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J Bone Joint Surg Am. 1993;75:1585-1592.

A Self-Administered Questionnaire for the Assessment of Severity of Symptoms and Functional Status in Carpal Tunnel Syndrome*

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ABSTRACT: We developed a self-administered questionnaire for the assessment of severity of symptoms and functional status in patients who have carpal tunnel syndrome. The reproducibility, internal consistency, validity, and responsiveness to clinical change of scales for the measurement of severity of symptoms and functional status were evaluated in a clinical study. The scales were highly reproducible (Pearson correlation coefficient, r = 0.91 and 0.93 for severity of symptoms and functional status, respectively) and internally consistent (Cronbach alpha, 0.89 and 0.91 for severity of symptoms and functional status, respectively). Both scales had positive, but modest or weak, correlations with two-point discrimination and Semmes-Weinstein monofilament testing (Spearman coefficient, r = 0.12 to 0.42).

In thirty-eight patients who were operated on in 1990 and were evaluated a median of fourteen months postoperatively, the mean symptom-severity score improved from 3.4 points preoperatively to 1.9 points at the latest follow-up examination, while the mean functional-status score improved from 3 to 2 points (5 points is the worst score and 1 point is the best score for each scale). Similar improvement was noted in twenty-six patients who were evaluated before and three months after the operation.

We concluded that the scales for the measurement of severity of symptoms and functional status are reproducible, internally consistent, and responsive to clinical change, and that they measure dimensions of outcomes not captured by traditional measurements of impairment of the median nerve. These scales should enhance standardization of measurement of outcomes in studies of treatment for carpal tunnel syndrome.

*No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article. Funds were received in total or partial support of the research or clinical study presented in this article. The funding sources were the Brigham Orthopedic Foundation, the National Institutes of Health (Grant AR36308), the Agency for Health Care Policy and Research (Grant H506326), and post-doctoral fellowships from the Arthritis Foundation (Dr. Katz) and the Agency for Health Care Policy and Research (Dr. Levine).

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Medical care has entered an era of critical assessment and accountability[6,24-26], as health-care providers, patients, insurers, government agencies, and employers seek to determine whether specific interventions satisfy the needs of patients. The general medical and orthopaedic communities have responded to this mandate by calling for studies of the outcomes of treatment of common conditions. This research requires measures of outcome that address patients' principal concerns[6,26], which, in orthopaedic conditions, include relief of symptoms and functional improvement[2].

Outcome studies are needed for assessment of the treatment of carpal tunnel syndrome, a frequent cause of disability of the upper extremities occurring in 0.1 per cent of the general population[28] and in 1 to 5 per cent of workers in certain occupations[8]. Carpal tunnel release is the most commonly performed operation on the hand, accounting for approximately 200,000 procedures each year in the United States[18,19] and incurring direct medical costs in excess of one billion dollars annually. The reported success rates of carpal tunnel release have ranged from 70 to more than 90 per cent[4,10-12,15,20,22,23,27,29]. However, the results have generally been evaluated with regard to neuromuscular impairment and other physical findings, while patients have been more concerned with symptoms and function[2]. Relief of symptoms and functional status have generally been assessed with measures that have not been standardized or proved reproducible, valid, or responsive to clinical change. Furthermore, instruments for the assessment of discomfort and function have typically been administered by the surgeon who performed the operation, creating the opportunity for observer bias. Not surprisingly, there has been disagreement among hand surgeons about the expected outcomes of carpal tunnel release[5]. More rigorous study of treatment for carpal tunnel syndrome will be enhanced by better measures of outcome.

TABLE I

SYMPTOM SEVERITY SCALE

The following questions refer to your symptoms for a typical twenty-four-hour period during the past two weeks (circle one answer to each question).

How severe is the hand or wrist pain that you have at night?
1 I do not have hand or wrist pain at night.
2 Mild pain
3 Moderate pain
4 Severe pain
5 Very severe pain

How often did hand or wrist pain wake you up during a typical night in the past two weeks?
1 Never
2 Once
3 Two or three times
4 Four or five times
5 More than five times

Do you typically have pain in your hand or wrist during the daytime?
1 I never have pain during the day.
2 I have mild pain during the day.
3 I have moderate pain during the day.
4 I have severe pain during the day.
5 I have very severe pain during the day.

