

Research article

Romanian validation study of the Boston questionnaire in patients with carpal tunnel syndrome

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Abstract: A single The Boston Carpal Tunnel Questionnaire is a common tool for evaluating the symptoms and function of patients with carpal tunnel syndrome (CTS). It includes the Functional Status Scale and the Symptom Severity Scale. It has been validated in numerous languages and is the most frequently employed patient-reported outcome measure in CTS. The objectives of this study was to evaluate the acceptability, responsiveness, reliability, and validity of the Romanian version. We conducted a two-parts study: the first part involved the translation and cross-cultural adaptation of the The Boston Carpal Tunnel Questionnaire - Romanian version, while the second part was a prospective cohort clinical study that was designed to psychometrically validate the The Boston Carpal Tunnel Questionnaire. We collected demographic characteristics and The Boston Carpal Tunnel Questionnaire scores for thirty-one patients with CTS and performed descriptive and inferential statistics. Our results showed a very good construct validity and excellent reliability (Cronbach's alpha = 0.79) for Boston Carpal Tunnel Questionnaire -Romanian version and the Kaiser-Meyer-Olkin of 0.732, which is considered acceptable (a value above 0.70 is usually statistically significant for factor analysis). Regarding to Bartlett's Approx sphericity test. Chi-Square 641,401, is statistically significant. In conclusion, Boston Carpal Tunnel Questionnaire is a consistent frequently employed patient-reported outcome that can evaluate the symptom burden of CTS and its effect on the ability to conduct daily activities. The structural validity of the BCTQ was investigated in this study among patients with varying degrees of CTS.

Keywords: Boston questionnaire, severity symptoms, functional status, validation process

1. Introduction

Validation of questionnaires or surveys according to the methodology is necessary because they will be widely used in research and current medicine to collect quantitative data from both patients and health practitioners. The data of interest that can be highlighted by such a tool may include a range of qualitatively or quantitatively quantifiable information (e.g. presence of degree of motor or sensory impairment) as well as patients' subjective perceptions of their current health status

(e.g. intensity of pain experienced, burning paresthesia, causalgia, allodynia and psychological status) [1].

From a clinical point of view the use of a questionnaire in routine practice can be advantageous in terms of time management as well as material resources. There are situations when an international questionnaire measuring the degree of impairment of an organ or anatomical structure may not be readily available or applicable, or the questionnaire may not be provided in the patient's native language (Boynton et al., 2004).

Research in this direction may therefore lead to the development of a new instrument or the validation of a questionnaire by translating an existing instrument from an international language. In conducting thorough investigations that objectively investigate the type of pathology to be studied or investigated by means of an instrument or questionnaire, it is paramount that the psychometric principles, methodological rules and techniques associated with questionnaire development/translation and validation are followed [1].

The Boston Questionnaire was conceptualized and validated by Levine et al. at Brigham and Women's Hospital. It was developed as a diagnostic tool for individuals who have been diagnosed with CTS. This instrument comprises a series of questions that quantify the severity of symptoms and is constructed of 11 items. This clinical assessment tool assesses the degree of severity regarding the impact of the disease on the patient [2].

The Boston Questionnaire has a severity scale that quantifies symptoms or assesses the degree of pain, numbness, weakness, tingling, and difficulty performing physical tasks associated with fine motor dysfunction during a typical day in the past 2 weeks. Items assessing the functional status scale examine the interaction between the degree of symptoms and the functional ability to perform tasks, such as button closing, writing, and tasks of daily living. These questionnaires also quantify and reflect the ability to perform a range of activities on a typical day within the past two weeks [2].

Responses are quantified using a Likert-type scale, where a score of 1 denotes a minimal level of symptoms or mild difficulties, while a score of 5 denotes a maximum level of symptom severity or inability to perform functional tasks. Initially the responses are summed and then averaged, thus a higher score reflects an impairment in functional status [3].

Aim of the study

The main purpose of this study is to validate the Boston questionnaire, a psychometric instrument that measures the severity of CTS and associated pain symptoms. At the moment in Romania this questionnaire has not been submitted to the validation process, which is why the medical staff is forced to use the original English version, which is usually inaccessible for many patients, the assessment being unreliable from a clinical point of view. Thus, the main aim of the study is to validate the Boston questionnaire by respecting all the methodological principles and rules for validating questionnaires, as well as adapting the questionnaire as adequately as possible to the Romanian socio-cultural, religious, ethical and linguistic space.

Of interest in the study was the evaluation of the degree of severity of CTS and its impact on daily activities. Thus, this instrument assesses both the physical status and the perception of pain, which is often the main cause of disability among these patients.

From a clinical point of view, CTS is a disabling condition in the advanced stages of the disease, but there is some evidence in the literature that the time until the patient reaches a major degree of disability is relative, being individual to each patient. The main consequence is the decrease in the degree of physical autonomy, this is directly associated with a number of negative effects on the perception of the level of quality of life.

From a clinical point of view, the process of validating the Boston questionnaire is useful in current clinical practice, but also for research purposes, an analysis of the need to validate this psychometric instrument, which determines the most sensitive and specific measurement of the degree of impairment or severity of CTS in a population from a given culture and geographical area, is currently a standard in medical practice. This tool can provide both indirect and direct information on the degree of therapeutic management of CTS.

