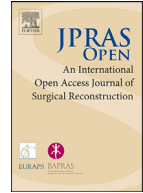




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Original Article

Measurement properties of the Danish version of the Boston Carpal Tunnel Questionnaire

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ABSTRACT

Background and Aims: Patient reported outcome measures are often used in medical research to evaluate symptoms and functional status in patients. The Boston Carpal Tunnel Questionnaire is specifically designed to evaluate functional status and symptom severity in patients with Carpal Tunnel Syndrome. The aim of this study was to validate and examine the measurement properties of the Functional Status Scale and Symptom Severity Scale from the Danish translated Boston Carpal Tunnel Questionnaire.

Material and Methods: We analyzed 88 prospectively enrolled patients in the validity and responsiveness group and 31 prospectively enrolled patients in the reliability group. Patients in the validity and responsiveness group answered the Quick Disabilities of the Arm, Shoulder and Hand Questionnaire and the Danish translated Boston Carpal Tunnel Questionnaire preoperatively and after surgery. Patients in the responsiveness group answered the same questionnaire two times prior to surgery.

Results: Responsiveness of the two subscales were high (Effect Size 0.99/1.76; Standardized Response Mean 0.86/1.50). Correlation to

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the Danish validated QuickDASH was high (ρ 0.75/0.89). Test-retest reliability was high (ICC 0.94/0.90) and the internal consistency was high (Cronbach's alpha 0.93/0.92).

Conclusion: Our study shows satisfactory results of both subscales of the Danish translated Boston Carpal Tunnel Questionnaire. This makes it highly useful when conducting research on patients with Carpal Tunnel Syndrome.

Trial registration: The Danish Data Protection Agency: jr. nr. 2007-58-0010

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Introduction

Carpal tunnel syndrome (CTS) is a common neuropathy of the hand and wrist, with symptoms such as pain, numbness and tingling in the hand and/or wrist.¹ It is estimated that the European prevalence of CTS is 1–7%² and surgical decompression of the carpal tunnel is one of the most common hand surgical procedures. Due to the high incidence, several studies have examined predictors of the surgical outcome in CTS patients. To do so, it is crucial to use well-established measures to evaluate the function and symptom severity in CTS patients. The Boston Carpal Tunnel Questionnaire (BCTQ) is a CTS specific questionnaire used to assess function and symptoms.³ The BCTQ is divided into two parts: The Symptom Severity Scale (SSS) and the Functional Status Scale (FSS), which examine the symptom severity and the level of disability, respectively. The BCTQ has been validated and evaluated in several languages, including Swedish,⁴ Portuguese,⁵ Spanish,⁶ Chinese,⁷ Greek,⁸ Turkish,⁹ and Polish.¹⁰ A Danish validation of the BCTQ is not available. The purpose of this study was to examine the psychometric properties of the Danish version of the BCTQ including the SSS and FSS subscales. This was done through validity, responsiveness and reliability.

Materials/patients and methods

The Danish translated BCTQ we used was translated at our institution more than 20 years ago.¹¹

For the validation of the psychometric properties of the Danish translated BCTQ, we used the checklist in the Consensus-Based Standards for the Selection of Health Status Measurement Instrument (COSMIN)[12, 13] as guideline and inspiration. The COSMIN checklist includes 4 items; validity, responsiveness, reliability and interpretability.^{12,13} As the purpose of this study was to examine the measurement properties of the Danish translated BCTQ, we did not assess the interpretability but focused on validity, responsiveness and reliability.

Data was collected in two Danish hospitals. At one hospital data was collected to evaluate validity and responsiveness, and at the other hospital data was collected to evaluate reliability of the Danish translated BCTQ (DBCTQ). At both clinics the same indication was used where all operations were performed in local anesthesia and the postoperative procedure was the same. In both groups patients with nerve conduction studies verified idiopathic CTS were included. The patients from both hospitals were asked to complete an identical set of questionnaires including both the Quick Disabilities of the Arm, Shoulder and Hand Questionnaire (QDASH) and the Danish translated BCTQ.

Validity and responsiveness group

The patients in the validity and responsiveness group were recruited in the Department of Orthopaedics at Hospital of Southern Jutland, Sønderborg, Denmark, from March 2018 to December 2018.