How often do you have hand or wrist pain during the daytime?
1 Never
2 Once or twice a day
3 Three to five times a day
4 More than five times a day
5 The pain is constant.

How long, on average, does an episode of pain last during the daytime?
1 I never get pain during the day.
2 Less than 10 minutes
3 10 to 60 minutes
4 Greater than 60 minutes
5 The pain is constant throughout the day.

Do you have numbness (loss of sensation) in your hand?
1 No
2 I have mild numbness.
3 I have moderate numbness.
4 I have severe numbness.
5 I have very severe numbness.

Do you have weakness in your hand or wrist?
1 No weakness
2 Mild weakness
3 Moderate weakness
4 Severe weakness
5 Very severe weakness

Do you have tingling sensations in your hand?
1 No tingling
2 Mild tingling
3 Moderate tingling
4 Severe tingling
5 Very severe tingling

How severe is numbness (loss of sensation) or tingling at night?
1 I have no numbness or tingling at night.
2 Mild
3 Moderate
4 Severe
5 Very severe

How often did hand numbness or tingling wake you up during a typical night during the past two weeks?
1 Never
2 Once
3 Two or three times
4 Four or five times
5 More than five times

Do you have difficulty with the grasping and use of small objects such as keys or pens?
1 No difficulty
2 Mild difficulty
3 Moderate difficulty
4 Severe difficulty
5 Very severe difficulty

TABLE II
FUNCTIONAL STATUS SCALE

On a typical day during the past two weeks have hand and wrist symptoms caused you to have any difficulty doing the activities listed below? Please circle one number that best describes your ability to do the activity.

Activity	No Difficulty	Mild Difficulty	Moderate Difficulty	Severe Difficulty	Cannot Do at All Due to Hand or Wrist Symptoms
Writing	1	2	3	4	5
Buttoning of clothes	1	2	3	4	5
Holding a book while reading	1	2	3	4	5
Gripping of a telephone handle	1	2	3	4	5
Opening of jars	1	2	3	4	5
Household chores	1	2	3	4	5
Carrying of grocery bags	1	2	3	4	5
Bathing and dressing	1	2	3	4	5

In this paper, we report the development of a self-administered questionnaire for the assessment of severity of symptoms and functional status in patients who have carpal tunnel syndrome, and the results of a study demonstrating that the instrument is reproducible, internally consistent, valid, and responsive to clinical change.

Materials and Methods

Development of the Questionnaire

We consulted a panel of hand surgeons, rheumatologists, and patients, who identified six critical domains for the evaluation of carpal tunnel syndrome: pain, paresthesia, numbness, weakness, nocturnal symptoms, and over-all functional status. A Symptom Severity Scale incorporating these six clinical areas was developed (Table I). The scale consists of eleven questions with multiple-choice responses, scored from 1 point (mildest) to 5 points (most severe). The over-all symptom-severity score is calculated as the mean of the scores for the eleven individual items.

Twelve functional activities commonly affected by carpal tunnel syndrome were also identified. After pilot-testing, questions pertaining to four activities (driving, typing, sports, and working with tools), which did not apply to or were left unanswered by a substantial number of patients, were eliminated. The eight remaining activities comprised the Functional Status Scale (Table II). We chose activities commonly performed by a broad range of patients, including younger workers who have occupation-associated carpal-tunnel syndrome and the elderly. This approach minimizes missing data, which compromise the analysis of study results. In some circumstances, the scale could be modified by the addition of items relevant to specific samples under study, such as work-related activities for samples comprised exclusively of workers. The answers were rated from 1 point (no difficulty with the activity) to 5 points (cannot perform the activity at all). The over-all score for functional status was calculated as the mean of all eight items. Items that were left unanswered or that were not applicable were not included in the calculation of the over-all score.