Objectives

Taking into account the application of standards and guidelines on the clinical and therapeutic management of patients with CTS, the assessment of disease severity is a vital element in the current clinical practice of neurologists. A higher degree of impairment directly illustrates the degree of motor or sensory impairment. First of all, due to its presentation, this pathology can be insidious and disabling, thus in order to quantify as reliably as possible the impact of the disease on both motor and sensory function, the application of the Boston questionnaire should be a standard clinical practice. Secondly, the Boston questionnaire can be considered to be a reliable tool in terms of direct monitoring of the effectiveness of the therapeutic or recovery plan, as well as of the evolution of the disease.

Main objectives

- to quantify as accurately as possible the level of severity of CTS in order to methodologically validate the Boston questionnaire.

Secondary objectives

- analyze clinical factors such as age and gender that could negatively or positively influence the methodological process of validating the Boston questionnaire;
- classification according to the electrodiagnostic examination result into mild, moderate and severe impairment and correlation with the score or mean score of the Boston questionnaire;
- analysis of all the items of the Boston questionnaire regarding their adaptation to the linguistic, cultural and ethical criteria of the Romanian space.

2. Results

The descriptive data on the age variable showed that the minimum age of the study group was 36 years and the maximum age was 74 years, with a mean of 56.26, the analysis of the distribution of the overall score of the Boston questionnaire showed a mean of 33.45 and median of 31.00 in the study group, as for the mean score of the Boston questionnaire the mean was 3.03 and median 2.81 (Table 1).

Table 1. Descriptive variables analyzed in the study

	Age	General score	Mean score
Mean	56.26	33.45	3.0329
Median	56.00	31.00	2.8100
Std. Deviation	9.132	11.924	1.08524
Minimum	36	14	1.27
Maximum	74	55	5.00

Regarding the frequency of sex, a number of 28 women and 3 men were identified, 90.3 and 9.7 respectively (Table 2; Figure 1).

Table IV.2 Gender distribution in the study group

	Frequency	Percent
Famels	28	90.3
Mean	3	9.7
Total	31	100.0

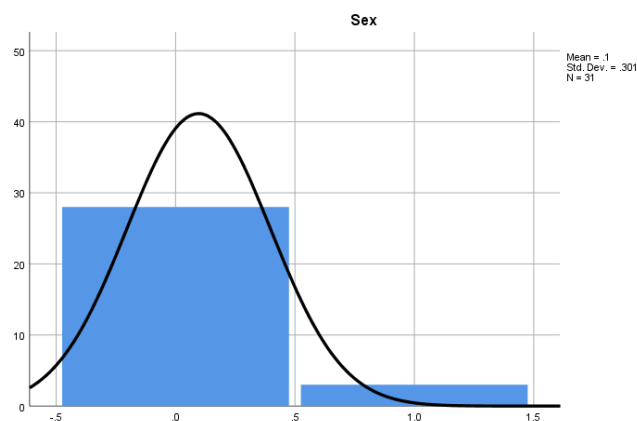


Figure 1. Histogram regarding the gender distribution in the study group

The statistical analysis of the average scores of the items regarding the composition of the Boston questionnaire identified the fact that for each item it varies between 2.42 and 3.35. Regarding the median values (average score) they are generally close to 3 for most items. The standard deviation in the present case demonstrated that there is a standard deviation that presents a variability being approximately between 1.03 to 1.39 for all items. In this study the Kurtosis indicator measures the degree of distribution of the tested variables, in the present case all variables showed a normal distribution except for item 10, and the Standard Error of Kurtosis is consistent across items at approximately 0.821 (Table 3).

Table 3. Descriptive analysis of Boston questionnaire component variables

	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11
Mean	3.10	3.19	2.84	3.10	3.26	3.35	2.48	3.26	3.29	3.16	2.42
Median	3.00	3.00	3.00	3.00	3.00	3.00	2.00	3.00	3.00	3.00	2.00
Standard deviation	1.193	1.195	1.214	1.398	1.290	1.082	1.180	1.032	1.071	1.036	1.285
Kurtosis	-.694	-.651	-.762	-1.242	-.813	-1.071	-.457	-.883	-1.007	.194	-.469
Kurtosis standard error	.821	.821	.821	.833	.821	.821	.821	.821	.821	.821	.821

Statistical validation of the Boston questionnaire

The application of the statistical analysis regarding the calculation of the “Correlation matrix” indicator in the present study had as its main purpose the highlighting of whether the variables belonging to the Boston questionnaire: Item 1-11 correlate with each other, but with other variables that would could influence these items in a positive or negative sense, the purpose being to exemplify a series of positive correlations, these being those that approach 1, or negative as it approaches -1. Applying this statistical analysis model demonstrates whether these variables have a potential correlation factor between them. Since this analysis called

"Correlation matrix" can confirm the hypothesis of the study regarding whether these variables can be used as diagnostic markers of STC severity (Table 4).

