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Cross-Cultural Adaptation, Validity and Reliability of Malay Version Boston Carpal Tunnel Questionnaire

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Abstract

This study aimed to assess the validity and reliability of the Malay version Boston Carpal Tunnel Questionnaire (M-BCTQ). A cross-sectional study was used to generate the final version of M-BCTQ that was administered to 55 patients for psychometric testing. M-BCTQ had excellent test-retest reliability with ICCs value 0.837 for Symptom Severity Scale (SSS) and 0.913 for Functional Status Scale (FSS). The Cronbach alpha coefficient for the internal consistencies was reported at 0.864 for SSS and 0.893 for the FSS. A strong correlation was found with the Malay version of Disability of Arm, Shoulder and Hand Questionnaire (MV-DASH) as Spearman correlation for construct validity was 0.791 for SSS and 0.831 for FSS.

Keywords: Carpal Tunnel Syndrome; Boston Carpal Tunnel Questionnaire; Reliability; Validity

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1.0 Introduction

Carpal Tunnel Syndrome (CTS) is a non-traumatic hand disorder that occurs from the entrapment of the median nerve that passes through the carpal tunnel in the wrist (Meyer et al., 2018)). Although the pathophysiology remains puzzling, CTS is related to the mechanical trauma and ischemic injury to the median nerve within the carpal canal (Werner & Andary, 2002). The increase of pressure in the carpal tunnel resulting in the reduction of intraneural microcirculation with the breakdown of the blood-nerve barrier and formation of intraneural and extraneural oedema (Aboonq, 2015; MacDermid & Doherty, 2004). CTS is commonly characterized by symptoms in the median nerve territory of the hand where the clinical presentations are intermittent paraesthesias and dysaesthesia that typically occurs at night and early in the morning (Hermiz & Kallianen, 2017). The extent and severity of the median nerve's compression often impact the manifestation of remaining sign symptoms that include pain, disrupted sleeping pattern and reduced functional dexterity (Hall et al., 2013). The diagnostic criteria that used in the different setting have made the reported prevalence of CTS vary widely. The broad choices of measures in diagnosing CTS commonly involving the use of clinical presentation such as nocturnal waking, a positive Phalen's test, a positive Tinel sign, sensory and motor deficits' test and electrophysiological and neurophysiological test (Graham, 2008). According to Padua et al. (2016), the diagnostic criteria results in better prevalence estimation than the use of electrophysiological measures. However, Mondelli, Giannini, & Giacchi (2002) found that the incidence results differ when the clinical presentation is used

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alone to describe the CTS. Accordingly, a better diagnosis should include the clinical criteria history from the patient's point of view, which is also able to guide the treatment outcomes and monitor progress. In this context, this can be achieved through the use of disease-specific outcome questionnaire that provides a more accurate assessment of complex evaluation on patient's discomfort.

Boston Carpal Tunnel Questionnaire (BCTQ) is the most preference patient-reported outcome measure (PROM) which explicitly assessing the CTS and has been most widely used in the last two decades (Rosales et al., 2016). BCTQ is a valid self-administered specific outcome to measure symptoms and functions of clients with CTS. It has been translated into different languages with high levels of reliability, validity and responsiveness (Multanen et al., 2019; Trybus et al., 2019; Hamzeh & Alworikat, 2019; Bougea et al., 2017; Otero-Alvaro, Marín, & Matas, 2016; Lue, Lu et al., 2014; Park et al., 2013; Imaeda et al., 2007; Sezgin et al., 2006;). BCTQ was validated in many languages; however, a Malay version of BCTQ is not available thus far. Hence, this study aimed to translate and evaluate the reliability and content-related validity Malay version BCTQ (M-BCTQ) for the use among Malay speaking people in Malaysia.