We hypothesized that the scales are reproducible, internally consistent, valid, and responsive to clinical change. These properties are critical for instruments used to measure health status[30]. Reproducibility, or test-retest reliability, refers to the ability of the instrument to give the same result when administered on separate occasions. Internal consistency reflects the ability of a scale to measure a single, coherent concept — in the current study, severity of symptoms and functional status of patients who have carpal tunnel syndrome. Validity refers to whether the instrument actually measures what it is purported to measure, and responsiveness to change reflects the instrument's ability to detect changes in clinical status. A clinical study was developed to test these hypotheses. The study protocol was approved by the Human Investigations Committee of Brigham and Women's Hospital, and participating patients gave informed, written consent. Two groups of patients were studied: a prospective cohort, for determination of the instrument's reproducibility, internal consistency, validity, and responsiveness to change, and a separate cohort who had had carpal tunnel release in 1990, for further documentation of responsiveness to change.

Prospective Cohort

Sixty-seven patients who had had carpal tunnel syndrome were recruited from the hand surgery and rheumatology practices of Brigham and Women's Hospital and from the hospital's Nerve Conduction Laboratory. Thirty-nine (58 per cent) of the patients were evaluated before carpal tunnel release, and twenty-eight (42 per cent) were being managed non-operatively. Seventeen patients (25 per cent) were men and fifty (75 per cent) were women. Nine patients (13 per cent) had applied for or were receiving Workers' Compensation. The median age was fifty-seven years (range, nineteen to eighty-eight years), and the median duration of symp-

toms was eighteen months (range, three to fifty-eight months). The first thirty-one patients to be recruited were included in the analysis of test-retest reproducibility; all sixty-seven were included in the analysis of internal consistency; and forty-three, for whom complete physical-examination data were available, were included in the analysis of validity. The thirty-nine patients who were to have operative management were enrolled in a prospective study of the outcome of carpal tunnel release. At the time of writing, twenty-six of these patients had completed the questionnaire preoperatively and at three months, and these patients were included in the evaluation of responsiveness to change. The follow-up evaluation is incomplete because the study is ongoing.

Reproducibility and Internal Consistency

Reproducibility, or test-retest reliability, was assessed by administration of the scales to the patients on two successive days. Correlation of the total scores between the first and second days was measured with the Pearson correlation coefficient and used as a measure of reproducibility. A correlation coefficient (r) of 0 indicates no correlation and a coefficient of 1.0 indicates perfect agreement (reproducibility) between the two scores.

Internal consistency, or the coherence of the scales, was assessed with the Cronbach alpha, which summarizes the inter-item correlations among all items in a scale. A Cronbach alpha of 1.0 represents perfect correlation among all items and indicates that the items measure a single construct. Lower values reflect less correlation among items. A Cronbach alpha of 0.8 is considered good and a value of 0.9 is regarded as excellent[7].

Validity is difficult to assess because there is no universally accepted standard for measurement of the severity of symptoms or the functional status of the hand. We compared the scores on the scales with more traditional measures of disability and impairment in carpal tunnel syndrome, including grip and pinch strength as measured with a dynamometer, sensory conduction velocity of the median nerve, and the results of two-point discrimination and Semmes-Weinstein monofilament testing (Table III)[9]. We hypothesized that the scales would have positive but weak correlations with these traditional measures, because the scales measure dimensions of disability not captured by physical examination or nerve-conduction tests. Two-point discrimination was performed five times on each digit with use of caliper tips set four millimeters apart. The total number of applications of the caliper that was perceived correctly on the first three digits was analyzed as a continuous variable. Semmes-Weinstein monofilaments (6.65, 5.07, 4.56, 4.31, 3.61, 3.22, 2.83, and 1.65) were applied at room temperature, with the wrist in neutral position. The numbers of filaments perceived by all digits of the affected hand were totaled and analyzed as a continuous variable. The physical examinations were performed by a research assistant (G. G. H.) who was not involved in the care of the patients. The same measurement equipment was used for the physical examination throughout the study. Validity was assessed with Spearman correlations between instrument scores and the just mentioned objective measures; the Spearman coefficient was used because of the limited sample size and non-normal distributions.