Table 4. Results of the "Correlation matrix" analysis

Correlation Matrix														
	Varsta	Sex	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Mean score
Age	1.000	.113	.160	.255	.246	.378	.295	.172	.193	.183	.143	.377	.348	.289
Sex	.113	1.000	-.302	-.232	-.320	-.105	-.320	-.311	-.328	-.295	-.402	-.148	-.280	-.297
Item 1	.160	-.302	1.000	.864	.797	.742	.838	.837	.772	.830	.851	.774	.850	.906
Item 2	.255	-.232	.864	1.000	.810	.795	.842	.863	.762	.836	.911	.879	.869	.931
Item 3	.246	-.320	.797	.810	1.000	.861	.918	.872	.881	.814	.786	.735	.887	.931
Item 4	.378	-.105	.742	.795	.861	1.000	.920	.797	.801	.752	.695	.711	.854	.898
Item 5	.295	-.320	.838	.842	.918	.920	1.000	.880	.852	.839	.773	.775	.895	.953
Item 6	.172	-.311	.837	.863	.872	.797	.880	1.000	.783	.925	.908	.792	.862	.942
Item 7	.193	-.328	.772	.762	.881	.801	.852	.783	1.000	.773	.758	.654	.852	.880
Item 8	.183	-.295	.830	.836	.814	.752	.839	.885	.773	1.000	.885	.710	.799	.907
Item 9	.143	-.402	.851	.911	.786	.695	.773	.758	.885	1.000	.777	.838	.902	
Item 10	.377	-.148	.774	.879	.735	.711	.775	.792	.654	.710	.777	1.000	.829	.860
Item 11	.348	-.280	.850	.869	.887	.854	.895	.862	.852	.799	.838	.829	1.000	.946
Mean score	.289	-.297	.906	.931	.931	.898	.953	.942	.880	.907	.902	.860	.946	1.000

The most sensitive and significant results from a statistical point of view were obtained for the following series of variables:

- for the age criterion, a moderate correlation was identified with item 10 and 11 which quantifies paresthesia-type accusations during the night within the last 2 weeks, respectively the capacity of prehension with regard to item 11;
- for the gender/sex criterion this was presented a moderate correlation with item 9 which also quantifies only paresthesia-type sensibility disorders;
- item 1 which quantifies the degree of pain during the night shows a strong degree of correlation with all items of the Boston questionnaire, but shows a weak but negative correlation with the gender criterion;
- item 2, which quantifies the frequency of pain episodes during the night, shows a strong degree of correlation with all the items of the Boston questionnaire;
- item 3, which quantifies the frequency of pain episodes during the day, shows a strong degree of correlation with all the items of the questionnaire Boston and in this case the same type of correlation found in item 1 is maintained, with regard to the gender criterion;
- item 4 which quantifies the periodicity of pain during the day presents a degree of correlation of a strong type with all items of the Boston questionnaire, except in the case of the age variable where a weak correlation was noted;
- item 5, which quantifies the average duration of a painful episode per day, shows a strong degree of correlation with all the items of the Boston questionnaire, and a negative type with the sex variable;
- item 6, which quantifies the objective sensitivity disorders in the hand of the day shows a strong degree of correlation with all the items of the Boston questionnaire and a negative degree of correlation with the sex variable;
- item 7 that quantifies the degree of motor deficit in the hand shows a strong degree of correlation with all the items of the Boston questionnaire and negative type with the sex variable;
- for items 8-11 it shows the same pattern exemplified previously.

Cronbach's Alpha in the present case shows a value of 0.790, indicating a good level of internal consistency for each scale. A value between 0.7 and 0.8 generally indicates acceptable reliability. Cronbach's Alpha evaluated on the basis of standardized items revealed a value of 0.984, suggesting excellent reliability when the Boston questionnaire items are standardized (Table 5).

Table 5. The results of the Cronbach's Alpha analysis

Measuring the degree of reliability		
Cronbach's Alpha	Standardized Cronbach's Alpha	N Items
.790	.984	11

In Table 6 is represented the psychometric evaluation of the Boston questionnaire in order to reconfirm the reliability of this scale as follows:

-the media of the scale if one of the items is eliminated evaluates and observes the effect of eliminating the item on the global media of the scale, in this case the results have complied with the statistic norms;

-the marriage of the scale if one of the items is eliminated: this indicator shows whether a variation is lower, usually indicates a stronger coherence between the items;

-total corrected item correlation: this measures how well each item correlates with the total score of all other items, and the presence of higher values indicates that the item is well aligned with the overall scale, being statistically significant;

-multiple correlation at squared: this indicates whether the proportion of variation in the removed item is explained by the remaining items. High values in the present case suggest that the item shares much of the variance with the rest of the scale;

-Cronbach's alpha if one of the items was removed: this indicator evaluates if the respective item were removed, a higher value is obtained, compared to the general Cronbach's alpha, which suggests that the removed item could reduce the reliability of the scale.

Table 6. Re-analysis of the reliability of the Boston questionnaire translated into Romanian

Item-Total Statistics					
	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Item 1	62.50	478.810	.897	.940	.770
Item 2	62.40	477.076	.926	.943	.769
Item 3	62.77	477.220	.924	.954	.769
Item 4	62.43	470.116	.883	.973	.765
Item 5	62.33	471.747	.947	.982	.766
Item 6	62.23	481.151	.937	.953	.771
Item 7	63.13	482.257	.871	.937	.772
Item 8	62.33	485.195	.899	.969	.773
Item 9	62.30	483.597	.895	.974	.773
Item 10	62.43	487.495	.846	.972	.775
Item 11	63.20	474.372	.942	.958	.767
Scor general	32.80	132.372	.999	.999	.980

Kaiser-Meyer-Olkin and Bartlett test

The application of the Kaiser-Meyer-Olkin test indicates whether the proportion of the degree of variation of the tested variables of the Boston questionnaire shows a

common variation among them. A Kaiser-Meyer-Olkin value of 0.732, which is considered acceptable (a value above 0.70 is usually statistically significant for factor analysis).

