

Translation and Adaptation of the Diagnostic Criteria for Temporomandibular Disorders into the Malay Language: Psychometric Evaluation of Contents

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Aims: To develop the Malay DC/TMD through a formal cross-cultural adaptation (CCA) process for use in non-English speaking populations and to determine the reliability and validity of the Malay Graded Chronic Pain Scale (M-GCPS) and Malay Jaw Functional Limitation Scale (M-JFLS). **Methods:** The English DC/TMD was translated into the Malay language using the forward-backward translation procedures specified in the INFORM guideline. The initial Malay instrument was pre-tested, and any discrepancies were identified and reconciled before producing the final Malay DC/TMD. Psychometric properties of the M-GCPS and M-JFLS were evaluated using a convenience sample of 252 subjects and were assessed using internal consistency and test-retest reliability, as well as face, content, concurrent, and construct validity testing. Internal consistency was assessed using Cronbach's alpha, while test-retest reliability was examined using intraclass correlation coefficient (ICC). Concurrent and construct validity of both domains were performed using Spearman ρ correlation test. In addition, construct and discriminant validity were appraised using Kruskal-Wallis and Mann-Whitney U tests, respectively. **Results:** Cronbach's alpha values for the M-GCPS and M-JFLS were 0.95 and 0.97, respectively. The ICC was 0.98 for the M-GCPS and 0.99 for M-JFLS. The majority of the tested associations for both domains were found to be statistically significant, with good positive correlations. **Conclusion:** The M-GCPS and M-JFLS were found to be reproducible and valid. The Malay DC/TMD shows potential for use among Malay-speaking adults. *J Oral Facial Pain Headache 2020;34:323–330. doi: 10.11607/ofph.2624*

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TMMD refer to a diverse group of conditions affecting the TMJs, masticatory muscles, and their surrounding structures.¹ They present a significant public health problem and have been found to negatively impact quality of life.² Findings from a large prospective study established TMD as a “complex disorder with multiple causes consistent with a biopsychosocial model of illness.”³ Accordingly, TMD diagnosis entails a dual-axis approach comprising both physical and psychosocial status. The evidence-based Diagnostic Criteria for TMD (DC/TMD), which can be used in both research and clinical settings, was presented to the dental community in 2014.⁴ These criteria were developed based on the widely employed Research Diagnostic Criteria for TMD (RDC/TMD),⁵ with the aim of improving the sensitivity and specificity of diagnostic algorithms. Axis I of the DC/TMD consists of the TMD pain screener, TMD symptoms questionnaire, demographic profile, and a clinical examination to evaluate mandibular range of motion and associated pain/joint sounds, as well as TMJ and masticatory muscle tenderness on palpation. Specifications are offered for carrying out the examination and findings documentation. Axis II assesses pain-related disability and psychosocial status with an assortment of instruments, including the Graded Chronic Pain Scale (GCPS), Jaw Functional Limitation Scale (JFLS), Patient Health Questionnaire (PHQ), Generalized Anxiety Disorders (GAD) Scale, pain drawings, and the Oral Behavior Checklist (OBC).

The DC/TMD was first developed in English in the US. A two-step cross-cultural adaptation process is required to achieve equivalence for transfer to other countries and languages.⁶ These are (1) translation and (2) psychometric evaluation (ie, reliability and validation testing) of the adapted tool in the new country. Attention to language and the ethnic and cultural elements of the new country is essential, especially since data collection involves comprehension and communication of the adapted instrument.⁷ Southeast Asia is a subregion of Asia consisting of 11 different countries that are ethnically and culturally varied. Hundreds of different languages are spoken by the various ethnic groups, and multiple languages are often used in one country.

Malaysia is the sixth most populous country in Southeast Asia and comprises three major ethnic groups, namely Malay, Chinese, and Indian. The Malay language is the official language of Malaysia and is the mother tongue of most individuals in Malaysia. As not all Malaysians are proficient in English, there is a need to translate, culturally adapt, and test the psychometric properties of the Malay-language version of the DC/TMD before it can be deployed for clinical and community research.

The objectives of this study were thus to translate the original English version of the DC/TMD into the Malay language and to evaluate the reliability and validity of the contents in the translated instrument; specifically, the M-GCPS and M-JFLS. The GCPS and JFLS were selected for detailed evaluation, as they were specifically assessed in the German version of the RDC/TMD. This allowed for some degree of comparison between studies. Furthermore, the PHQ questionnaires have already been translated into the Malay language and validated.

