Cross-Cultural Adaptation of the Korean Version of the Boston Carpal Tunnel Questionnaire: Its Clinical Evaluation in Patients with Carpal Tunnel Syndrome Following Local Corticosteroid Injection

Dong-Jin Park,¹ Ji-Hyoun Kang,¹ Jeong-Won Lee,¹ Kyung-Eun Lee,¹ Lihui Wen,¹ Tae-Jong Kim,¹ Yong-Wook Park,¹ Tai-Seung Nam,² Myung-Sun Kim,³ and Shin-Seok Lee¹

¹Division of Rheumatology, Department of Internal Medicine, ²Departments of Neurology, and ³Orthopedic Surgery, Chonnam National University Medical School & Hospital, Gwangju, Korea

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Address for Correspondence: Shin-Seok Lee, MD  Division of Rheumatology, Department of Internal Medicine, Chonnam National University Medical School & Hospital, 42 Jebong-ro, Dong-gu, Gwangju 501-757, Korea  Tel: +82.62-220-6591, Fax: +82.62-225-8578  E-mail: shinseok@chonnam.ac.kr

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INTRODUCTION

Carpal tunnel syndrome (CTS) is a prevalent disease that affects about 0.1% of the general population (1, 2), and 1%-5% of workers in certain occupations (3). CTS results from median nerve compression at the carpal tunnel level in the wrist, and is a frequent cause of compression neuropathy. CTS affects females more than males, and its incidence increases with age (4). The diagnosis of CTS is based on the symptoms and signs and electromyographic (EMG) studies. Characteristic symptoms in patients with CTS include nocturnal pain, numbness, and tingling sensation in the radial sides of hands; Tinel's sign and Phalen's sign are common indicators of CTS. Although EMG diagnostic studies are highly specific, false-negative rates vary from 10%-20% (5). Recently, ultrasonography of the median nerve has emerged as an alternative to EMG studies (6, 7). Management of CTS depends on the severity of symptoms; treatment options include nonsurgical local corticosteroid injections and surgical carpal tunnel release.

Previously, CTS severity measurements and treatment outcomes were assessed by neuromuscular studies and objective signs by physicians, and did not incorporate the patient’s perspectives. Recently, Levine et al. introduced the Boston Carpal Tunnel Questionnaire (BCTQ), a reliable and valid self-administered disease-specific outcome questionnaire for CTS (8). The questionnaire is a patient-based outcome measure of patient symptoms and functions. The BCTQ has been translated into many languages and validated in several countries (9-11); however, a Korean version of the BCTQ has not been developed.

We generated and validated a Korean culture and language-adapted version of the BCTQ (K-BCTQ) to introduce a suitable tool for measurement of the severity of symptoms, functional status, and responsiveness to local corticosteroid injection therapy in patients with CTS.
MATERIALS AND METHODS

Population and study design
Between March and November 2011, we evaluated 54 consecutive patients with CTS at the rheumatology, neurology and orthopedic surgery practices of Chonnam National University Hospital, which is a tertiary and academic center in Korea. Included participants were over 18 yr of age, and had confirmed CTS diagnosed by characteristic symptoms, signs and electro-physiological study done by a designated neurologist. Exclusion criteria were as follows: severe neuropathy such as diabetic peripheral neuropathy, history of wrist trauma or surgery and having severe hand discomfort due to other diseases. All patients were included in the test-retest reliability and internal consistency analyses. The re-test was performed 2 weeks after the original test, with no intervention given to patients during the 2-week interval. Of the 54 patients, 29 were enrolled in the prospective study that assessed responsiveness to clinical change. The patients were managed by ultrasonography-guided local corticosteroid injection therapy (40 mg of triamcinolone acetonide), and evaluated by the same rheumatologist at a 3-month follow-up visit who had 1 yr experience with this procedure.

