Correlating Nerve Conduction Studies and Clinical Outcome Measures on Carpal Tunnel Syndrome: Lessons From a Randomized Controlled Trial

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Abstract: The reported relationships between nerve conduction studies (NCS) and outcome measures in carpal tunnel syndrome (CTS) are weak to moderate. However, selection of patients may have confounded nonrandomized studies. NCS have potentially great value in selecting patients for a specific treatment and in objectively assessing the efficacy of treatments in CTS, especially if they correlate significantly with clinical outcome measures. To investigate the relationship between clinical outcome measures for the severity of complaints and NCS in patients treated for CTS, data were obtained from a multicenter randomized controlled trial on the efficacy of splinting versus surgery for CTS. At baseline and 12 months after randomization, clinical outcome measures were assessed and NCS were performed. In total, 138 patients completed the questionnaires and underwent repeated NCS. Relationships were analyzed with Spearman rank correlation coefficients and Pearson correlation coefficients. All NCS parameters showed highly significant improvement compared with baseline ($P < 0.001$). Modest correlations (<0.4) were found between the neurophysiologic and clinical outcome measures after 12 months, and between the changes in these different categories of outcome measures. This study confirms that the parameters of NCS improve significantly after treatment for CTS, but the modest correlations between neurophysiologic and clinical outcome measures do not support that NCS are routinely performed in clinical practice to evaluate treatment effects. However, studies investigating the effects of treatment for CTS should incorporate both clinical outcome measures and NCS, because they are complementary. Furthermore, NCS can provide additional information to the clinician when treatment effects are unsatisfactory.

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Nerve conduction studies (NCS) are frequently used to confirm the clinical diagnosis of carpal tunnel syndrome (CTS), and as outcome measures in clinical trials (Ebenbichler et al., 1998; Gerritsen et al., 2002; Hoefnagels et al., 1997). However, the actual correlations between NCS and clinical outcome measures (such as severity scales and questionnaires) are weak to moderate (Dhong et al., 2000; You et al., 1999). This discrepancy, or "clinical-neurophysiologic paradox," is reflected in the ongoing discussion whether clinical or neurophysiological parameters must be used as the "gold standard" for the diagnosis of CTS. All clinicians who regularly see patients with CTS have come across those with typical and sometimes severe complaints, but normal or marginally abnormal NCS. However, it has been shown that the results of NCS in asymptomatic individuals can be abnormal (Atroshi et al., 1999).

Despite these obvious inconsistencies, NCS undoubtedly have merits. They can demonstrate objective evidence of nerve dysfunction and may aid in the selection of patients for a specific treatment, especially if there is a reasonable correlation between pretreatment results of NCS and clinical outcome.

Because the symptoms and difficulties in performing daily activities determine why patients seek treatment and how they judge the effects of treatment, outcome measures should reflect these aspects. Both clinical and neurophysiologic outcome measures have been proposed, but these differ in their stronger and weaker points. Although patients with similar complaints may have different scores on self-administered questionnaires such as the Symptom Severity Scale and the Functional Status Scale, the intrarater reliability is high (Atroshi et al., 1998; Levine et al., 1993). However, self-administered questionnaires are more susceptible to con-

founding by subjective information provided by the patients than the objective data collected in NCS. However, the results of NCS may also vary over time and between performers because of environmental factors (e.g., temperature) and technical skills or equipment (Bleasel and Tuck 1991; Chaudhry et al., 1991; Kimura, 1997).

Most clinicians consider the relief of symptoms and improvement of functional status to be the most important determinants of a treatment's success. Hence, for NCS to play a role in the outcome assessment, it is important that the results of NCS correlate strongly with clinical outcome measures. Several studies have addressed this question, and have reported weak correlations (<0.5) between the results of NCS and symptoms or functional status (Dhong et al., 2000; Levine et al., 1993; You et al., 1999).