Materials and Methods

Study Design and Ethics

This study was approved by the Medical Ethics Committee, Faculty of Dentistry, University of Malaya (reference number: DF OS1623/00699[P]). It was divided into two phases, and written informed consent was obtained from all study participants.

Phase 1: Translation and Cross-Cultural Adaptation

Phase 1 involved translation of the English DC/TMD into the Malay language based on the procedures specified by the International Network for Orofacial Pain and Related Disorders Methodology (INFORM) guideline.⁷ All domains in Axis I and Axis II of the English DC/TMD were translated, as well as the required examiner commands (RECs) in the DC/TMD

protocols. The RECs serve to facilitate maximum reliability in clinical techniques for both researchers and clinicians. The forward translation involved translating the English DC/TMD into the Malay language. Three translators were involved in the forward translation. They were all effectively bilingual, with Malay as their native language and English as their second language. One of the forward translators was oblivious to the instrument's intent and concept, while the other two translators were knowledgeable of the instrument's content (M.K.A.M.T. and S.M.I.). The three independent forward translations were then synthesized into a single Malay version. A final review of the Malay translation was conducted by the translation team before it was back-translated into English. Back-translation was performed by two other bilingual back-translators who were both English- and Malay-language experts. The back-translated versions were then reviewed against the English DC/TMD by an independent reviewer appointed by the consortium before it was further evaluated by four experts on the subject matter who were not involved in either the forward- or back-translation processes. The purpose of this expert panel was to ensure content soundness and sufficiency of the Malay DC/TMD.

The draft of the Malay DC/TMD was established and pre-tested on 10 indiscriminate adult subjects who were monolingual or bilingual. The purpose was to assess the face validity of the draft Malay DC/TMD; specifically, the ambiguity of translated components in terms of construct and understanding. Following this, all 10 subjects were interviewed face-to-face to discuss their perceptions and impressions of the pre-final instrument. Any inappropriate items or translation errors were identified and improved. Revisions of the forward- and back-translations were conducted to correct response errors of the subjects. A comprehensive Malay-language instrument was produced and sent to the DC/TMD Consortium for review and was then approved before being subjected to psychometric evaluation. It is available for download from the INfORM site (<https://ubwp.buffalo.edu/rdc-tmdinternational/>).

Phase 2: Evaluation of Psychometric Properties

Study sample. Psychometric assessment of the Malay DC/TMD was conducted at the Faculty of Dentistry, University of Malaya, Kuala Lumpur, Singapore, from September 2016 to February 2018. Sample size was calculated based on the 5:10 ratio of subjects to question items.⁸⁻¹⁰ Based on this ratio, the minimum sample size required for this study was 105 subjects, as the maximum number of items in any DC/TMD instrument was 21 (ie, 21 items × 5 subjects). A convenience sample consisting of 252

subjects was recruited. They consisted of 165 non-TMD individuals and 87 TMD patients aged 18 years or older. The subjects were recruited from among random individuals who visited the dental faculty for various reasons, as well as from existing staff and administration. TMD subjects must present with one or more TMD symptoms listed in the DC/TMD symptom questionnaire, including pain in the jaws, TMJ, or adjacent structures at rest or during function. To be included in the study, subjects must be able to read and understand Malay and answer the Malay DC/TMD. Subjects with an organic TMJ pathology (such as benign or malignant tumors of the TMJ), history of TMJ trauma, and/or significant medical morbidity (such as cardiovascular diseases, respiratory disorders, kidney failure, neurologic deficits, psychiatric disorders, or malignancies) were excluded.

Another convenience sample of 40 individuals was selected for test-retest reliability. All 40 individuals, consisting of 20 non-TMD and 20 TMD subjects, answered the same questionnaire 2 weeks after the initial administration. This time period was necessary to minimize recall bias and confirm the test-retest reliability of the questionnaire.¹

Content evaluation. The psychometric properties of the Malay DC/TMD content were examined by means of the M-GCPS and M-JFLS. The 7-item M-GCPS consists of the components: characteristic pain intensity (CPI), interference of activities score, and disability points for disability days plus the interference score. A chronic pain grade that ranges from 0 (none) to 4 (severely limiting) was subsequently determined. The JFLS is a 20-item instrument that assesses limitations in masticatory function, vertical jaw mobility, and verbal/nonverbal communication. Four supplementary instruments were employed for various validity testing. The CPI and interference in function domains of the Malay version of the Brief Pain Inventory (M-BPI) were used to validate the CPI and the interference in activities component of the M-GCPS, respectively. Each pair measured the similar constructs of pain intensity and functional interference. Similarly, the functional limitation domain of the Malay Oral Health Impact Profile 14 (M-OHIP-14) was utilized to corroborate the M-JFLS, as both scales measure functional limitations. Perception of oral/jaw health status and treatment needs were appraised with the self-reported global oral health questionnaire. This, together with a tailored "limited mouth opening" item, was compared to the M-JFLS for construct validity.