Development of the Korean version of the BCTQ
The BCTQ, also referred to as the Levine scale, Brigham and Women’s Carpal tunnel Questionnaire, and Carpal Tunnel instrument, is a patient-based outcome measure. The questionnaire consists of two multi-item scales: the Symptom Severity Scale (SSS) and the Functional Status Scale (FSS). The SSS refers to six critical domains for evaluation of CTS, and contains questions regarding severity of pain, paresthesia, numbness, weakness, nocturnal symptoms, and over-all functional status. The FSS refers to eight functional activities affected by CTS, including writing, buttoning of clothes, holding a book while reading, gripping of a telephone handle, opening of jars, performing household chores, carrying grocery bags, bathing and dressing. The response scales ranges from 1 (mildest) to 5 (most severe) points, and the overall SSS and FSS scores are calculated as the mean of the scores.

After obtaining permission from the developer of BCTQ, the translation and linguistic validation process were performed as follows. In this study, three native Korean-speaking bilingual translators, with or without abundant clinical experience, translated the original questionnaire into the Korean version. Both versions of the questionnaire were fully discussed to reach consensus among the authors and translators. Two additional translators participated to confirm the conceptual equivalence and improve clarity in each individual phrase. Lastly, three native-English speaking bilingual translators converted the Korean version back into English to assess the conceptual equivalence. A detailed description of this process can be found in our previous works (12, 13).

The Korean version of the Disability of the Arm, Shoulder and Hand Questionnaire (K-DASH) and EuroQol (EQ-5D)
To measure the construct-validity, we compared the K-BCTQ with the K-DASH (12), a region-specific instrument of health related to quality of life, and the EQ-5D, a generic instrument of health related to quality of life. The DASH is a self-rated measure of upper-extremity disability and symptoms and includes 30 items with a response scale of 1-5. Of the 30 items, 21 questions refer to the degree of difficulty in performing different physical activities, five refer to the severity of symptoms (pain, activity-related pain, tingling, weakness and stiffness), and four refer to the impact on social activities, work, sleep and self-image (14).

The EQ-5D, validated previously in the Korean language (15), consists of two components: a descriptive system and the EQ visual analogue scale (EQ VAS). The descriptive system comprises five quality-of-life dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression; each dimension has three levels: no problems, some problems and extreme problems. The EQ VAS records self-rated health on a vertical, visual analogue scale (16). Here, we used only the EQ-5D descriptive system to measure patients’ quality of life. We hypothesized that patients with higher EQ-5D scores would have lower condition-specific K-BCTQ scores, indicating lower disease activity.

Statistical analyses
The test-retest reliability, assessed by administering the BCTQ to the same patients twice at a 2-week interval, was measured using intra-class correlation (ICC); results greater than 0.7 were interpreted as having appropriate reliability. The internal consistency was assessed using by Cronbach’s alpha coefficient, which summarizes inter-item correlations among all items in a scale. With a range of 0 to 1, Cronbach’s alpha scores greater than 0.7 indicate satisfactory correlation, values of 0.8 indicate good correlation, and values of 0.9 indicate excellent correlation. Using Spearman’s correlation coefficient, the validity was assessed by comparing the correlation of the SSS and FSS of the CTS questionnaire with the K-DASH and EQ-5D in all patients. We hypothesized that the K-DASH would have a stronger correlation than the EQ-5D because K-DASH contained questions about hand problems. Moreover, as mentioned previously, we hypothesized that patients with high K-BCTQ scores would have lower EQ-5D scores, representing a negative correlation between the two instruments. The responsiveness (the ability of the CTS questionnaire to reflect clinical change) was assessed by comparing pre- and post-treatment scores in 29 patients who participated in the prospective study that assessed responsiveness, and by calculating the effect size.

All statistical tests were two-sided and P values less than 0.05 were considered to indicate statistical significance. Statistical
analysis was performed using SPSS for Windows (version 18.0; SPSS, Chicago, IL, USA).

**Ethics statement**
All patients provided informed consent twice (at the time of study initiation and before local corticosteroid injection therapy), and the study received approval by the institutional review board of Chonnam National University Hospital (IRB No. 2010-08-135). The registration number of this study (KCT0000050) was assigned by the Clinical Research Information Service, which is the primary registry of the WHO International Clinical Trials Registry Platform.