In a prospective study evaluating the effects of surgically treated CTS, the usefulness of the self-administered Boston Questionnaire (BQ) in qualifying severity of symptoms and functional state of patients before surgery, and also in showing improvement after surgery, was confirmed. However, it was not possible to predict the patient-oriented results of the operation from the presurgical BQ score. In contrast, the degree of improvement in sensory and motor distal conduction velocities could be forecast from presurgical values. Still, no significant correlations were found between the degree of improvement in the symptom severity or functional status scores and the nerve conduction values (Mondelli et al., 2000). The authors suggested that both methods should be used together because they are complementary.

Another prospective study reported a significant relationship between clinical improvement and improvement in sensory nerve conduction velocity (SNCV) after surgery (Dudley Porras et al., 2000). In fact, the study did not assess the actual correlations between the improvement in SNCV and the clinical improvement as measured by questionnaire, but only documented the improvement in SNCV after surgery. No relationship was found between the results of the preoperative electromyographic studies and the preoperative clinical symptom and functional status scores, and there were several patients who had major symptoms and minimal changes on electrodiagnostic tests, and vice versa. Hence, the conclusions made by the authors that the SNCV has a significant relationship with clinical improvement, and that it is an objective way of measuring postoperative outcome and the patient's ability to return to their activities, are not substantiated by the evidence presented.

Because none of the aforementioned studies randomized patients to treatment, the results may have been influenced by the selection of patients on clinical and/or neurophysiologic grounds.

The objective of our study was to investigate whether the results of NCS correlate with clinical outcome measures or changes thereof in patients participating in a randomized controlled trial on the efficacy of splinting versus surgery.

MATERIALS AND METHODS

The data for this study were obtained from a multicenter randomized controlled trial comparing the efficacy of splinting and surgery for the relief of CTS symptoms (Gerritsen et al., 2002).

Study Population

Patients were selected by neurologists in 13 participating hospitals. To be included in the trial, patients had to meet the following criteria: (1) pain, paraesthesia, and/or hypoesthesia in the hand, in the area innervated by the median nerve; (2) confirmation of the clinical diagnosis by NCS, the methods of which are described below; (3) aged 18 years or older; (4) ability to complete written questionnaires (in Dutch); (5) not previously treated with splinting or surgery; (6) no history of wrist trauma (e.g., fracture) or surgery; (7) no history suggesting underlying causes of CTS (e.g., diabetes mellitus, pregnancy); (8) no clinical signs or symptoms, or findings in NCS, suggesting conditions that could mimic CTS or interfere with its validation (e.g., cervical radiculopathy, polyneuropathy); and (9) no severe thenar muscle atrophy. The eligibility of patients was checked again by one of the research physiotherapists in the hospital concerned. After patients had given written informed consent and the baseline assessment had been performed, they were randomly allocated to either wrist splinting during the night for at least 6 weeks, or open carpal tunnel release.

Nerve Conduction Studies

According to the guidelines of the (American Association of Electrodiagnostic Medicine, 1993), the following protocol was adopted (Ross and Kimura, 1995). Skin temperature was measured before testing, and hands with a temperature of less than 32°C were warmed (Denys, 1991). Both hands were tested. Sensory and motor nerve conduction was studied, using surface electrodes for stimulating and recording. Latencies were measured from the stimulus onset to the initial negative response, and amplitudes were measured from baseline to negative peak. The sensory nerve action potentials were recorded antidromically, with ring electrodes around the proximal (active) and distal (reference) interphalangeal joints. The ground electrode was attached to the distal region of the wrist. Median SNCV was measured from the wrist to the index and ring fingers. Ulnar nerve sensory conduction was measured from the wrist to the ring finger. The distances between the median and ulnar stimulation sides at the wrist and the recording electrodes on the ring finger were equal. The compound muscle action potential was recorded from the thenar eminence, with the active recording electrode placed over the abductor pollicis brevis muscle

belly. The reference electrode was placed over the abductor pollicis brevis tendon. Median nerve distal motor latency was measured with stimulating and recording cathodes 7 cm apart. Median motor nerve conduction velocity was measured in the forearm. Supramaximal stimulation was delivered to the elbow and wrist.