Statistical Analyses

Data were analyzed using SPSS Statistical Software version 22 (IBM), with the significance level set at .05. Demographic data were analyzed using descriptive sta-

tistics. Internal consistency was assessed by measuring Cronbach's alpha. Alpha values of 0.70 and 0.90 are considered acceptable for scale items and clinical studies, respectively.¹² Test-retest reliability was examined using intraclass correlation coefficient (ICC).

For validity testing, GCPS and JFLS scores were correlated with those of supplementary instruments. Processes for concurrent, construct, and discriminant validity have been detailed in other studies.¹³⁻¹⁵ As the present data were not normally distributed, nonparametric tests were used for statistical analysis. The M-GCPS and M-BPI were validated simultaneously, as were the M-JFLS and M-OHIP-14, via Spearman ρ correlation test, with a correlation value set at $r \geq 0.20$.¹⁵ The strength of a correlation can be described as weak ($r = 0.01$ to 0.29), moderate ($r = 0.30$ to 0.69), or strong ($r = 0.70$ to 1.00).¹⁶ For construct validation, the following associations were studied: (1) M-GCPS and self-reported global oral health questions (perceived oral/jaw health status, satisfaction level, and treatment need); (2) M-GCPS and M-OHIP-14; (3) M-JFLS and self-reported global oral health questions; (4) M-JFLS and M-OHIP-14 (functional limitation domain); and (5) M-JFLS and the tailored limited mouth opening item (defined as painless active mouth opening ≤ 40 mm).¹⁷ The verbal query for this item was, "In your opinion, can you open your mouth wide (40 mm/three-finger breadth) without feeling pain in your jaw?" Response options for this question were either yes or no.

Construct validity was also established using the Spearman ρ correlation test, as data were nonparametric in nature. The M-GCPS and M-JFLS scores were related to the M-OHIP-14 scores. Kruskal-Wallis test was also conducted to compare outcomes of the three global oral health questions. Furthermore, the association between the M-JFLS and the limited mouth opening question was examined by means of Mann-Whitney U test. Based on the expected associations, 14 hypotheses were formulated and tested (Table 1). Discriminant validity was evaluated to assess the ability of the M-GCPS and M-JFLS to discriminate patients with and without TMD. The presence of TMD was established with the DC/TMD pain screener and a clinical examination. The mean ranks of subjects with and without TMD were compared using Mann-Whitney U test.

Results

Translation and Cross-Cultural Adaptation

No substantial issues were encountered during the forward- and backward-translation processes. Cross-cultural adaptation of the source instrument involved the consideration of common foods and

Table 1 Hypotheses Formulated for Associations of M-GCPS and M-JFLS with M-OHIP-14 and Global Oral Health Ratings

Hypotheses		Outcome
1	Subjects with poor oral/jaw health would have higher M-GCPS scores than those with good oral/jaw health.	Positive correlation(s)
2	Subjects who were dissatisfied with their level of oral/jaw health would have higher M-GCPS scores than those who are satisfied.	Positive correlation(s)
3	Subjects who needed oral/jaw treatment(s) would have higher M-GCPS scores than those who did not need any treatment(s).	Positive correlation(s)
4	Subjects with physical pain would have higher M-GCPS scores than those without physical pain.	Positive correlation(s)
5	Subjects with psychologic discomfort would have higher M-GCPS scores than those with no psychologic discomfort.	Negative correlation(s)
6	Subjects with physical disability would have higher M-GCPS scores than those with no physical disability.	Positive correlation(s)
7	Subjects with psychologic disability would have higher M-GCPS scores than those with no psychologic disability.	Positive correlation(s)
8	Subjects with social disability would have higher M-GCPS scores than those with no social disability.	Negative correlation(s)
9	Subjects who are handicapped would have higher M-GCPS scores than those who are not handicapped.	Negative correlation(s)
10	Subjects with poor oral/jaw health would have higher M-JFLS scores than those with good oral/jaw health.	Positive correlation(s)
11	Subjects who were dissatisfied with their level of oral/jaw health would have higher M-JFLS scores than those who were satisfied.	Positive correlation(s)
12	Subjects who needed oral/jaw treatment(s) would have higher M-JFLS scores than those who did not need treatment(s).	Positive correlation(s)
13	Subjects with jaw functional limitation(s) would have higher M-JFLS scores than those with no jaw functional limitations.	Positive correlation(s)
14	Subjects with limited mouth opening would have higher M-JFLS scores than those without limited opening.	Positive correlation(s)