The Bartlett test of sphericity is a parameter that checks whether the original matrix of the Boston questionnaire is significantly different from a proposed but identical matrix, which would indicate whether the items are sufficiently related or consistent with each other. The Chi-square value is approximately 641.401, thus this test is statistically significant ($p < 0.001$), in conclusion, this proves that the correlation matrix is suitable for factor analysis (Table 7).

Table 7. Kaiser-Meyer-Olkin and Bartlett test results

KMO and Bartlett's Test ^a		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.732
Bartlett's Test of Sphericity	Approx. Chi-Square	641.401
	df	91
	Sig.	.000
a. Based on correlations		

Statistical analysis of communalities

Table 8 shows the statistical analysis of communalities that specifically highlights the degree of variation for each tested element that could be explained or influenced by a number of other factors proposed by the statistical analysis model. Statistically initial communalities are always 1.0 for raw communalities and represent the total variance of the items before extraction. Following the extraction process, the obtained data showed how much of the variation of each item is explained by other factors after extraction, as for example: for item 1 it shows a communality extraction of 0.832, which means that 83.2% of the variation of item 1 is explained by the other factors. Gender presents a low extraction value of 0.132, which means that the tested factors explain only 13.2% of the variation of this variable, suggesting that it is not well represented by the other factors.

Table 8. The results of the commonality analysis

Communalities				
	Raw		Rescaled	
	Initial	Extraction	Initial	Extraction
Varsta	77.444	77.443	1.000	1.000
Sex	.093	.012	1.000	.132
Item 1	1.344	1.117	1.000	.832
Item 2	1.361	1.181	1.000	.868
Item 3	1.357	1.188	1.000	.875
Item 4	1.955	1.622	1.000	.830
Item 5	1.614	1.474	1.000	.913
Item 6	1.114	.994	1.000	.893
Item 7	1.214	.958	1.000	.790
Item 8	.993	.815	1.000	.821
Item 9	1.082	.892	1.000	.825
Item 10	.990	.735	1.000	.743
Item 11	1.471	1.337	1.000	.909
Media scorului	1.080	1.079	1.000	.998
Extraction Method: Principal Component Analysis.				

In Figure 4 a Scree Plot is plotted to show whether the principal components of a factor analysis are valid and to visualize the eigenvalues that are statistically significant for each component. On the X-axis is plotted the number of components tested in this case was from 1 to 11. The Y-axis highlights the corresponding eigenvalues for each component.

The first two components have much higher eigenvalues than the rest, the first being around 80 and the second close to 12. This confirms that these two components explain most of the total variance of the Boston questionnaire. For the second component, the eigenvalues decrease sharply and then flatten out, indicating that these additional components do not contribute significantly to explaining the total variance of this questionnaire. The later components of the graph, in particular the second one, have eigenvalues close to zero, which means that they contribute very little to explaining the total variance of the questionnaire.

In conclusion, the steep slope in the graph suggests that the first two components are the most important and the additional components do not provide much more useful information. Thus, keeping only the first two components would probably be sufficient to reduce the dimensionality of the statistical analysis.

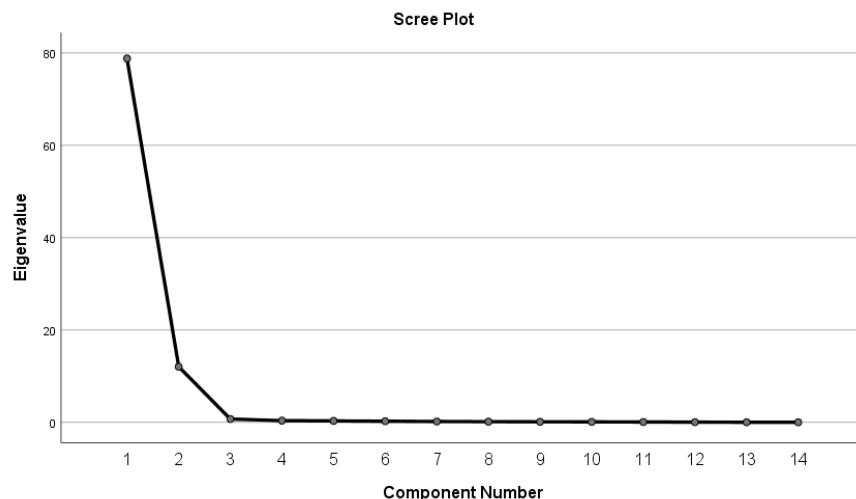


Figure 4. Correlation on Scree Plot analysis

Sensitivity analysis of age, sex mean score and overall score measured by Receiver operating characteristic (ROC)

For the age criterion we obtained a value of "Area under the curve" $AUC = 0.671$, indicating a moderate discriminatory ability in relation to the Boston questionnaire. The confidence interval is $CI = 0.440-0.903$ and the p-value is not significant in this case $p = 0.155$, suggesting that the result is not statistically significant. Analysis of the sex variable: $AUC = 0.435$, indicating a weak discriminatory power, being less than 0.5. The confidence interval is $CI = 0.214, 0.656$, and the result is not statistically significant $p = 0.588$.