2.0 Literature reviews

Previously, the severity of symptoms of CTS was determined based on clinical symptoms and signs by a physician accompanied by neuromuscular studies. Recently, however, PROM is preferred than performance-based tests of hand functions (Yücel & Seyithanoğlu, 2015). Usually, this is due to the performance-based tests that require specific training and types of equipment to attend, thus takes a longer time to complete. While the PROM is easy to conduct and clinically useful in determining the client's perception of their hand function and barriers in engaging daily living activities. PROM has better consideration to assess the level of patient's discomfort and impact on their social and employment status (Trybus et al., 2019). It can also determine the subjective aspect of a patient's condition, which is more reliable and administrable.

Several PROMs designed to assess symptoms, functional status and the treatment outcomes in CTS (Ollivere et al., 2009; Turner et al., 2010). Among the results, which often found in the literature in addition to BCTQ are the Michigan Hand Outcomes Questionnaire (MHQ) and Disabilities of Arm, Shoulder, and Hand Questionnaire (DASH) (Appleby, Neville-Smith, & Parrott, 2009; Levine et al., 1993). MHQ measured the health status and functionality of clients with hand disorders (Waljee et al., 2011). It is a valid, reliable and responsive measure of hand and upper extremity conditions such as rheumatoid arthritis, distal radius fracture and CTS (Shauver & Chung, 2009; Kotsis & Chung, 2005; Chung et al., 1998). It has been translated into many languages (Ebrahimzadeh, Birjandinejad, & Kachooei, 2015; Koziej et al., 2018; Meireles et al., 2014). DASH is an instrument that assessed the disability status and client's symptoms with hand and upper limbs conditions (Hudak, Amadio, & Bombardier, 1996). DASH comprises of 30 items, which rated on a five-point Likert Scale. It has established excellent reliability and validity in the various language (Greenslade et al., 2004; Hobby, Watts, & Elliott, 2005), including the MV-DASH by Al-Husuny et al., (2006). The MV-DASH has reported as having high internal consistency (Cronbach's alpha= 0.99), inter-rater reliability (ICC=0.943), and good face validity.

BCTQ, the Levine scale (Levine et al. 1993), is a disease-specific instrument designed to assess symptoms severity and functional status of CTS's client. It comprised of two definite scales, 11-items in the Symptoms Severity Scale (SSS) and 8-items in the Functional Status Scale (FSS) which rated using a five-point rating scale. The total score is the sum of each item, and the higher score interprets the more significant disability. This PROM should be tailored and validated to the appropriate population and regional language and culture, especially in Malaysia, with a large proportion of about 32 million people. Malay is Malaysia's official language, as it is the primary means of communication commonly spoken by major ethnic groups in Malaysia, i.e. Malay, Chinese and Indian. Malay is the world's ninth most spoken language in the world, with over 200 million speakers (Baker & Eversley, 2000). It can be accepted as one of the world's most widely spoken language. Given this situation, it is necessary to develop the Malay version of instrument specifically for the CTS patients to meet the needs of speakers in the fields of education and healthcare. The method of cross-cultural adaptation is necessary to be used to ensure the translated instrument is adapted culturally across different cultures of ethnicity in Malaysia. At the same time, the content reaches the equivalence as the original version of BCTQ.

3.0 Materials and methods

3.1 Participants

Participants that recently diagnosed with idiopathic CTS in less than 3-months recruited from outpatients at the Hand and Microsurgery Unit of Selayang Hospital, Malaysia, from November 2018 to March 2019. The criteria for the diagnosis included typical clinical symptoms of CTS and results of physical examination and electrophysiological test. The typical symptoms, including nocturnal and associated paraesthesia of the hand, could be in one or both sides. However, only one hand with the worst symptoms was chosen for the study. Exclusion criteria were as follows: a patient who are under 18 years old, patient with the existence of other diseases that cause hand symptoms, including hypothyroidism, polyneuropathy, severe neuropathy of diabetes, history of hand trauma or surgery and recently confirm of pregnancy. A total sample of 65 patients and ten professional therapists were involved in this study. Of the 65 patients, ten patients have enrolled in the face validity study, along with ten professional therapists in content-related validity study. The remaining 55 patients who did not participate in the face validity study then participated in the reliability and validity study.