M-GCPS = Malay Graded Chronic Pain Scale; M-JFLS = Malay Jaw Functional Limitation Scale; M-OHIP-14 = Malay Oral Health Impact Profile.

Table 2 Descriptive Statistics of Demographic Data

Characteristic	Items	No. ^a	%
Gender	Male	68	27.0
	Female	176	69.8
Age, y	18–30	176	69.9
	31–40	55	21.8
	41–50	6	2.4
	51–60	5	2.0
	≥ 61	2	0.8
Race	Malay	182	72.2
	Chinese	31	12.3
	Indian	36	14.3
	Kadazan/Iban	1	0.4
	Other Bumiputera	1	0.4
Marital status	Married	67	26.6
	Staying together	1	0.4
	Single/never married	184	73.0
	Level of education	Primary school	3
Level of education	Secondary school	55	21.8
	Diploma/college	109	43.3
	Degree	80	31.7
	Masters/PhD	5	2.0
Income, RM	≤ 1,200	36	14.3
	1,201–2,500	50	19.8
	2,501–5,000	72	28.6
	5,001–7,500	59	23.5
	7,501–10,000	16	6.3
	≥ 10,001	19	7.5

^aTotal sample was less than 252 for some variables due to missing data (eg, age and gender).

musical apparatus. The back-translated instrument was matched to the source version. All of the concepts and meanings of the translated version were retained with some adjustments.

Evaluation of Psychometric Properties

Demographic data. Demographic data are reflected in Table 2. The majority of the subjects were female (69.8%) and aged between 18 and 30 years old (69.9%). Almost three-quarters (72.2%) were Malay, and 73% were either single or not married. All subjects were literate, and 77% had received tertiary education. The majority were from the middle-income group.

Internal consistency and test-retest reliability. Cronbach's alpha coefficients for the M-GCPS and M-JFLS are shown in Table 3. Both instruments were found to have high internal consistency, with alpha values of 0.95 for the M-GCPS and 0.97 for the M-JFLS. The ICC values for test-retest reliability of the M-GCPS and M-JFLS are shown in Table 4. The ICC for total score of the M-GCPS was 0.98 (95% CI: 0.96 to 0.99) and was 0.99 (95% CI: 0.98 to 0.99) for the M-JFLS. The ICCs for all subdomains of the M-GCPS and M-JFLS were above 0.90.

Concurrent validity. Concurrent validity of the M-GCPS and M-JFLS is shown in Table 5. The M-GCPS subdomains CPI ($r = 0.56, P < .01$) and interference score ($r = 0.60, P < .01$) were significantly correlated with the M-BPI. The correlations were positive and moderate. The correlation between the M-JFLS and M-OHIP-14 was also positive and moderate ($r = 0.56, P < .01$).

Construct validity. Findings of construct validity are presented in Table 6. Moderate positive correlations were observed between the M-GCPS and the three OHIP subdomains of physical pain ($r = 0.37, P < .01$), physical disability ($r = 0.34, P < .01$), and psychologic disability ($r = 0.34, P < .01$). Conversely, neg-

Table 3 Internal Consistency (Cronbach's α) for M-GCPS and M-JFLS

Domain	Internal consistency	Cronbach's α based on standardized items	No. of items
M-GCPS	0.95	0.96	7
M-JFLS	0.97	0.97	20

M-GCPS = Malay Graded Chronic Pain Scale Version 2; M-JFLS = Malay Jaw Functional Limitation Scale.