Sensitivity to Clinical Change

Sensitivity, or responsiveness to clinical change, was assessed by comparison of the preoperative and postoperative scores in two cohorts of patients who had had carpal tunnel release. The first group included thirty-eight patients who had had carpal tunnel release in 1990 and were evaluated a median of fourteen months (range, eight to nineteen months) after the operation. The median age was fifty-nine years (range, twenty-two to eighty-eight years). Twenty-eight patients (74 per cent) were women, and four patients (11 per cent) had applied for Workers' Compensation. The patients were asked to complete one set of the scales by referring to their current status and another set by recalling their preoperative status. Sensitivity to change was expressed as the effect size, calculated as the mean difference between the preoperative and follow-up scores divided by the standard deviation of this difference[16]. An effect size of 0.50 has been documented after drug therapy for rheumatoid arthritis[1], and sizes of 0.90 to 1.30 have been noted with established measures after hip arthroplasty[13,16]. In general, effect sizes of more than 0.5 are considered moderate and those of more than 0.8, large[3]. The patients also indicated, on a 5-point scale, their satisfaction with the results of the operation. Changes in the scores were correlated with the extent of satisfaction, with use of the Spearman correlation coefficient.

The preoperative status was measured retrospectively in these patients who had been operated on in 1990. Because of concern that this might introduce bias, responsiveness to change was also assessed in twenty-six patients from the previously described prospective cohort. These patients, who had open carpal-tunnel release, completed forms preoperatively and three months postoperatively.

All data were 100 per cent verified for accuracy of entry and were analyzed with the SAS software package (SAS Institute, Cary, North Carolina).

Results

Reproducibility

The correlation between the scores on the two successive administrations of the questionnaire, according to the Pearson correlation coefficient, was 0.91 for the Symptom Severity Scale and 0.93 for the Functional Status Scale, indicating excellent reproducibility.

TABLE III

CORRELATIONS BETWEEN SELF-REPORTED SCORES ON THE SYMPTOM-SEVERITY AND FUNCTIONAL-STATUS SCALES AND TRADITIONAL CLINICAL MEASURES OF CARPAL TUNNEL SYNDROME*

	Symptom Severity	Functional Status	Grip Strength	Pinch Strength	Two-Point Discrimination	Semmes-Weinstein Monofilament Testing
Symptom severity	1					
Functional status	0.63†	1				
Grip strength	0.38‡	0.50†	1			
Pinch strength	0.47§	0.60†	0.79†	1		
Two-point discrimination	0.15	0.42§	0.43§	0.40§	1	
Semmes-Weinstein monofilament testing	0.17	0.24	0.23	0.24	0.60†	1
Median-nerve sensory conduction velocity	0.11	0.12	0.30	0.18	0.40‡	0.33

*All correlations were performed with the Spearman coefficient. All correlations are in the expected direction; worse status is associated with worse impairment. Thirty-six patients were analyzed for correlations involving nerve-conduction velocity. Forty-one, forty-two, or forty-three patients were analyzed for all other correlations.

†$p < 0.001$.

‡$p < 0.05$.

§$p < 0.01$.

Internal Consistency

The Cronbach alpha was 0.89 for the Symptom Severity Scale and 0.91 for the Functional Status Scale, indicating high inter-item correlations within each scale. This implies that the scales function well as unidimensional indices of severity of symptoms and functional status. The items within each scale — for example, paresthesia and numbness — are highly correlated with one another and thus are not independent. It is this intercorrelation that makes the multi-item scale precise, with a high signal-to-noise ratio.

Validity

The symptom-severity score was 3.0 ± 0.96 points (mean and standard deviation) and the functional-status score was 2.65 ± 0.96 points. Correlations between the scores on the scales and a variety of physical measurements were determined (Table III). All correlations were in the expected direction; that is, worse scores for severity of symptoms and function were associated with more severe impairment. The scores for severity of symptoms had moderate correlations with grip and pinch strength and weak correlations with two-point discrimination, pressure sensitivity on Semmes-Weinstein monofilament testing, and sensory conduction velocity of the median nerve.

The functional status scores had a high correlation with severity of symptoms, indicating that patients who had severe symptoms had major functional limitations. The functional status scores had a moderate correlation with grip and pinch strength and a fair or poor correlation with objective measures of sensory function of the median nerve. These results indicate that the two scales and traditional, objective measures of dysfunction of the median nerve capture different, complementary aspects of outcome.