3.2 Study design

Three phases of the study were conducted, i.e., (1) translation and language validity, (2) face validity and content-related validity, and (3) test re-test reliability, internal consistency and construct validity. Translation and cross-cultural adaptation process were performed according to the guidelines by Sousa & Rojjanasrirat (2011) and Beaton et al., (2000).

Phase 1: Translation and language validity

The original questionnaire was forward translated into Malay by two bilingual independent translators that generated two versions of M-BCTQ. Both versions were reviewed, and any differences were resolved by a bilingual occupational therapist that produced a single harmonized forward translation version. Then, the harmonized version was blindly back-translated to English by the third and fourth translators to provided two back-translated versions. A committee was formed to compare and analyze between the two back-translated versions, and between both back-translated versions and the original English version. A consensus was obtained by reviewing and resolving any discrepancies regarding conceptual and semantic equivalence to develop the prefinal version of M-BCTQ.

Phase 2: Face validity and content-related validity

A questionnaire was distributed to ten patients and ten expert reviewers from the professional therapists. The therapists were a native speaker of Malay language, which had at least three years of clinical experience in treating patients with CTS. Sample size with a minimum of 10 participants was recruited for each pretesting (Beaton et al., 2000; Sousa & Rojjanasrirat, 2011). The patients were asked to give a response to ten statements of the questionnaire that comprises of ten areas based on their experience of using the prefinal version of M-BCTQ. For content validity, the same questionnaire was used along with three open-ended questions that asked the professional therapists' opinions and suggestion to further support the content equivalent and structure of the items in the prefinal version. The questionnaire using the 4-points Likert response scale measuring the levels of agreement were employed, i.e., 1: strongly disagree to 4: strongly agree. Content validity index at the item level (I-CVI) and the scale level (S-CVI/Ave) by Lynn (1986) was calculated as an empirical measurement analysis to validate the items and scale. The necessary modification was made to continue developing the prefinal version for psychometric testing.

Phase 3: Test re-test reliability, internal consistency and construct validity

A total of 55 patients with CTS were asked to administer the prefinal version of M-BCTQ for the psychometric testing. All issues and suggestions were addressed and resolved to produce the final version of M-BCTQ. The psychometric testing involves test re-test reliability on the same patients within 2-weeks, internal consistency and constructs validity by correlating between both scales in the final version of M-BCTQ and MV-DASH.

3.3 Statistical analysis

Test re-test reliability by using ICC was assessed by administrating to the same patients with the value above than 0.7 considered as having appropriate reliability (Streiner & Norman, 2002). Internal consistency was measured by Cronbach's alpha coefficient with alpha value more than 0.7 considered as satisfactory, values more than 0.8 found as good, while values more than 0.9 considered as excellent correlation. Construct validity was assessed using Spearman's correlation coefficient by carrying out trials on the relationship between SSS and FSS of the final version of M-BCTQ and MVDASH with the correlation coefficient (Rs) value more than 0.7 indicates a strong correlation. All statistical tests were using IBM SPSS statistic 22.0 and P values less than 0.05 were considered to indicate statistical significance.

3.4 Research ethics

Ethical approvals to conduct this study were granted by the Research Ethics Committee, Universiti Teknologi MARA and the Medical Research and Ethics Committee, Ministry of Health, Malaysia (NMRR-18-970-40770(IIR)).

4.0 Results

4.1 Face validity and content-related validity

A group of 10 patients with typical signs and symptoms of CTS and ten bilingual OTs and PTs participated in the face and content validity assessment. All participants found that the prefinal version of the M-BCTQ was clear and presented no difficulty in answering the questions. 7 (70%) of the expert reviewers were OTs while 3 (30%) were PTs. Table 1 and Table 2 shows the demographics of the patient and expert reviewers, respectively, in the face and content validity's phase. Content validity index (CVI) used in this phase to analyze the themes selected for the process of face validity and content validity. Table 3 presented the CVI values from all participants in the face and content validity process. Number 1 indicates the favourable rating, while the unfavourable score has indicated by 0. I-CVI values of 0.78 (Lynn, 1986) or above and S-CVI/Ave values of 0.90 (Waltz, Strickland, & Lenz, 2010) or above were the minimum acceptable indices to achieve. This study has found that S-CVI/Ave values were 0.93 for face validity and 0.90 for content validity, while all items were above 0.78 (I-CVI), indicating the M-BCTQ has a good face and content validity. None of the participants suggested that any issue should be included or omitted from the scale. Some experts suggested the response format should be placed in a table. All recommendations were taken for the final modification of the translated version according to the importance and relevancy.