Table 4 Test-Retest Reliability (ICC) of M-GCPS and M-JFLS

Subdomain (n = 40)	Single measure	95% CI
M-GCPS total score	0.98	0.96–0.99
CPI	0.99	0.98–0.99
Interference score	0.99	0.98–0.99
Disability points	0.99	0.98–0.99
M-JFLS total score	0.99	0.98–0.99
Mastication	0.99	0.98–0.99
Vertical jaw mobility	0.98	0.97–0.99
Verbal and nonverbal communication	0.99	0.98–1.00

M-GCPS = Malay Graded Chronic Pain Scale Version 2; M-JFLS = Malay Jaw Functional Limitation Scale; ICC = intraclass correlation coefficient.

Table 5 Concurrent Validity of M-GCPS and M-JFLS with Associated Supplementary Instruments

Concurrent validity	Correlation coefficient (ρ)	<i>P</i> value
M-GCPS and M-BPI		
Characteristic Pain Intensity	0.56	< .01
Interference score	0.60	< .01
M-JFLS and M-OHIP-14	0.56	< .01

M-GCPS = Malay Graded Chronic Pain Scale Version 2; M-JFLS = Malay Jaw Functional Limitation Scale; M-BPI = Malay Brief Pain Inventory; M-OHIP-14 = Malay Oral Health Impact Profile.

Table 6 Construct Validity: Correlations of M-GCPS and M-JFLS with M-OHIP-14 Subdomains

Associations	Correlation coefficient (μ)	<i>P</i>
M-GCPS		
Physical pain	0.37	
Psychologic discomfort	-0.14	< .01
Physical disability	0.34	
Psychologic disability	0.34	
Social disability	-0.40	
Handicap	-0.37	
M-JFLS		
Functional limitations	0.48	< .01

M-GCPS = Malay Graded Chronic Pain Scale Version 2; M-JFLS = Malay Jaw Functional Limitation Scale; M-OHIP-14 = Malay Oral Health Impact Profile.

Table 7 Construct Validity: Comparison of M-GCPS and M-JFLS Scores Between Different Categories of Global Oral Health Ratings

Global oral health	M-GCPS, median (IQR)	M-JFLS, median (IQR)	<i>P</i>
Perceived oral/jaw health			
Excellent	0.18 (0.39)	0.63 (0.98)	< .01
Good	0.29 (0.49)	0.65 (1.41)	
Fair	0.77 (0.86)	1.53 (1.82)	
Poor	1.59 (1.24)	3.20 (2.73)	
Very poor	3.25 (0.50)	5.70 (1.42)	
Perceived satisfaction with oral/jaw health			
Very satisfied	0.32 (0.53)	0.73 (1.45)	< .01
Satisfied	0.38 (0.61)	0.75 (1.48)	
Moderate	1.27 (1.10)	2.66 (2.31)	
Dissatisfied	2.00 (0.94)	3.65 (1.83)	
Very dissatisfied	2.50 (2.12)	4.13 (3.39)	
Perceived need for oral/jaw treatment(s)			
Yes	1.36 (1.28)	2.77 (2.57)	< .01
No	0.35 (0.58)	0.85 (1.68)	
Don't know	0.90 (0.87)	1.49 (1.58)	

M-GCPS = Malay Graded Chronic Pain Scale Version 2; M-JFLS = Malay Jaw Functional Limitation Scale.

active correlations were noted between the M-GCPS and other M-OHIP-14 subdomains, including psychologic discomfort ($r = -0.14$, $P < .01$), social disability ($r = -0.40$, $P < .01$), and handicap subdomain ($r = -0.37$, $P < .01$). Overall, the correlations ranged from weak to moderate. The M-JFLS showed a moderate

positive correlation with the OHIP functional limitations subdomain ($r = 0.48$, $P < .01$).

Associations of the M-GCPS and M-JFLS with global oral health ratings are shown in Table 7. The scores for both the M-GCPS and M-JFLS increased progressively, from "excellent" to "very poor" for

Table 8 Construct Validity: Differences in M-JFLS Scores Between Subjects With and Without Limited Mouth Opening (n = 200)

Association	Can you open wide enough?	Median (IQR)	Mean rank	P
M-JFLS score	Yes (n = 141)	0.11 (1.04)	89.67	< .01
	No (n = 59)	2.22 (3.43)	126.39	

M-JFLS = Malay Jaw Functional Limitation Scale; IQR = interquartile range.