Overall score analysis: $AUC = 0.978$, indicating excellent discriminatory ability. The confidence interval is $CI = 0.930, 1.000$, and the result is statistically significant $p < 0.001$. Mean score: $AUC = 0.978$, similar to the overall score, with excellent discriminability. The confidence interval is $CI = 0.930, 1.000$ and is statistically significant $p < 0.001$. Interpretation: 'Mean score' and 'Overall score' have excellent performance in categorizing the outcome, as indicated by high AUC values close to 1 and statistical significance level. Age has a moderate predictive ability but is not statistically significant.

Sex has a very poor discriminatory ability, with an AUC below 0.5, meaning that it performs worse than random chance. The entire statistical analysis was reported according to the following cut off: classification of disease severity according to electrodiagnostic examination (Table 9); (Figure 3).

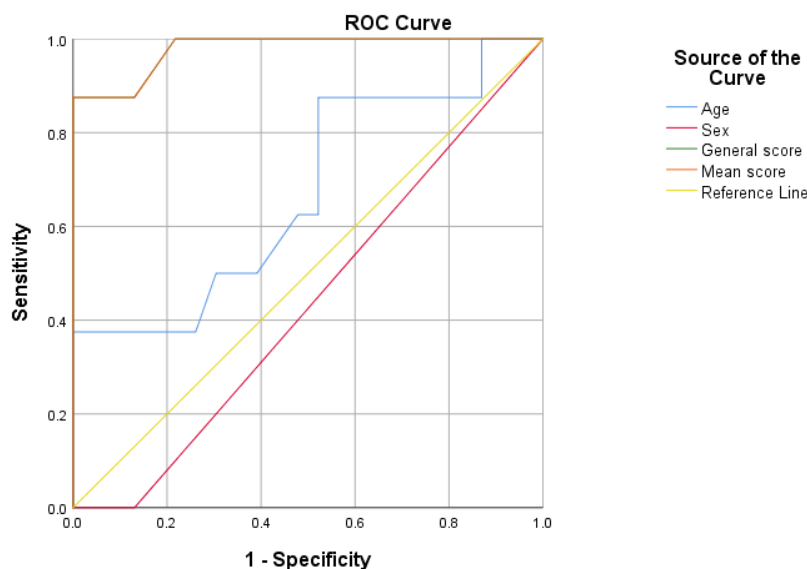


Figure 3. Sensitivity analysis of the criteria age, gender mean score and overall Boston questionnaire score

Table 9. ROC curve results on age, gender mean score and overall score of the Boston questionnaire

Area Under the Curve					
Test Result Variable(s)	Area	Std. Error ^a	Asymptotic Sig. ^b	Asymptotic 95% Confidence Interval	
				Lower Bound	Upper Bound
Varsta	.671	.118	.155	.440	.903
Sex	.435	.113	.588	.214	.656
Scor general	.978	.024	.000	.930	1.000
Media scorului	.978	.024	.000	.930	1.000

3. Discussion

In a systematic review of the psychometric properties of the Boston Questionnaire, it was found that the Boston Questionnaire is a disease-specific instrument designed to assess the severity of symptoms and the functional status of the patient. This instrument is commonly used in current clinical practice, but also in the context of disseminating the results of research studies focusing on interventions in response to standard or surgical therapy for CTS.

The research team conducted a systematic review of the existing literature on the usefulness of the psychometric applicability of the Boston Questionnaire in order to highlight the sensitivity and specificity regarding the validity, reliability and discriminatory ability of this clinical instrument.

The main results of the research were: one study was identified that assessed the face and content validity on the internal consistency of the scale, the study involved

a number of 43 participants. Another series of studies, 8 in this case, examined the construct validity of the questionnaire on a sample of 932 participants. In addition, a further 4 studies assessed reliability in a sample of 126 participants. The acceptability of the questionnaire was assessed in 8 studies involving 978 participants.

The conclusions of this study noted that the Boston questionnaire is a highly standardized measure, focused on the clinical assessment of patients presenting with specific signs and symptoms of CTS, and has high sensitivity and specificity in capturing the transition from one stage of CTS to another, as well as the grading of symptoms, or functional status. A body of evidence in the literature regarding its psychometric properties supports that this questionnaire is a valid, reliable, responsive and acceptable instrument for most patients, thus arguing its use as a primary measure in validating the diagnosis of CTS [4].

Analysis conducted by Jerosch-Herold et al. on the usefulness of revising the Boston questionnaire, because despite the fact that this psychometric instrument is very widely used, there is still a number of data that highlight that its psychometric properties are limited, due to the fact that its use by modern psychometric instruments is limited and cannot be generalized. From a methodological point of view, the data obtained from the application of the Boston questionnaire were analyzed by applying a mathematical model, called the Rasch model.

The results of the study revealed that a total number of 600 CTS subjects confirmed by exclusive electrodiagnostic examination of the right hand, subjects were randomly selected from the database and analyzed. Thus, the mean age of the study group was 48.8 years and 73% were women. The initial statistical analysis showed that the 19 items could not be analyzed as a "linear construct", since all subsequent analyses were performed using subscales.