Flow Diagram

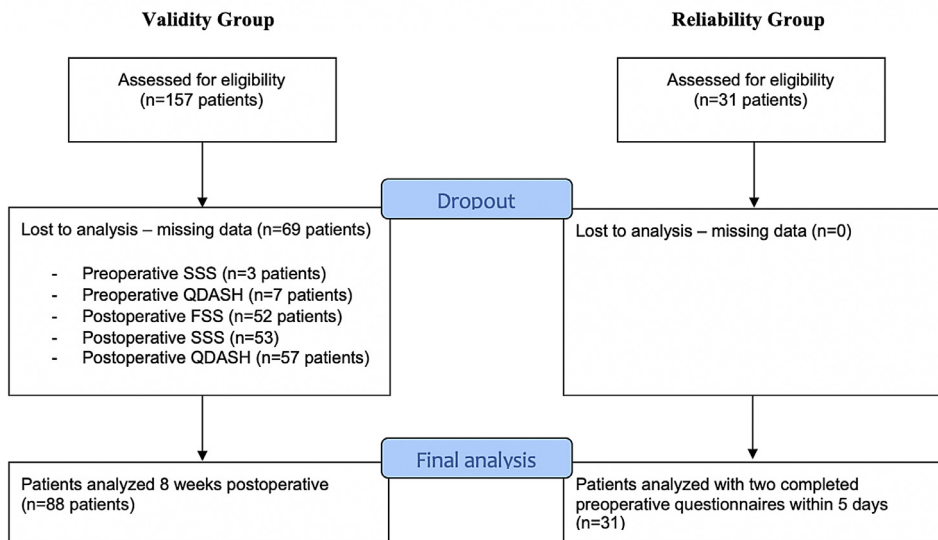


Fig. 1. Flow diagram for the Validity Group and the Reliability Group.

Table 1

Patient characteristics in the validity/responsiveness group and the reliability group

Characteristics	Validity and responsiveness group (N = 88)	Reliability group (N = 31)
Age, mean ± SD (range)	60 ± 16 [57–63]	57 ± 16 [51–63]
Gender (Male / Female)	41 / 47	13 / 18
Dominant hand, %	55%	68%
Diabetes, %	10%	10%
DBCTQ: FSS, mean ± SD	2.6 ± 0.9	2.7 ± 0.9
DBCTQ: SSS, mean ± SD	3.0 ± 0.8	2.9 ± 0.8
QDASH, mean ± SD	43.1 ± 23.0	44.0 ± 22.3

SSS = Symptom Severity Scale. FSS = Functional Status Scale. QDASH = Quick Disability of the Arm Shoulder and Hand questionnaire.

Patients in this group were asked to complete the questionnaire preoperatively and again 8 weeks postoperatively. The patients completed the questionnaire preoperative at the time when the decision to operate was made at the hospital, and 8 weeks postoperative where the questionnaire was sent home to the patients. We recruited 157 patients (61% females) with a mean age of 58 years (range: 22–89). After patient drop out due to insufficient questionnaire completion (missing preoperative SSS $n = 3$, preoperative QDASH $n = 7$, postoperative FSS $n = 52$, postoperative SSS $n = 53$, postoperative QDASH $n = 57$) the analyzed cohort consisted of 88 patients (53% females) with a mean age of 60 years (range: 22–88), (Fig. 1). The patients were excluded if they had more than one missing item in the QDASH, or more than two missing items in either FSS or SSS.

The mean time from surgery to follow-up was 68 ± 16 days. Further patient characteristics are given in Table 1.

Reliability group

The patients in the reliability group were recruited in the Department of Orthopaedics at Holstebro Regional Hospital, Holstebro, Denmark, from April 2019 to October 2019. Patients in this group

were asked to complete the questionnaire two times prior to surgery. We recruited 31 patients (58% females) with a mean age of 57 years (range: 21–85), (Fig. 1). The patients were asked to complete the questionnaire at the first visit at the hospital, and they were asked to return a second BCTQ again after five days. The mean time between the two assessments was 5 ± 4 days. There was complete follow-up in this group. Further patient characteristics are given in Table 1.