Table 9 Discriminant Validity of M-GCPS (n = 248) and M-JFLS (n = 200)

Questionnaire	Group	Median (IQR)	Mean rank	P
M-GCPS	Non-TMD (n = 162)	0.05 (0.17)	93.74	< .01
	TMD (n = 86)	3.83 (4.33)	181.67	
M-JFLS	Non-TMD (n = 134)	0.05 (0.60)	78.44	< .01
	TMD (n = 66)	2.72 (3.52)	145.29	

M-GCPS = Malay Graded Chronic Pain Scale; M-JFLS = Malay Jaw Functional Limitation Scale.

perceived oral/jaw health and from “very satisfied” to “very dissatisfied” for perceived satisfaction with oral/jaw health. This trend was statistically significant ($P < .01$). In addition, subjects with perceived oral/jaw treatment need had significantly higher M-GCPS and M-JFLS scores compared to those with no perceived need. Last, the association between the M-JFLS and limited mouth opening is presented in Table 8. Subjects who could not open their mouth wide had a significantly higher median JFLS score (median = 2.22, interquartile range [IQR] = 3.43, $P < .01$) than those who could open their mouth wide (median = 0.11, IQR = 1.04, $P < .01$).

Discriminant validity. The results of discriminant validity are reflected in Table 9. Subjects with TMD had a significantly higher M-GCPS score (median = 3.83, IQR = 4.33, $P < .01$) than those without TMD (median = 0.05, IQR = 0.17, $P < .01$). Subjects with TMD also had a significantly higher M-JFLS score (median = 2.72, IQR = 3.52, $P < .01$) than those without TMD (median = 0.05, IQR = 0.60, $P < .01$).

Discussion

Translation of the English DC/TMD to the Malay language was done according to the INfORM translation and adaptation DC/TMD protocol¹⁸ and the guidelines

for establishing cultural equivalency of instruments.¹⁹ In this study, the translation and cross-cultural adaptation of the DC/TMD was done for the Malay-speaking subjects in Malaysia.²⁰ Most of the forward- and back-translations of the DC/TMD from the source language to the Malay version were straightforward and simple due to their unambiguous meanings. However, during the translation process, some words were rephrased or added from the source instrument in order to make the content culturally relevant to the Malaysian population.¹⁹ For example, the word “temple” was translated differently by the three forward translators. Upon discussion, the committee agreed to choose *tepi dahi sebelah kanan atau kiri* (side of the forehead, left or right) as the best translation. However, the translated Malay words caused some confusion among the subjects during pre-testing. Based on their feedback, it was decided that the word “temple” should be retained at the end of the Malay translation in brackets to help the subjects understand the sentence better. In terms of the food items, “macaroni” and “pureed food” in the source instrument were replaced by *kuey teow* (a type of Malaysian noodle) and *bubur kanji* (starch porridge) in the Malay version, respectively. Also, during pretesting, there were suggestions to include examples of musical instruments in the OBC domain of the DC/TMD. Thus, the committee unanimously agreed to include “saxophone,” “trumpet,” and “violin” in the Malay version to promote completeness of the item.

A culturally adapted instrument could modify the reliability and validity of the source instrument.²⁰ Thus, it is prudent that the translated instrument possesses the same measurement properties needed for the designed utilization. This can be achieved by testing its internal consistency, reliability, and validity.²¹ In the present study, the internal consistency and test-retest reliability were measured using Cronbach's alpha and ICC, while validity testing was done by means of concurrent, construct, and discriminant validity.^{10,14,20}

For internal consistency, the α value depicts the degree of correlation of an item with a scale and of an individual item with itself in the same domain.²² The Cronbach's α values for both the M-GCPS and M-JFLS were more than 0.90, and thus clinically adequate. With values of 0.95 and 0.97 for the M-GCPS and M-JFLS, respectively, the internal consistencies were high when compared to the Malay RDC/TMD²⁰ and the German RDC/TMD, which had α values ranging between 0.72 and 0.88.¹⁷ The variance may be attributed to minor disparities in the translation processes, as well as dissimilarities in instrument versions.

The ICC is used to measure intrarater reliability of scale measures at two different periods of time, which, in the present case, was 2 weeks. The gap of 2 weeks was selected to reduce remembrance recall bias arising from the first test.²⁰ The ICC value will

be close to 1 when the different measures of quantity are equal and comparable between items, while the ICC value is expected to be lower or approach 0 when there is little agreement between items.²³ ICC values of the M-GCPS and M-JFLS were both close to 1 (0.98 and 0.99, respectively) and indicated very strong agreement between the two time periods.