The first representative subscale was the symptom severity scale, which showed a high interdependence with the other subscales. This could be achieved through the creation of 4 clinical tests, which allowed transforming the raw symptom severity score into a linear but also generalizable measure.

The second most representative subscale was the one that quantified functional status, in this case it was identified that there were a number of flaws in its applicability and psychometric integrity. The group of researchers proposed that this subscale should be adjusted for a more specific and sensitive differentiation of the items analyzing the functional status of patients with CTS.

The study findings showed that the existence of a single total score generated from all clinical items of the Boston questionnaire is not entirely psychometrically valid, and that the severity and functional subscales should be treated separately when addressing this type of questionnaire application [5].

To analyze as statistically sensitive as possible whether a clinical instrument such as the Boston questionnaire has met the methodological rules regarding its validation, it involves conducting a study on a group of 20-50 patients, applying statistical validation tests and then comparing the results obtained with similar analyses.

In the validation study of the Boston questionnaire in the Greek version, 2 essential criteria were analyzed: the feasibility and the degree of validity on the Greek entistic population. Also the translation process was carried out from the original English version, subsequently the group of investigators carried out the translation and adaptation process into Greek, then the questionnaire was translated again from Greek into English by a native English and Greek speaker, the same algorithm was applied in the present study [6].

Reliability measures were calculated using internal consistency scales, specifically Cronbach's α and item-total correlation.

Validity analysis was demonstrated by correlating the Boston questionnaire scores with the Canterbury severity scale for categorizing the severity evidenced in the electrodiagnostic examination, in the present study a similar reporting was

performed, this was according to the degree of sensory nerve conduction impairment into mild, moderate and severe type of impairment.

The results of this study revealed that the Greek version of the Boston questionnaire showed a high reliability Cronbach's α index showed a value of 0.89 for the symptom severity scale and 0.93 for the functional status scale. In contrast, in the present study, a statistically significant Cronbach's α 0.79 was calculated as an overall Cronbach's α score.

The results regarding the validity of the questionnaire in the case of the Greek regression, the Pearson correlation coefficient was calculated, which showed a value of 0.53 for the symptom severity scale and 0.68 for the functional status scale, showing moderate correlations, whereas in the present study we opted for the calculation of the "Correlation matrix" indicator, which showed positive correlations with all the items of the Boston questionnaire.

The analysis of the ROC curve of the Boston questionnaire Greek version showed that the symptom severity scale presents a high degree of discrimination of subjects with low degree of impairment on the status of electrodiagnostic severity compared to subjects with high degree of electrodiagnostic severity was 1.95, showing a degree of sensitivity equal to 75.5% and specificity equal to 68.3%. In the present research the ROC curve analysis was performed between the age criterion, the mean overall score of the Boston questionnaire according to the following cut-of: severity of the degree of impairment according to the nerve conduction velocities of the electrodiagnostic examination.

In conclusion, the analysis of the results regarding the validation process of the Greek version of the Boston questionnaire certifies that it is a valid and reliable screening tool for the assessment in clinical practice of symptoms and functional status in patients with CTS, thus it becomes a useful tool for physicians as a complementary method to the clinical and electrodiagnostic examination [7].

In the validation study of the Dutch version of the Boston questionnaire, the group of researchers aimed to analyze the degree of validity, reliability, responsiveness and acceptability, these being the main desiderata of the study, from the methodological point of view the validation process was carried out by adopting a longitudinal version, but also interventional, more specifically in this case according to the response to treatment. The research tracked the change in the Boston questionnaire score before carpal tunnel release surgery and then 6-8 months post-surgery.

Results regarding the statistical indicators of the validation process showed a statistically significant degree of the internal consistency indicator, Cronbach's α = 0.825. On the other hand, in the present study, significant results of Cronbach's α indicator were obtained, but also in the case of "Kaiser-Meyer-Olkin" of 0.732, being considered an acceptable value, this indicator emphasizes that the translated version in Romanian presents a normal internal consistency.

In conclusion, it has been shown that the Dutch version of the Boston questionnaire has a high degree of reliability, validity, responsiveness and statistical acceptability, aiming to assess the degree of symptom severity and associated functional disability of patients with CTS. This approach regarding the method of validating the Boston questionnaire according to response to surgical treatment may be considered a confounding bias, as this scale was originally designed for the clinical assessment of patients with CTS [8].

The quantification of the psychometric properties of the symptom severity and functional scales were also assessed in the validation study of the Danish version of the Boston questionnaire. A total of 88 patients were enrolled in the study and a prospective analysis was performed. Sensitivity and specificity assessments regarding the degree of validation and reliability were also reported in this case in relation to response to surgical treatment of the CTS part [9].

The results of the study on the degree of responsiveness of the two component subscales of the Boston questionnaire were found to have a high sensitivity, thus the

effect size was 0.99/1.76. With respect to the measurement of the degree of reliability by the test-retest method was 0.94/0.90, and with respect to the results on internal consistency was high, Cronbach's alpha showed a value of 0.93/0.92 for each component [9].

The conclusion of this study emphasizes that the 2 subscales showed satisfactory results, and that the validation process in Danish complies with statistical methodological rules. In comparison to the present study in which the degree of variation for each item of the tested questionnaire was assessed, which could be explained or influenced by a number of other factors proposed by the statistical analysis model, such as age and gender, as epidemiologically the pathology being more common in females, with a median occurrence at about 50 years of age. The results of the communalities in this case showed that they are sensitive and statistically valid, compared to the Danish validation study where the analysis of these variables is missing.