**RESULTS**

The K-BCTQ was self-administered by 54 consecutive patients with typical symptoms and signs of CTS and CTS diagnosis confirmed by an electrophysiological study performed at the Chonnam National University hospital. The median age of the study population was 50 yr (range: 18-65 yr) and 50 (92.5%) patients were female. The questionnaire was administered to all patients twice at an interval of 2 weeks.

Test-retest reliability was assessed using the ICCs recorded from the first and second self-administrations of the K-BCTQ before treatment of CTS. The ICCs were 0.931 (95% confidence interval [CI], 0.882-0.960; P < 0.001) for the SSS and 0.844 (95% CI, 0.731-0.909; P < 0.001) for the FSS. The internal consistencies, assessed using Cronbach's alpha, were 0.929 for the SSS and 0.951 for the FSS (Table 1).

To assess construct validity, the K-BCTQ was compared with the K-DASH and EQ-5D; all observed correlations were as hypothesized. Before treatment for CTS, a high correlation was observed between the symptom severities of the K-BCTQ and K-DASH (r = 0.867, P < 0.001), and between the function severities of the K-BCTQ and K-DASH (r = 0.873, P < 0.001). After treatment for CTS, a high correlation was observed in both scales (r = 0.800, P < 0.001; r = 0.838, P < 0.001, respectively). Correlations between the K-BCTQ and EQ-5D both before (r = -0.637; r = -0.698, respectively) and after local injection therapy (r = -0.488; r = -0.430, respectively) were weaker than those between K-BCTQ and K-DASH (Table 2).

Responsiveness was assessed in a prospective follow-up study of local corticosteroid injection therapy, as determined by mean score and effect size. The effect size of symptom severities of the K-BCTQ was 0.67, and that of functional severities was 0.58 (Table 3). The effect size of K-DASH was similar (0.59) to that of the symptom and functional severities of the K-BCTQ, whereas the effect size of EQ-5D was lower (0.17) than those of K-BCTQ and K-DASH.

**DISCUSSION**

In the present study, we produced the Korean version of self-administered BCTQ, and provided evidence of its acceptable reproducibility and internal consistency. In addition, we showed that the K-BCTQ can reflect clinical changes following local corticosteroid injection.

Although objective evidence has been shown to be important for assessing CTS, including signs of neuromuscular impairment and physical findings such as Tinel's sign and Phalen's sign, a discrepancy between objective evidence and symptoms

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**Table 1. Test-retest reliability in 54 patients with carpal tunnel syndrome**

| Reliability | Symptom Severity Scale (Mean (SD)) | Functional Status Scale (Mean (SD)) |
|-------------|------------------------------------|-------------------------------------|
| Test-retest reliability | 2.48 ± 0.95 | 2.22 ± 1.23 |
| Mean (SD) for first measure | 2.44 ± 0.97 | 2.12 ± 0.95 |
| Mean (SD) for second measure | 0.931 (0.882-0.960) | 0.844 (0.731-0.909) |
| ICC (95% CI) | < 0.001 | < 0.001 |
| Internal consistency | Cronbach’s alpha | 0.929 | 0.951 |

**Table 2. Correlation coefficient between K-BCTQ, K-DASH and EQ-5D**

| Injection type | K-DASH | EQ-5D |
|---------------|--------|-------|
| K-BCTQ, pre-injection (n = 54) | Mean (SD) | 28.5 ± 21.7 | 0.80 ± 0.12 |
| | Spearman's correlation coefficient with SSS | 0.867† | -0.637† |
| | Spearman's correlation coefficient with FSS | 0.873† | -0.698† |
| K-BCTQ, post-injection (n = 29) | Mean (SD) | 9.17 ± 0.84 | 0.92 ± 0.05 |
| | Spearman's correlation coefficient with SSS | 0.800† | -0.488* |
| | Spearman's correlation coefficient with FSS | 0.838† | -0.430* |