Three types of validity testing were conducted: concurrent validity, construct validity, and discriminant validity. Concurrent validity refers to scores on a distinct instrument that correlate with a regular approved instrument or a gold-standard tool.²⁴ In this study, concurrent validity was tested between the pain measures M-GCPS and M-BPI, while the M-JFLS was validated against the M-OHIP-14 jaw function limitation subdomain. A strong positive correlation exists if the correlation coefficient with the gold standard is at least 0.70.²⁴ Positive and moderate correlations were observed for the M-GCPS and M-JFLS and their comparison instruments. The four comparison instruments—the M-BPI, M-OHIP-14, global oral health rating, and the tailored limited mouth opening item—were selected, as they measured similar constructs to the contents of the M-DC/TMD. In this context, it was anticipated that the M-GCPS and M-JFLS would be highly correlated with the four chosen indices, per the present findings. Notably, strong positive correlations indicated that both the M-GCPS and M-JFLS were highly relevant in the study population.

Construct validity determines how well a test measures what it is believed to measure and is usually associated with hypothesis testing.²⁵ In this study, a total of 14 specific hypotheses were formulated for the M-GCPS (9 hypotheses) and M-JFLS (5 hypotheses). Most of these constructed hypotheses were found to be in accordance with recognized outcomes, except for three hypotheses involving associations between the M-GCPS and three other subdomains of the M-OHIP-14, specifically psychologic discomfort, social disability, and handicap. For the psychologic discomfort subdomain, one of the items was based on discomfort due to foods stuck in between teeth/dentures. This un-specific question was not related to TMD and explained the negative association. Negative associations with the social disability and handicap subdomains could be attributed to responses relating more to teeth and the mouth rather than the jaws/TMJ status, as the questions were generalized to all three structures. Associations are expected to differ if a condition-specific (ie, TMD) oral health–related quality of life tool is used. The translated instruments were endorsed, as more than 75% of the results were in agreement with the formulated specific hypotheses.²⁴ These findings provided support for the construct validity of the M-GCPS and M-JFLS.

Discriminant validity was assessed by the capacity of the M-GCPS and M-JFLS to differentiate

between asymptomatic controls and subjects with TMD. TMD subjects presented significantly higher M-GCPS and M-JFLS scores than the control group. These findings concurred with those of the Malay version of the RDC/TMD.²⁰ Based on the tests conducted, the content of the Malay DC/TMD can be considered reliable and valid for use in research and clinical settings in the Malaysian population.

The present study is not without its limitations. First, the scope of the study was limited to only Axis II of the Malay version of the DC/TMD, as with previous similar studies.^{17,20} Moreover, Axis II of the DC/TMD consists of many domains and instruments whose appraisal is beyond the scope of a single study. Only the M-GCPS and M-JFLS were selected for evaluation, as they were also investigated in previous similar RDC/TMD–based studies. Sample sizes for sociodemographic data, as well as the various domains, varied somewhat due to incomplete forms arising from pen-and-paper data capture. Moreover, the socio-demographic characteristics of the subjects may not represent the general Malaysian population. However, in studies on cross-cultural validation of scales, a representative sample is not compulsory. The presence of TMD was established mainly through self-reported symptoms, which may pose some subjectivity and bias. Future studies could incorporate actual DC/TMD Axis I diagnoses for reliability and validity testing of other translated Axis II domains.

Conclusions

This study describes the translation and cross-cultural adaptation process of the Malay language version of the DC/TMD. It also provides empirical evidence for the reliability and validity of the Malay DC/TMD; specifically, the M-GCPS and M-JFLS. Further research is warranted to determine the psychometric properties of the other Axis II domains of the Malay DC/TMD.

Key Findings

- The M-GCPS and M-JFLS were found to be reliable and valid.
- The Malay DC/TMD is a promising instrument for assessing pain intensity, pain-related disability, and jaw functional limitations in Malay-speaking adults.