The criteria used to confirm the clinical diagnosis of CTS were: (1) SNCV (index finger) $\leq$ 41.9 m/second in patients younger than 55 years or $\leq$37.3 m/second in patients 55 years or older, or distal sensory latency (DSL) (index finger) $\geq$ 3.5 milliseconds (Kimura, 1979), or (2) median-ulnar DSL difference (ring finger) $>$ 0.4 milliseconds (Charles et al., 1990), or (3) distal motor latency $\geq$ 4.34 milliseconds (Kimura, 1979).

Outcome Assessment

In the randomized controlled trial a distinction was made, a priori, between primary and secondary outcome measures. The primary outcome measures were considered to be the most relevant for both the patients and the clinicians.

At baseline and 12 months after randomization, the patients visited the hospital and completed written questionnaires. The following (primary) outcome measures for severity of complaints were used: (1) the number of nights that the patient awoke due to the symptoms during the past week; (2) the severity of the main complaint, pain, and paraesthesia at night and during the day during the past week, scored by the patient on an 11-point numerical rating scale, ranging from 0 ("no symptoms") to 10 ("very severe symptoms") (van der Windt et al., 1998); and (3) the mean score on the Symptom Severity Scale (11 questions about symptoms experienced during the past 2 weeks; 1 = mildest, 5 = most severe) and the Functional Status Scale (eight items concerning difficulties in performing various activities of daily living during the past 2 weeks; 1 = no difficulty, 5 = cannot perform activity at all) (Levine et al., 1993).

The NCS were repeated 12 months after randomization. The following nerve conduction parameters were used as (secondary) outcome measures: SNCV (index finger) (meters per second); DSL (index finger) (milliseconds); median-ulnar DSL difference (ring finger) (milliseconds); and distal motor latency (milliseconds).

Statistical Analysis

The relationships between the actual values of the different nerve conduction parameters and the different outcome measures for complaints 12 months after randomization were assessed with Spearman rank correlation coefficients, because the scores on the outcome measures for complaints did not follow a normal distribution. For both the nerve conduction parameters and the outcome measures for severity of complaints, change scores (difference between baseline and follow-up) were calculated for each patient separately. Subsequently, the relationships between the changes in the different nerve conduction parameters and the changes in the different outcome measures for complaints were assessed with Pearson correlation coefficients, because the change scores closely followed a normal distribution. A strong correlation was arbitrarily defined as 0.7 or higher.

RESULTS

Study Population

A total of 176 patients were included in the trial. Table 1 shows the baseline characteristics of the study population. A total of 156 patients completed the questionnaires 12 months after randomization, and 138 of them also underwent the repeated NCS. Of the 18 patients who did not undergo the repeated NCS but who completed the questionnaires at home, 13 simply did not wish to visit the hospital again, and five explicitly refused to undergo NCS again because they had found it too painful the first time. There were some missing values for the nerve conduction parameters at baseline and follow-up, either because these parameters had not been measured or because there was no sensory or motor response that could be measured.

Correlation Between Neurophysiological and Clinical Outcome Measures

Table 2 shows the values of the outcome measures for the severity of complaints and the nerve conduction parameters at baseline and 12 months after randomization. The changes in outcome measures between baseline and follow-up are also presented. All NCS and clinical outcome parameters improved significantly compared with baseline ($P < 0.001$).

In Table 3, the Spearman rank correlation coefficients are presented for the relationships between the values of the different nerve conduction parameters and the different outcome measures for complaints 12 months after randomization. Only modest correlations were found (range 0.01 to 0.33). The strongest correlations were found between the "number of nights waking up due to symptoms" and the

TABLE 1. Demographic Characteristics of the Study Population

Number of Patients	176
Age in years (mean, SD)	49 (11)
Female/male (%)	143 (81)/33 (19)
Duration of complaints (weeks)*	52 (23,104)
Bilateral complaints (%)	104 (59)
Dominant side most affected (%)	116 (66)
Previous episode of CTS complaints (%)	53 (30)

SD, standard deviation.
*Median and interquartile range.