Sensitivity to Clinical Change

Thirty-eight patients who had been operated on in 1990 completed the questionnaire in 1991 (a median of fourteen months after the operation), with regard to the preoperative and current severity of symptoms and functional status. The preoperative symptom-severity score was 3.4 ± 0.67 points (mean and standard deviation); postoperatively, it was 1.9 ± 1.0 points. This indicated substantial responsiveness to clinical change. The effect size was 1.4. The preoperative functional-status score was 3.0 ± 0.93 points, compared with a postoperative score of 2.0 ± 1.1 points; again, this demonstrated substantial improvement. The effect size of the score on the Functional Status Scale was 0.82. As an additional indicator of both responsiveness and validity, improvement in symptoms and functional status was analyzed

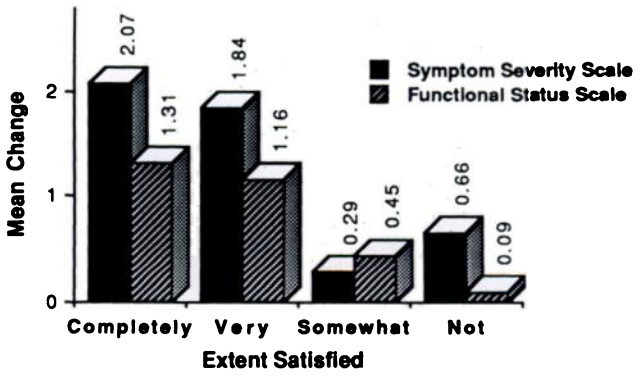

FIG. 1

Graph showing the mean changes in the scores for severity of symptoms (solid bars) and functional status (striped bars), from the time before the operation to a median of fourteen months after carpal tunnel release, plotted according to patients' self-reported satisfaction with the result of the operation. The greatest improvement is evident in the patients who were most satisfied with the operative result.

according to the patient's satisfaction with the over-all result of the operation (Fig. 1). Greater satisfaction with the result was associated with greater improvement in the scores for both severity of symptoms and functional status. The correlation between satisfaction with the result of the operation and improvement in the scores, measured with the Spearman coefficient, was 0.52 for the Symptom Severity Scale ($p = 0.0007$) and 0.29 for the Functional Status Scale ($p = 0.09$).

In the prospective cohort of patients, the score on the Symptom Severity Scale improved from 3.1 ± 0.9 points preoperatively to 2.0 ± 1.0 points three months postoperatively, for an effect size of 1.13. Similarly, the score on the Functional Status Scale improved from 2.7 ± 1.0 points preoperatively to 2.1 ± 1.1 points, for an effect size of 0.71. The correlations between satisfaction with the result of the operation and improvement in the scores on the questionnaire were 0.50 for the Symptom Severity Scale and 0.54 for the Functional Status Scale ($p < 0.01$ for each). These data confirm the responsiveness of the scales in a prospective cohort and, furthermore, indicate that substantial improvement occurs in the first three months postoperatively; this finding is consistent with clinical experience[5].

Discussion

Studies of carpal tunnel release have generally included relief of symptoms and improvement in function as outcomes but have not used standardized measures of demonstrated reproducibility or validity. Severity of symptoms and functional status are the principal reasons that patients seek treatment; therefore, they should be the most critical outcomes used to measure response. Thus, we developed scales for measurement of severity of symptoms and functional status, to be used in studies of outcomes of treatment for carpal tunnel syndrome.

Studies of treatment for carpal tunnel syndrome, and those of treatment of other orthopaedic conditions[17], should use a range of outcome measurements, including objective measures of impairment, complications, and patient-oriented measures such as severity of symptoms and functional status. There should also be measurement of important baseline variables that may be associated with outcome, such as demographic data and Workers' Compensation status. Thus, the scales that we developed are intended to supplement, not to replace, the variables usually measured in clinical studies.

The critical measurement properties of questionnaire scales include ease of administration, reproducibility, internal consistency, validity, and responsiveness to clinical change[30]. Our scales are self-administered and can be completed in less than ten minutes, imposing negligible burden on patients and investigators.