Table 1: Demographics of the patients.

Variables	n
Gender,	
Women	8
Men	2
Age mean (SD)	43.2 (9.016)
Affected hand, n (%)	
Right	3 (30)
Left	2 (20)
Both	5 (50)

Table 2: Demographics of the expert reviewers.

Variables	n
Gender,	
Women	8
Men	2
Age group (years)	
20 – 29	6
30 – 39	4
40 – 49	0
Profession,	
Occupational therapist	7
Physical therapist	3
Academic qualification	
Diploma	8
Degree	2
Master's degree	0
Working experience (years)	
3 – 9	6
10 – 19	4
20 – 29	0

Table 3: I-CVI and S-CVI/Ave values for the phase of face validity and content-related validity.

Areas	Face validity (n=10) I-CVI	Content-related validity (n=10) I-CVI
Communicate	0.9	1
Relevant	0.8	1
Easy to use	1	1
Comprehensive	1	0.8
Willing to repeat	0.9	0.9
Burden	1	0.8
Overlong	0.8	0.8
Embarrassing	1	1
Overcomplicated	0.9	0.9
Upsetting	1	0.8
mean (S-CVI/Ave)	0.93	0.90

4.2 Test-Retest, Internal Consistency, And Construct Validity

A total of 55 consecutive patients with typical signs and symptoms of CTS confirmed by medical officers at the Selayang Hospital had agreed to participate and included in the psychometric testing. The mean age was 45.9 years (SD = 9.826), of whom 45 (81.8%) were women, and 10 (18.2%) were men. Symptoms of both hands were affected by CTS in 22 (40%) patients followed by the right side in 21 (38.2%) and the left hand in 12 (21.8%). Most of the patients were Malays 37 (67.3%) followed by Chinese 10 (18.2%) and Indian 8 (14.5%). All patients had no difficulties in answering the prefinal version of M-BCTQ and required 6-10 minutes to complete it. No ceiling and floor effects have found. Table 4 described the demographic characteristics of the patients in test-retest, internal consistency, and construct validity assessment.

Test-retest reliability assessed by using the ICCs that recorded from the same patients at a two-week interval for the first and second self-administration of the M-BCTQ. The average period between the two tests was 16.7 ± 6.4 days. Both scales of M-BCTQ had excellent test-retest reliability, with the values of ICCs were greater than 0.8. The ICCs were 0.837 (95% confidence interval [CI], 0.736-0.902) for the SSS and 0.913 (95% confidence interval [CI], 0.856-0.948) for the FSS. Table 5 presents the results of test-retest reliability. The Cronbach alpha coefficient for the internal consistencies was reported at 0.864 for SSS and 0.893 for the FSS. These Cronbach alpha values are considered good correlation as the value are greater than 0.8. Detailed results of internal consistencies and the effect of item deletion on alpha values are presented in Table 6 and 7. The intercorrelation of both scales (FSS and SSS) in the final version of M-BCTQ demonstrated a strong correlation with correlation coefficient values of 0.716 (p<0.001). A high correlation was reported between the scores of SSS and MV-DASH (rs = 0.79, p<0.001, two-tailed), that indicated satisfactory convergent validity the symptoms severity scale of both instruments. The score of FSS and MV-DASH also reported high correlation (rs = 0.83, p<0.001, two-tailed), indicating excellent convergent validity between both instruments.