Questionnaires

The BCTQ is a questionnaire used to evaluate symptom severity and functional status in CTS patients, and is both responsive, reliable and valid.³ It consists of two subscales: an 8-item subscale for functional status (FSS) and an 11-item subscale for symptom severity (SSS). The FSS examines hand function through 8 statements on daily activities. The SSS examine symptom severity through 11 statements on e.g. weakness, numbness and pain. On both subscales, the items are answered on a 5-point scale from 1 (no difficulty / no symptoms) to 5 (cannot perform the activity at all / the worst symptoms) for the FSS and SSS respectively. A single score is then calculated for each subscale as the mean of the scores on the 8-item FSS and 11-item SSS.

To enable a comparison of the DBCTQ to a validated tool, the patients were also asked to fill out the QDASH. The QDASH is an 11-item shortened version of the original 30-item Disabilities of the Arm, Shoulder and Hand Questionnaire (DASH) used to evaluate patient disability and function in the arm, shoulder and hand.¹⁴ The QDASH has been showed to be comparable to the full DASH ($r=0.98$) with both similar construct validity and responsiveness compared to the full DASH.^{15–17} We used a translated and validated Danish translated version of the QDASH.¹⁸ Due to comparability reasons, the QDASH was used in this study.

Statistical analyses

Normally distributed data is presented using means, standard deviations (SD), and 95% confidence intervals (95% CI) and non-normally distributed data is presented using medians with interquartile range. Normality of data was assessed using Quantile-Quantile plots (Q-Q plots).

In the validity and responsiveness group we analyzed acceptability, responsiveness and construct validity.

Acceptability

To assess the acceptability we used floor and ceiling effects with an acceptance level of 15%¹⁹ and skewness considered acceptable in the range from -1 to 1 as suggested by existing literature.²⁰

Responsiveness

In the COSMIN checklist they do not suggest the use of responsiveness measures like Effect Size (ES) and Standardized Response Mean (SRM) as they are considered measures of change magnitude after intervention rather than a measure of quality. However, we used the SRM and the ES to analyze the responsiveness of the SSS- and FSS subscales of the DBCTQ as they can affect sample size calculations in future studies. The SRM was calculated as the mean of the change scores divided by the standard deviation of the change scores. ES was calculated using Cohen's D where the mean of the change scores is divided by the pooled standard deviation of the first and second measurement. For both SRM and ES we considered a value between 0.2 and 0.5 as small, a value between 0.5 and 0.8 as moderate, and a value above 0.8 as large.²¹

Construct validity

As suggested in the COSMIN checklist the validity can be assessed using construct validity and hypothesis testing. The construct validity was examined through the convergent validity of both the FSS and SSS of the DBCQT using the Pearson's correlation between these and the Danish QDASH. We hypothesized that both the FSS and SSS subscale of the DBCTQ would have moderate to strong positive correlations with the Danish QDASH.

Table 2

Responsiveness of the Danish FSS, SSS of the DBCTQ and QDASH with mean scores, mean differences, ES and SRM.

Scale	Pre-operative Mean \pm SD	Follow-up Mean \pm SD	Difference Mean \pm SD	ES	SRM
DBCTQ: FSS	2.6 \pm 0.9	1.7 \pm 0.8	0.8 \pm 1.0	1.0	0.9
DBCTQ: SSS	3.0 \pm 0.8	1.7 \pm 0.6	1.3 \pm 0.8	1.8	1.5
QDASH	43.1 \pm 23.0	21.1 \pm 18.5	22.0 \pm 22.7	1.1	1.0

FSS = Functional Status Scale, SSS = Symptom Severity Score, QDASH = Quick Disability of the Arm, Shoulder and Hand Questionnaire. ES = Cohen's D Effect Size, SRM = Standardized Response Mean.

