considered less relevant in classifying the subject's response and can be eliminated.

Table 3. Unidimensionality questionnaire

	Eigenvalue	Observed	Expected
Total raw variance in observations	59.45	100%	100%
Raw variance explained by measures	33.45	42.7%	42.8%
Raw variance explained by person	5.96	6.8%	6.9%
Raw variance explained by items	27.48	35.8%	36.0%
Raw unexplained variance (total)	26	43.7%	44.1%
Unexplained variance in 1st contrast	4.30	7.2%	16.5%
Unexplained variance in 2nd contrast	3.41	5.7%	13.1%
Unexplained variance in 3rd contrast	2.58	4.3%	9.9%
Unexplained variance in 4th contrast	2.39	4.0%	9.2%
Unexplained variance in 5th contrast	2.07	3.5%	8.0%

Table 3 showed that the raw variance explained by the measure shows a value above 40%, and the eigenvalue for unexplained variance in the first contrast is above 2. Thus, Tables 2 and 3 showed that the COMDQ-26 questionnaire has good construct validity. (Bond, 2015; Gunardi et al., 2020; Yap et al., 2021) In this study, all construct validity criteria were met, and the Indonesian version of the COMDQ-26 questionnaire has good construct validity.

4 CONCLUSION

The Indonesian version of the COMDQ-26 questionnaire has good construct validity, validity shown from the Cronbach alpha value of 0.83 and item reliability of 0.92 with a separation of 3.35. However, the questionnaire answer choice was considerably vague/uncertain for the Indonesian population. Further research needs to be done to confirm the use of the Indonesian version of COMDQ-26.

CONFLICT OF INTEREST

There is no conflict of interest for this study

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