Table 4: Demographics of the patients

Variables	Values
Gender, n (%)	
Women	45 (81.8)
Men	10 (18.2)
Age mean (SD)	45.9 (9.83)
Affected hand, n (%)	

Right	21 (38.2)
Left	12 (21.8)
Both	22 (40)
Employment status, n (%)	
Employed	41 (74.5)
Unemployed	8 (14.5)
Retired	6 (11)
Races, n (%)	
Malay	37 (67.3)
Chinese	10 (18.2)
Indian	8 (14.5)
Others	0

Table 5: Results on test-retest reliability, using intra-class correlation (ICC)

Test-retest Reliability	Symptom Severity Scale	Functional Status Scale
Mean (SD) for first measure	2.43 ± 0.58	1.95 ± 0.66
Mean (SD) for second measure	2.32 ± 0.58	1.87 ± 0.68
ICC (95% CI)	0.837 (0.736 – 0.902)	0.913 (0.856 – 0.948)
Floor effects (%)	0	0
P value	< 0.001	< 0.001

SD: standard deviation

Table 6: Mean values, correlations, and Cronbach α coefficient for SSS.

	Mean	Std. deviation	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted	Cronbach's Alpha
SSS							0.864
Q1	2.53	0.81	24.218	34.914	0.573	0.852	
Q2	2.31	0.90	24.436	35.732	0.422	0.862	
Q3	2.44	0.74	24.309	35.403	0.583	0.852	
Q4	2.64	1.19	24.109	30.173	0.725	0.839	
Q5	2.47	1.14	24.273	30.869	0.707	0.840	
Q6	2.62	0.87	24.127	35.002	0.516	0.855	
Q7	2.18	0.79	24.564	35.436	0.529	0.855	
Q8	2.55	0.77	24.200	36.089	0.479	0.858	
Q9	2.51	0.69	24.236	35.813	0.580	0.852	
Q10	2.71	1.01	24.036	35.110	0.412	0.865	
Q11	1.80	0.78	24.946	34.015	0.711	0.843	

Table 7: Mean values, correlations, and Cronbach alpha coefficient for FSS.

	Mean	Std. deviation	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted	Cronbach's Alpha
FSS							0.893
Q1	1.67	0.69	13.891	23.247	0.558	0.889	
Q2	1.75	0.95	13.818	20.263	0.740	0.872	
Q3	1.71	0.71	13.855	21.756	0.785	0.871	
Q4	1.89	0.76	13.673	21.743	0.725	0.875	
Q5	2.07	1.03	13.491	19.884	0.707	0.876	
Q6	2.25	0.90	13.309	21.625	0.596	0.887	
Q7	2.53	0.98	13.036	20.702	0.653	0.882	
Q8	1.69	0.84	13.873	21.632	0.661	0.880	

Table 8: Correlation between M-BCTQ and MV-DASH.

M-BCTQ (n = 55)	MVDASH
Mean (SD)	28.30 ± 17.12
Spearman's correlation coefficient with SSS	0.791
Spearman's correlation coefficient with FSS	0.831

5.0 Discussion

BCTQ was developed for use in a heterogeneous sample of patients of a wide age range with CTS (Levine et al., 1993). This evaluation tool has values that assessing the subjective discomfort and functional capacity of the hand in quick and easy in comparison to other outcome measures. This current study has introduced the M-BCTQ according to the guideline that designed for use in cross-cultural health care research. This guideline was to ensure the M-BCTQ is cross-culturally validated and reliable for the Malaysian population. No changes were made base on the original version. The results of the psychometric testing of M-BCTQ were comparable to other validation studies. The empirical measurement analysis by using CVI in content validity has verified content equivalence and structure format of items and scale of M-BCTQ as good as the original version.

The majority of patients in the current study were women (81.8%), which women are more likely than men to encounter CTS (Burton et al., 2018). About 22% of patients had bilateral CTS, which affects their abilities to perform daily living tasks thoroughly. While approximately 41% of patients still working in different industries, which require their hands to sustain their productivity. The social

consequences for the patient may lead to lost days of work, job changes and high healthcare cost as the symptoms encountered (Feuerstein et al., 1998). Participation of various races of the patient from Malay, Chinese and Indian, as Malaysian's native speakers, represented the significant ethnicity in Malaysia. It is essential and valuable in the evaluation of the translated scale to ensure its usefulness according to Malaysian's context and perspectives. A systematic method of forward and backward translation by translators on the M-BCTQ has a high-quality translation. Involvement of experts' participation among OTs and PTs for their agreement on usability and accuracy of items in both M-BCTQ's scale has assured the content-related validity were firmly retained.