Reproducibility reflects whether the same result is obtained on repeated administrations, assuming no clinical change. Both of our scales were highly reproducible, with test-retest correlation coefficients of 0.91 (Symptom Severity Scale) and 0.93 (Functional Status Scale). By way of comparison, inter-rater agreement among radiologists on the presence of osteoarthrosis (measured with the kappa statistic, with 1.0 indicating perfect agreement and 0, no agreement) has been reported[14] to be 0.35. Furthermore, agreement between two raters on the presence of electrocardiographic abnormalities has been found to be 0.70[14]. Thus, while occasionally denigrated as so-called soft outcomes, questionnaires such as ours are, in fact, more reproducible than many measures that are considered objective.

Internal consistency indicates the extent that a scale of questions measures a single concept — in the current study, severity of symptoms or functional status of the hand. Higher internal consistency is generally associated with lower error variance or greater precision. These are desirable statistical properties: the lower the error variance, the fewer patients needed in a clinical study to demonstrate differences between groups. The internal consistencies of the Symptom Severity Scale and the Functional Status Scale (Cronbach alpha, 0.89 and 0.91, respectively) are excellent. By way of comparison, the Cronbach alphas for the health perception, physical function, and mental health subscales of the SF-36, an established measure of health status, were 0.84, 0.93, and 0.79, respectively, in a sample of rural elderly subjects[21]. Our scales could probably be shortened slightly and still have acceptable internal consistency; this strategy should be addressed in future research.

Validity refers to whether the scale measures what it is purported to measure. There is no universally accepted standard for the measurement of severity of symptoms or functional status against which to compare our scales. If there were, the scales would not be necessary. We hypothesized that more severe symptoms would be positively but weakly correlated with greater sensory impairment of the median nerve. The data support our hypothesis (Table III), indicating that severity of symptoms and functional disability cannot be estimated by sensibility or nerve-conduction testing. If symptoms and function are the outcomes of interest, they must be assessed directly.

Responsiveness to clinical change is also a critical attribute of outcome measures. Changes in the scores obtained with use of the instrument should mirror clinical improvement. We obtained scores for preoperative and postoperative status in patients who had had carpal tunnel release, an intervention that we assumed would lead to a striking decrease in severity of symptoms and improvement in functional status. Our data documented such improvements, both in the cohort of patients evaluated more than a year after the operation and in the prospective cohort evaluated three months postoperatively. The data demonstrate that satisfaction with the outcome of the operation was highly correlated with an improvement in the symptom severity score and moderately correlated with an improvement in the func-

tional status score, providing additional evidence of the validity of these scales.

Our study has potential limitations. Our instrument was developed for use in heterogeneous samples of patients, including younger workers and the elderly. We chose functional activities performed regularly by a broad spectrum of patients to minimize missing data. Investigators who want to study a more homogeneous group, such as assembly-line workers, could add items to the Functional Status Scale that are particularly germane to that population. All of the activities in our scale should be retained, however, so that a core set of activities can be compared across studies.

Only nine (13 per cent) of the patients were receiving Workers' Compensation. While we expect that the measurement properties of the instrument are similar regardless of whether or not a patient is receiving Workers' Compensation, not enough of our patients were receiving Workers' Compensation for us to conduct a separate analysis of this variable. It is possible that patients receiving Workers' Compensation might over-report symptoms or functional impairment on questionnaires. This hypothesis has not been proved and requires further study.

Our study was performed in a single academic center; future work should assess the generalizability of these findings in the community setting.

Another limitation of our study was that data on the preoperative status in the cohort that had had the operation in 1990 were obtained retrospectively, in 1991. These recollections may be less accurate than prospectively collected data and may also be biased by the operative outcome. Therefore, we presented data from our ongoing prospective study that confirmed the responsiveness of the instrument.

There is broad consensus that rigorous outcomes research is needed to distinguish interventions that are effective from those that are not. This task requires standardized, patient-centered measures that can be administered at a low cost; have proved reliability, validity, and responsiveness; and can be compared across studies. The Symptom Severity and Functional Status Scales meet these criteria and can be used to evaluate the course of carpal tunnel syndrome and the effectiveness of operative and non-operative interventions.

Note: The authors thank Dr. Clement B. Sledge for his encouragement, Dr. Matthew H. Liang for his many helpful suggestions, and Maura Iverson Daly, B.S.P.T., M.P.H. for her assistance in the collection of the data.

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