Relative and absolute reliability

In the reliability group we analyzed the relative and absolute reliability and internal consistency. This was done using Intraclass Correlation Coefficient (ICC), Standard Error of Measurement (SEM) and Minimal Detectable Change (MDC) which are all a part of the COSMIN checklist.^{12,13}

We used the ICC to assess the relative reliability where a value equal to or above 0.75 is considered excellent. To assess the absolute reliability, we used the SEM and MDC. We calculated the SEM as the standard deviation of both test scores multiplied with the square root of 1-ICC. The MDC was calculated as $(SEM * 1.96 * \sqrt{2})$ [7]. Finally, Cronbach's alpha was used to evaluate the internal consistency as suggested in the COSMIN checklist.^{12,13}

All statistical analyses were made using STATA, version 15 IC (Stata Corp, College Station, TX, USA).

Ethics

The study was registered in The Danish Data Protection Agency: jr. nr. 2007-58-0010. All patients gave their informed consent. No further registration or permissions were needed according to Danish Law. Conflicts of interest: None. Conflicts of funding: None.

Results

Patient demographic and baseline values of FSS, SSS and QDASH in the validity and responsiveness group and reliability group are presented in [Table 1](#). Beside of a tendency towards a higher percentage of patients with CTS in the dominant hand in the reliability group, there was no difference in patient characteristics between the two groups.

Acceptability

We did not find skewness outside the range of -1 to 1 in the baseline measurements of either FSS, SSS, or QDASH. In both FSS, SSS, and QDASH there was no ceiling effect at baseline and the floor effects was 4.6% for FSS, 0% for SSS and 1.1% for QDASH at baseline.

Eight weeks postoperatively there was also no ceiling effect for either FSS, SSS, or QDASH. The floor effect was increased to 14.8% for FSS, 12.5% for SSS and 8.0% for QDASH 8 weeks postoperatively, but all remained within the limit of 15.0%. However, the skewness criterion of -1 to 1 was not met 8 weeks postoperatively for neither FSS (1.4), SSS (1.1) nor QDASH (1.1).

Responsiveness

We found large ES's and SRM's for both FSS, SSS of the DBCTQ and QDASH. The largest values for both ES and SRM was found in the SSS. The lowest values for both ES and SRM was found in the FSS, [Table 2](#).

Table 3

Intraclass Correlation Coefficient, Standard Error of Measurement, Minimal Detectable Change and Cronbach's alpha for the Danish FSS, SSS of the DBCTQ and QDASH with mean scores, mean SEM differences, ES and SRM.

Scale	ICC	SEM	MDC	Alpha
DBCTQ: FSS	0.94	0.22	0.61	0.93
DBCTQ: SSS	0.90	0.25	0.69	0.92
QDASH	0.91	3.16	8.76	0.95

FSS = Functional Status Scale, SSS = Symptom Severity Score, QDASH = Quick Disability of the Arm, Shoulder and Hand Questionnaire. ICC = Intraclass Correlation Coefficient, SEM = Standard Error of the Measurements, MDC = Minimal Detectable Change, Alpha = Cronbach's alpha.