The present study demonstrated high levels of reliability and validity of M-BCTQ in patients with CTS. The ICC was calculated for the test re-test reliability for the present study. It is more accurate, adequate and unbiased for an estimate of re-test correlation for any sample size (Hopkins, 2000). The value of ICC of both scales in M-BCTQ was higher than 0.8 that testify to excellent test-retest reliability. The excellent value of ICC for SSS showing comparable results with previously validated version, while, the FSS value was as high up to 0.9, similarly with Arabic and Spanish translation (Hamzeh & Alworikat, 2019; Otero-Alvaro et al., 2016). Although the agreement was reached between the first and second measures within the 2-weeks interval as compared to previous studies (Ebrahimzadeh et al., 2015; Lue et al., 2014) which were shorter (within a week), ICC in the current study shows excellent test reliability. Thus, the translated questionnaire traded as comprehensible and reliable as the version contained in the other languages.

The Cronbach alpha coefficient of M-BCTQ in both scales demonstrated good internal consistency. It was very similar to the Arabic and Persian version (Hamzeh & Alworikat, 2019; Hassankhani et al., 2018), as well as to previous validation studies. Only the Polish (Trybus et al., 2019) and Korean (Park et al., 2013) version demonstrated excellent internal consistency for both scales with the Cronbach alpha coefficient value more than 0.9. There is no significant effect on the Cronbach alpha values for the individual item deletion. Thus, all items in the M-BCTQ were in the same domain and correlated with each other.

M-BCTQ was compared with MV-DASH to evaluate the convergent validity as per the previous study in other languages (Hamzeh & Alworikat, 2019; Trybus et al., 2019; Lue et al., 2014; Park et al., 2013; Imaeda et al., 2007). The current study found a strong correlation in both scales of M-BCTQ and MV-DASH that showed good validity, but, only the Korean version has shown a better relationship than the current study. MV-DASH is a region-specific outcome measure designed to evaluate the entire upper limb impairment and symptoms, highly responsive to CTS patients (Hudak et al., 1996). In many studies, the MV-DASH's 30-item disability/symptom scale has been shown to have the same domain as in the M-BCTQ, making it the critical basis for the validation process of the new translated version. Previous studies were also conducted to evaluate the validity of their translation version BCTQ with other outcome measurements such as the more general questionnaire of Short Form 36 (SF-36) (Sezgin et al., 2006) and with the more specific questionnaire of the Michigan Hand Outcomes Questionnaire (MHQ) (Trybus et al., 2019), found deficient and negative correlation, respectively, to reflect different domains.

6.0 Conclusion and recommendation

Limitation of the current study includes a small sample size from a single medical centre. Multicenter studies involving non-surgical and surgically treated patients were planned to enhance generalization. Secondly, the responsiveness of the M-BCTQ was not done to complete the process of validation. Future study should take higher sample sizes into account and include the responsiveness process to the particular intervention and time for further testing of M-BCTQ.

Findings from this current study that were derived through the use of sufficient statistical analysis have verified that the M-BCTQ has excellent reliability with the ICCs value of 0.837 for the SSS and 0.913 for the FSS. At the same time, the Cronbach alpha coefficient was reported at 0.864 for SSS and 0.893 for the FSS. A strong correlation between both subscales of M-BCTQ and the MV-DASH established the concurrent validity. Thus, the M-BCTQ can be widely used as an evaluation tool for patients with CTS as a primary outcomes measure of clinical and post-operative treatment for Malay speaking population in Malaysia. The applicability of this M-BCTQ will support the evidence-based practice in the development of the framework for healthcare according to Malaysian context and perspectives.

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