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References

1. Yap AU, Dworkin S, Chua EK, List T, Tan KBC, Tan HH. Prevalence of temporomandibular subtypes, psychological distress and psychosocial dysfunction in Asian patients. *J Orofac Pain* 2003;17:21–28.
2. Dahlström L, Carlsson GE. Temporomandibular disorders and oral health-related quality of life. A systematic review. *Acta Odontol Scand* 2010;68:80–85.
3. Slade GD, Fillingim RB, Sanders AE, et al. Summary of findings from the OPPERA prospective cohort study of incidence of first-onset temporomandibular disorder: Implications and future directions. *J Pain* 2013;14:116–124.
4. Schiffman E, Ohrbach R, Truelove E, et al. Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) for clinical and research applications: Recommendations of the international RDC/TMD consortium network and orofacial pain special interest group. *Oral Facial Pain Headache* 2014;28:6–27.
5. Dworkin S, LeResche L. Research diagnostic criteria for temporomandibular disorders: Review, criteria, examinations and specifications, critique. *J Craniomandib Disord* 1992;69:301–355.
6. Epstein J, Santo RM, Guillemin F. A review of guidelines for cross-cultural adaptation of questionnaires could not bring out a consensus. *J Clin Epidemiol* 2015;68:435–441.
7. International Network for Orofacial Pain and Related Disorders Methodology, 2017. <https://ubwp.buffalo.edu/rdc-tmdinternational/>. Accessed June 18, 2020.
8. Floyd FJ, Widaman KF. Factor analysis in the development and refinement of clinical assessment instruments. *Psychol Assess* 1995;7:286–299.
9. He SL, Wang JH, Wang MH, Deng YM. Validation of the Chinese version of the halitosis associated life-quality test (HALT) questionnaire. *Oral Dis* 2012;18:707–712.
10. He SL, Wang JH. Reliability and validity of a Chinese version of the oral health impact profile for edentulous subjects. *Qual Life Res* 2015;24:1011–1016.
11. Hashim AN, Yusof ZY, Esa R. The Malay version of the Early Childhood Oral Health Impact Scale (Malay-ECOHIS) -- assessing validity and reliability. *Health Qual Life Outcomes* 2015;13:190.
12. Bland JM, Altman DG. Cronbach's alpha. *BMJ* 1997;314:572.
13. Aisyaturridha A, Naing L, Nizar AJ. Validation of the Malay brief pain inventory questionnaire to measure cancer pain. *Symptom Manage* 2016;31:13–21.
14. Saub R, Locker D, Allison P, Disman M. Cross-cultural adaptation of the oral health impact profile (OHIP) for the Malaysian adult population. *Community Dent Health* 2007;24:166–175.
15. Feise RJ, Menke JM. Functional rating index: A new valid and reliable instrument to measure the magnitude of clinical change in spinal conditions. *Spine Phila Pa* 2001;26:78–87. Erratum in: *Spine* 2001;26:596.
16. Altman DG. *Practical Statistics for Medical Research*. London: Chapman and Hall, 1991.
17. John MT, Hirsch C, Reiber T, Dworkin SF. Translating the research diagnostic criteria for temporomandibular disorders into German: Evaluation of content and process. *J Orofac Pain* 2006;20:43–52.
18. Ohrbach R. Translation and adaptation of the DC/TMD protocol. International Network for Orofacial Pain and Related Disorders Methodology. Revised 29 September 2017. <https://buffalo.app.box.com/s/fugxw2tt9iz4zf5j9lygvfyvdj2fzrhx>. Accessed 1 October 2020.
19. Ohrbach R, Bjorner J, Jezewski MA, John MT, Lobbezoo F. Guidelines for establishing cultural equivalency of instruments. International Network for Orofacial Pain and Related Disorders Methodology. Updated 11 May 2013. https://ubwp.buffalo.edu/rdc-tmdinternational/wp-content/uploads/sites/58/2017/01/Guidelines-for-Translation-and-Cultural-Equivalency-of-Instruments-2013_05_118608.pdf. Accessed 1 October 2020.
20. Khoo SP, Yap AU, Chan YH, Bulgiba AM. Translating the research diagnostic criteria for temporomandibular disorders into Malay: Evaluation of content and process. *J Orofac Pain* 2008;22:131–138.
21. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self report measures. *Spine* 2000;25:3186–3191.
22. de Lucena LB, Kosminsky M, da Costa LJ, de Góes PS. Validation of the Portuguese version of the RDC/TMD axis II questionnaire. *Braz Oral Res* 2006;20:312–317.
23. Vetter TR, Schober P. Agreement analysis: What he said, she said versus you said. *Anesth Analg* 2018;126:2123–2128.
24. Terwee CB, Bot SD, de Boer MR, et al. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol* 2007;60:34–42.
25. Souza AC, Alexandre NMC, Guirardello EB. Psychometric properties in instruments evaluation of reliability and validity. *Epidemiol Serv Saude* 2017;26:649–659.