The translation process of the Boston questionnaire Bulgarian version presents a number of similarities in terms of the validation process, but also in terms of cultural-linguistic adaptation, processes that were carried out under the international validation norms of questionnaires. Also in this case the degree of psychometric properties of the Boston questionnaire, Bulgarian version, was evaluated, the main aim of the study was to analyze the reliability, validity and responsiveness of the Bulgarian version, these being the vital elements that highlight whether this questionnaire complies with the psychometric rules. The evaluation of the sensitivity of the Bulgarian translated version was reported based on the score obtained 3 months after the minimally invasive CTS intervention [10].

Results of this study were divided into two categories, as follows Cronbach's alpha coefficient calculation was 0.88 for symptom severity scale evlaue and 0.87 for functional status. Sensitivity analysis of the Bulgarian version was correlated with other instruments that objectively quantify [10].

The present study analyzed by means of the scree plot which revealed that the first two components have much higher eigenvalues than the rest of the scale, the first being around 80 and the second close to 12, these values indicate that these two components explain most of the total variance of the Boston questionnaire, thus the analysis of the degree of pain is the most sensitive factor of this scale.

The psychometric analysis of the Boston questionnaire before the validation of the Spanish version, the group of researchers emphasizes the need for validation of this instrument, since it is used worldwide and is easy to apply in a short time. Regarding the methods used regarding the validation of the Spanish version, there were 3 experts in treating CTS, they supervised the whole validation process, thus the target group was sampled in 2 categories, the first study was a pilot study that included a number of 20 individuals with the aim of analyzing the degree of accessibility and comprehension of the translated Spanish version, later the analysis regarding the reliability and validation of the questionnaire was conducted on a cohort of 90 subjects [11].

The results of this study revealed that the Cronbach's alpha indicator for the severity scale was 0.91 and for the functional scale was 0.87. Analysis of the degree of sensitivity on the correlation with the 2 subscales in relation to the dynamometric determinations $r=0.77$ for the severity scale and $r=0.75$, these results demonstrate an increased degree of correlational level, but the degree of muscle atrophy may be a confounding bias. The conclusion of the group of researchers on the validation of the Spanish version demonstrated that the version validated by them complies with the statistical methodological rules and can be widely used by Spanish medical professionals [11].

Compared to the present study, the Spanish validation study differs in the methodology of patient selection, but also in the testing modality, pilot study, and subsequent analysis of the target group.

The validation study of the Boston questionnaire in the Philippanian language aimed to evaluate the degree of sensitivity and reliability in relation to the response or evolution of symptomatology according to the surgical treatment of carpal tunnel after a specific interval, 2 weeks. From a methodological point of view, the study followed the same principles of translation rules and stastic analysis as the present study [12].

In contrast, the only difference compared to the present study concerns the fact that the Phyllophone version required some minor modifications in order to harmonize and cross-culturally adapt the language nunantions. Also, the stastic indicators that measured the degree of reliability in the present case Cronbach's alpha was 0.93, which reflects that the degree of internal consistency is high and the intraclass correlation coefficient is higher than 0.8. The conclusion of this study demonstrates that the application of the Boston questionnaire to patients undergoing carpal tunnel release surgery is a reliable method to control postoperative course [12].

In comparison with the data presented previously in the present study, it was found that in the analysis of communalities, the age variable positively "loaded" positively on all questionnaire items, which shows a strong relationship between these variables. On the other hand, for the sex variable, the degree of "loading" shows a moderate relationship with the other items of the questionnaire. These data reflect the fact that age and gender may be major factors in influencing the reliability of the results obtained from the Boston questionnaire.

The study on the validation process of the Polish version was necessary because it aimed to assess the degree of association of CTS symptoms with insomnia and daytime sleepiness, and finally with therapeutic response. The results of the study showed that the reliability of the questionnaire translated into Polish showed a high level of statistical evidence, thus for the degree of assessment of the severity of symptomatology Cronbach's α was 0.91, and for the functional scale it was 0.93, subsequently the obtained results were correlated to analyze the degree of sensitivity and specificity with nerve conduction studies. The conclusion of the study relevant that the Boston questionnaire is a reliable and methodologically valid clinical tool and allows indirect measurement of the therapeutic response, and consequently it was evidenced that a satisfactory therapeutic intervention is associated with improvement in the degree of insomnia, in contrast on the degree of daytime sleepiness does not seem to have any impact [13].

The results of the present research assessed the degree of sensitivity and specificity by means of ROC analysis of the overall score and the mean score according to the severity of the changes obtained in the electrodiagnostic examination, thus for the overall score AUC: 0.978, respectively the mean score AUC: 0.978, demonstrate that the relationship between clinical and paraclinical assessment are complementary and validate the reliability of using the Boston questionnaire in current clinical practice.

4. Materials and Methods

The author's consent was not necessary to validate and use this questionnaire in this paper, as it was provided by a governmental institution. The process of translating the questionnaire was carried out as follows: in the first stage, the translation from English into Romanian was carried out by two different translators, then both versions were harmonized and any possible linguistic discrepancies were harmonized. As for the translation from Romanian into English, this process was carried out by a native English speaker, but Romanian speaker.