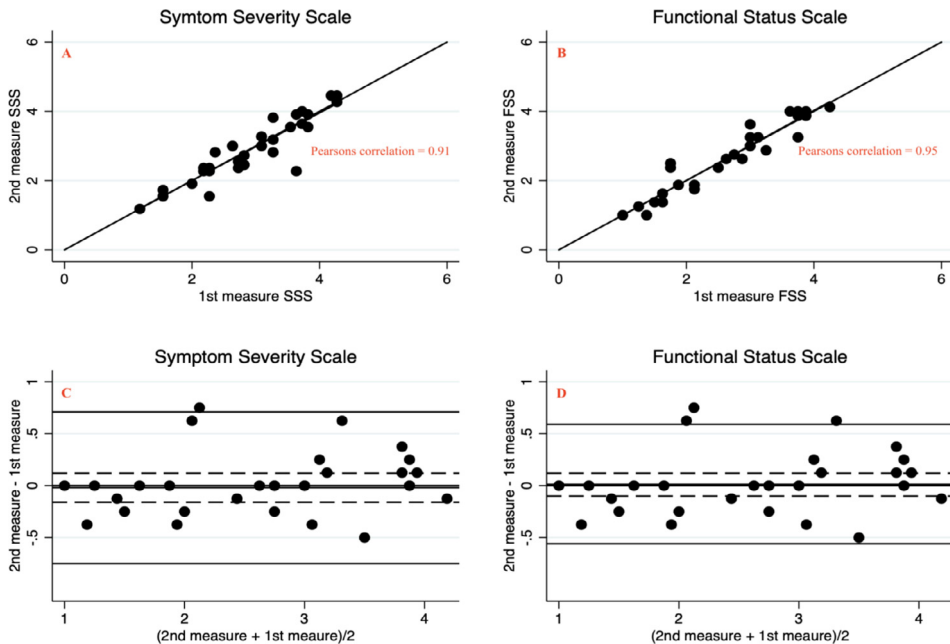


Fig. 2. Bland-Altman and scatterplot of the first and second measurement of the SSS and FSS of the BCTQ. A: Scatterplot and Pearson's correlation of the first and second assessment of the Symptom Severity Scale. B: Scatterplot and Pearson's correlation of the first and second assessment of the Functional Status Scale. C: Bland-Altman plot with 95% confidence interval for mean difference and 95% prediction interval for the difference between first and second assessment of the Symptom Severity Scale. D: Bland-Altman plot with 95% confidence interval for mean difference and 95% prediction interval for the difference between first and second assessment of the Functional Status Scale.

Construct validity

Both the SSS and the FSS were highly correlated with QDASH ($\rho=0.77$ and 0.85 respectively) at the preoperative assessment. At the 8-week follow-up the correlation appeared almost the same for both SSS and FSS of the DBCTQ ($\rho=0.75$ and 0.89), respectively.

Test-retest reliability

The FSS and SSS of the DBCTQ showed high relative reliability (ICC), high absolute reliability (SEM and MDC) and high internal consistency (Cronbach's Alpha). See Table 3 for the scores of FSS, SSS of the DBCTQ and QDASH.

Using Pearson's correlation, we found high correlation between first and second measurement of both the SSS and FSS of 0.91 and 0.95 respectively. The two Bland-Altman plots in Fig. 2 shows that

the average difference between first and second measurement of SSS and FSS of the DBCTQ was not affected by the patients' score on the two subscales. This shows the reliability is the same for patients with severe symptoms as for patients with mild symptoms.

Discussion

The aim of this study was to examine the measurement properties of the FSS and SSS subscales from the Danish BCTQ evaluating responsiveness, validity and reliability. Overall, the results from this study shows good responsiveness, validity and reliability of both the FSS and the SSS subscales.

This study showed ES's of 0.99 and 1.76, and SRMs of 0.86 and 1.50, for the FSS and SSS, respectively, which indicate a higher responsiveness of the SSS. For both measures, we considered a value < 0.5 as small, a value between 0.5 and 0.8 as moderate, and a value > 0.8 as large.²¹ The values from this study are considered high, making it useful for research on changes in symptoms and functionality in patients with carpal tunnel syndrome. The highest responsiveness we have been able to find in the existing literature was found in a Chinese validation of the BCTQ where they found ES's of 0.56 and 1.12, and SRMs of 0.62 and 1.03, for the FSS and SSS respectively.⁷

The construct validity of the FSS and SSS was examined using a correlation analysis to the Danish validated QDASH¹⁸ and revealed high correlations both preoperatively and postoperatively on both BCQT subscales. Only the Iranian validation study of the BCTQ also used the QDASH to evaluate construct validity and found Pearson's correlations of 0.70 and 0.64, for FSS and SSS, respectively. In this Danish validation of the BCQT we found correlations of 0.84 and 0.79 preoperatively, and 0.91 and 0.75 postoperatively, for the FSS and SSS, indicating high validity. The high construct validity is important and useful for research purposes as it shows that both subscales measures what they are intended to when compared to the QDASH. However, given as the purpose of this study was to validate the psychometric properties of a questionnaire assumed to be more accurate than the QDASH and DASH for CTS patients, the construct validity is not directly stating a high validity of the Danish BCTQ.