*P < 0.05, †P < 0.001. K-BCTQ, Korean version of the Boston Carpal Tunnel Questionnaire; K-DASH, Korean version of the Disability of the Arm, Shoulder and Hand Questionnaire; EQ-5D, EuroQol; SSS, Symptom Severity Scale; FSS, Functional Status Scale.
and functional status in patients with CTS is sometimes observed. Therefore, in the assessment of severity of CTS and evaluation of treatment outcome, the patients’ perspectives and concerns are considered important in clinical practice. Recently, a specific CTS measurement tool for measurement of the symptoms and functional status of patients with CTS was developed; its reliability and validity have been confirmed (17).

The original version of the BCTQ showed high correlation coefficients in test-retest reliability measurements \( (r = 0.91 \text{ and } r = 0.93 \text{ for the SSS and the FSS, respectively}) \). Likewise, the Spanish version of the questionnaire showed high test-retest reliability \((r = 0.87 \text{ and } r = 0.85 \text{ for the SSS and the FSS, respectively}) \) (18). The Swedish version showed acceptable but lower correlation than the study mentioned previously \((r = 0.64 \text{ and } r = 0.71 \text{ for the SSS and the FSS, respectively}) \) (10). In this study, our data showed good correlation in terms of the test-retest reliability.

The Cronbach’s alpha coefficients of the K-BCTQ \((0.929 \text{ for the SSS and 0.951 for the FSS}) \) are indicative of the high internal consistency of the questionnaire. These results are similar to those of the original version of the BCTQ \((0.89 \text{ and } 0.91 \text{ for each scale}) \), indicating that both the Korean and original versions of the BCTQ have good correlations among the items.

The K-BCTQ was compared with two other measurements (K-DASH and EQ-5D) to assess construct-validity using Spearman’s correlation coefficient. All observed correlations were in the expected directions. In our study, a high correlation between K-BCTQ and K-DASH was found. Similarly, Gay et al. reported good correlation \((\text{Spearman’s correlation coefficient } 0.87) \) between the BCTQ and DASH (19). Although the correlation with the EQ-5D was in the expected direction, the correlation with EQ-5D was relatively weaker than that with K-DASH. The K-DASH is a region-specific instrument used to measure the symptoms and functional status of the upper-extremity, including the hand (14), and the EQ-5D is a generic measure of health status that does not focus on regional disabilities (16). We believed that the weaker correlation between K-BCTQ and EQ-5D could be attributed to this difference of measurement.

Responsiveness to local corticosteroid injection is an important aspect in the outcome measurement of CTS. Effect sizes of more than 0.5 are considered moderate and those of more than 0.8 are considered large. We obtained pre- and post-treatment questionnaire scores to assess its ability to reflect clinical improvement using a prospective method. Surgical treatment is generally preferred in severe cases of CTS, whereas nonsurgical treatment is reserved for mild-to-moderate CTS. Several studies have shown that local corticosteroid application provides clinical improvement and could be a primary treatment option for CTS (20, 21). In our study, local corticosteroid injection therapy showed a moderate effect size at the 3-month follow-up. Effect size measured by K-DASH showed similar results to those of the K-BCTQ. As expected, the absolute value of the effect size using EQ-5D was smaller than those found with other measurement tools. Our responsiveness result supports the use of local corticosteroid injection therapy as a treatment for CTS, and the responsiveness of the Korean version seems to be acceptable in clinical practice.

This study had some limitations. Our study was performed in a single tertiary center. Although all subjects were Korean and were able to skillfully read the Korean language, we performed a cross-cultural adaptation process wherein some elderly patients required some assistance when completing the questionnaire because they were somewhat confused about the meanings of numbness and tingling. However, most patients completed the K-BCTQ without any hesitation.

In summary, despite the linguistic differences, the K-BCTQ represents a standardized patient-based instrument for assessing the severity of symptoms and functional status in patients with CTS. Future clinical practice should include the K-BCTQ to improve the quality of medical care associated with CTS.

DISCLOSURE

The authors have no conflicts of interest to disclose.

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