This validation process was performed on a group of 31 patients diagnosed with clinical and electrodiagnostic CTS, from the "Prof. Dr. Nicolae Oblu" Emergency Clinical Hospital "Prof. Dr. Nicolae Oblu" Iași.

This tool is mainly addressed to subjects with specific clinical symptoms of CTS, but also to those at risk of developing this syndrome in order to guide clinical or therapeutic behavior. The present group consisted exclusively of patients in whom

the electrodiagnostic examination revealed mild, moderate and severe pathologic changes. The subjects were selected on the basis of certain inclusion criteria:

- written agreement of the patient to participate in this study;
- patient diagnosed with CTS;
- age over 18 years;
- presence of clinical elements suggestive of median nerve damage, both subjective (paresthesias in the form of numbness, burning, tingling, etc.) and objective (sensory tubulation and motor deficit, trophic changes such as atrophy of the tendon eminence);
- presence of electrodiagnostic elements suggestive of median nerve neuropathy.

Exclusion criteria:

- age younger than 18 years;
- patient refusal to participate in this study;
- Patients with severe coagulation disorders in whom electrodiagnostic examination is not possible;
- presence of psychiatric conditions that severely impair judgment.

In order to achieve the most methodologically reliable validation of this questionnaire and to circumvent a number of inadequate results in terms of compliance with all the rules concerning the translation and application process were the most important components of the study.

Another recommendation with regard to the methodological process of validation concerns the research team involved in this process who were trained on how to collect and apply the questionnaire in the most accurate way possible, according to the general recommendations for analyzing these instruments.

The data were collected in a confidential database to which only the principal investigator had access, the statistical data processing was carried out anonymously, and each subject included in the study was given a recognition code at the time of data enrolment, as the processing of the final results will in no way allow the identification of the patients' identity.

Statistical analysis of the data was performed using SPSS (Statistical Package for the Social Sciences, Chicago, Illinois version 23.0), the data analyzed were:

- Demographic data: median, mean, Min-Max, SD (female/male; age; overall score of the Boston questionnaire and the mean of this score, severity score according to the analysis of the electrodiagnostic examination);
- Cronbach's alpha coefficient (α)-subscales;
- alpha coefficient;
- Kaiser-Meyer-Olkin (KMO) statistical-correlations subscales;
- Bartlett's sphericity test-correlation subscales;
- Rotated factor loadings (mental component, physical component and subscales).
- Receiver operating characteristic (ROC) analysis of the variables age, sex, severity score according to the electrodiagnostic examination in relation to the overall score of the Boston questionnaire and the mean of this score.

5. Conclusions

The particularity of this study consisted in validating and measuring the feasibility of the Boston questionnaire through a series of statistical methods in order to assess the severity of symptoms associated with CTS. The validation process did not require "harmonization" in terms of translation from English into Romanian.

All the methods of stastic analysis have demonstrated that the version translated into Romanian can reliably contribute to the evaluation of the degree of CTS associated symptomatology, or of the treatment applied, or in some particularized cases this tool can be a sufficiently sensitive and specific method to predict the probability of performing a surgical intervention to release the carpal tunnel.

Until now in Romania there is no validated Romanian version of the Boston questionnaire, and medical staff and researchers are forced to use the original English version, which is often an inaccessible method for most patients. Thus, the present research has successfully fulfilled the aim of validating the Boston questionnaire in Romanian.

Regarding the application of the validation methodology of the Boston questionnaire, it met all the statistical criteria, as well as the translation process, the adaptation of the questionnaire to the Romanian socio-cultural space. Also, this study had as secondary objective to validate this instrument according to the severity of the electrodiagnostic examination, especially the nerve conduction velocity in order to validate the sensitivity and specificity of the applied stastic method. In this regard, it was highlighted that in the ROC analysis, the age variable, the mean score and the overall score are the most important indicators that correlate with the severity of symptoms and functional status in patients with CTS.

Another important aspect refers to the fact that the validated Romanian version of the Boston questionnaire was accepted by all study participants, which indirectly demonstrates that this tool can be routinely applied in medical practice, especially by neurologists, and can also provide information on the effectiveness of medical or surgical treatment, and ultimately on the perception of health status.

Author Contributions: For research articles with several authors, a short paragraph specifying their individual contributions must be provided. The following statements should be used “Conceptualization, L.B; A.C, M.DT. and Y.Y.; methodology, C.M.I.A; software, E.MR.; validation, R.C., A.C. and L.B; formal analysis, C.M.I.A; investigation, R.C.; resources, L.B; data curation, M.DT.; writing—original draft preparation, L.B; writing—review and editing, A.C.; visualization, E.M.R.; supervision, L.B.; project administration, L.B.; funding acquisition, L.B. All authors have read and agreed to the published version of the manuscript.” Please turn to the CRediT taxonomy for the term explanation. Authorship must be limited to those who have contributed substantially to the work reported.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: In this section, please provide details regarding where data supporting reported results can be found, including links to publicly archived datasets analyzed or generated during the study. Please refer to suggested Data Availability Statements in section “MDPI Research Data Policies” at <https://www.mdpi.com/ethics>. If the study did not report any data, you might add “Not applicable” here.

Conflicts of Interest: The authors declare no conflict of interest.

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