Also, we examined the reliability of the Danish BCTQ using ICC, SEM, MDC and Cronbach's alpha. The ICC has also been examined in the Iranian, Polish, Arabic and Chinese validations of the BCTQ^{7,10,22,23} with ICC's ranging from 0.77 in the Iranian to 0.89 in the Arabic FSS, and from 0.54 in the Iranian to 0.88 in the Arabic SSS. The ICC's of 0.94 and 0.90 in this study shows high test-retest reliability of both subscales. When doing research, it is highly important that the reliability is as good as possible as it shows that the patients do not score differently if they were to fill out the questionnaire twice reducing the bias in research results.

Since the true score is always unknown, it is desirable to have a measure where repeated measures distribute as little as possible around the true score. A lower SEM then represents a lower uncertainty and a measured score closer to the true score. We examined the SEM, which was also done in the Polish and Chinese validations. These studies found slightly higher SEMs of the SSS of 0.32 and 0.31 compared to our finding of 0.25, and slightly higher SEMs of the FSS of 0.34 and 0.27 compared to our finding 0.22.

The SEMs from this study lead to MDCs of 0.61 and 0.69 for the FSS and SSS respectively. These values are slightly lower than those found in the Polish validation of 0.93 and 0.90 and those from the Iranian study of 0.75 and 0.86. As the MDC represents the amount of change that is needed to be beyond measurement variation, our study shows that the Danish BCTQ is useful to detect changes in functional status and symptom severity in CTS patients.

Lastly, we examined the internal consistency of both subscales. This was also done in the Turkish, Spanish, Iranian and Polish BCQT validation with reporting of Cronbach's alpha values of 0.88, 0.91, 0.88 and 0.92 for the FSS, and 0.82, 0.90, 0.86 and 0.91 for the SSS, respectively.^{6,9,10,22} These all represent values comparable to our findings, showing that the FSS and SSS has high internal consistency with closely related questions in the Danish validation as well as the aforementioned validations. It has been suggested, that Cronbach's alpha values should not exceed 0.9.²⁴ As the values for both the FSS and SSS are above 0.9 the questionnaire could potentially be shortened by one or more questions.

This study shows good properties with regards to responsiveness, validity and reliability of this Danish validation of the BCTQ. As the DBCTQ is designed to asses function and symptoms specifically

in CTS patients it does not include questions related to the shoulder and hand as in the DASH and QDASH. By aiming directly at the desired function and symptom of the hand in CTS patients, other possible disabilities in the arm and shoulder will not affect the measured score.

Study limitations should be mentioned in any study, and specifically for this study some selection bias may arise from the 69 (44%) excluded patients due to missing answers. However, the excluded patients did not differ from the included patients with regards to age, FSS, SSS, QDASH, diabetes or dominant hand. On the contrary, the excluded patients did differ in gender, where 71% of the excluded patients were females compared to the 53% females in the final study sample.

The inclusion of patients at two different clinics could cause bias due to differences in indications, surgical technique and postoperative treatment. At both clinics the same indication was used where all operations were performed in local anesthesia and the postoperative procedure was the same. However, the distribution of OCTS versus ECTS may be different. To reduce biased results, the patients included at one clinic was used as a validity and responsiveness group and the patients included at the other clinic were used as a reliability group.

Conclusion

This study shows satisfactory results of validity, responsiveness and reliability on both subscales of the Danish translated BCTQ. The Danish validated BCTQ is a useful tool to assess and evaluate function and symptoms in CTS patients. Using the Danish validated BCTQ in Danish research enables researchers to compare their study results to study results from other countries using the BCTQ. We suggest that the Danish version of the BCTS can and should be used when research is conducted on functional status and symptom severity in Danish speaking CTS patients.

Ethical approval

The study was registered in The Danish Data Protection Agency: jr. nr. 2007-58-0010. All patients gave their informed consent. No further registration or permissions were needed according to Danish Law.

Declaration of Competing Interest

None. The authors declare that they have no competing interests.

CRedit authorship contribution statement

S.B.M. Sebastian Breddam Mosegaard: Conceptualization, Formal analysis, Methodology, Project administration, Writing – original draft. **M.S. Maiken Stilling:** Conceptualization, Methodology, Supervision, Writing – review & editing. **M.B. Marianne Breddam:** Data curtion, Writing – review & editing. **T.B.H. Torben Bæk Hansen:** Data curtion, Conceptualization, Methodology, Supervision, Writing – review & editing.

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