TABLE 2. Clinical and Neurophysiological Outcome Measures at Baseline and 12 Months After Randomization

Outcome Measures	Baseline	Follow-up (12 months)	Change ¶ (Baseline and Follow-up)
Severity of complaints*	Median (interquartile range)		Mean (SD)
Nights/week waking up due to symptoms (0–7)	4 (1,7)	0 (0,0)	3.2 (2.9)
Severity main complaint	7 (6,8)	0 (0,1.3)	5.8 (2.9)
Pain (during the day)	4 (0,6)	0 (0,1)	2.9 (3.1)
Pain (at night)	5 (0,8)	0 (0,0)	4.2 (3.5)
Paraesthesia (during the day)	6 (3,8)	0 (0,1)	4.8 (3.2)
Paraesthesia (at night)	6 (3,8)	0 (0,0.3)	5.0 (3.4)
Symptom severity score (1–5)	2.5 (1.8,3.0)	1.1 (1,1.5)	1.1 (0.8)
Functional status score (1–5)	2.1 (1.5,2.9)	1 (1,1.4)	0.9 (0.9)
Nerve conduction parameters			
SNCV (index finger, m/s)	37.8 (8.9)	44.2 (7.3)	7.4 (9.6)
DSL (index finger, ms)	4.2 (1.0)	3.5 (0.6)	0.8 (0.9)
Median-ulnar DSL difference (ring finger, ms)	1.7 (1.2)	0.9 (0.7)	0.9 (1.2)
DML (ms)	5.6 (1.7)	4.5 (1.0)	1.1 (1.5)

SD, standard deviation; SNCV, sensory nerve conduction velocity; DSL, distal sensory latency; DML, distal motor latency.
*Range of scores is 0 to 10 (10 indicating severe complaints), unless indicated otherwise.
¶Change between baseline and follow-up for all clinical and NCS outcome measures; $P < 0.001$ (paired samples test).

TABLE 3. Correlations Between Neurophysiological and Clinical Outcome Measures at Follow-up*

Outcome Measures	Nights/Week (Waking due to Symptoms)	Severity (Main Complaint)	Pain (Day)	Pain (Night)	Paraesthesia (Day)	Paraesthesia (Night)	Symptom Severity Score	Functional Status Score
SNCV	−0.21	−0.12	−0.04	−0.12	−0.19	−0.18	−0.14	−0.07
DSL	0.18	0.14	−0.03	0.07	0.15	0.16	0.10	−0.01
Median-ulnar DSL difference	0.33†	0.28	0.11	0.15	0.23	0.32†	0.19	0.02
DML	0.25	0.21	0.10	0.20	0.24	0.28	0.19	0.07

SNCV, sensory nerve conduction velocity; DSL, distal sensory latency; DML, distal motor latency.
*Twelve months after randomization; Spearman rank correlation coefficients.
†$P < 0.001$.

"median-ulnar DSL difference" 12 months after randomization (Spearman rank correlation coefficient 0.33, $P < 0.001$) and between "paraesthesia at night" and the "median-ulnar DSL difference" 12 months after randomization (Spearman rank correlation coefficient 0.32, $P < 0.001$).

In addition, Pearson correlation coefficients between the changes in the nerve conduction parameters and the changes in the outcome measures for complaints were calculated, and similar weak correlations (range 0.00 to 0.26) were found (data not shown).

DISCUSSION

We investigated the relationship between outcome measures for the severity of complaints and the results of NCS in patients treated for CTS in a randomized controlled trial. All NCS and clinical outcome parameters showed highly significant improvement compared to baseline. However, only modest correlations (<0.4) were found between the actual values of the different categories of outcome measures 12 months after randomization and between the changes in the different categories of outcome measures. Because the data for this study were obtained from a randomized controlled trial, the patients received different types of treatment. However, a separate analysis of the patients randomized to surgery (n = 66) showed correlations within the same range as for all patients (data not shown). Of the patients allocated to splinting (n = 72), 30 (42%) had undergone surgery at the time of the follow-up measurement 12 months after randomization. Hence, separate analysis of the

patients treated solely with splinting (n = 42) was performed and similar modest correlations were found (data not shown). Our findings regarding these correlations corroborate earlier observations. In a recent retrospective study in 62 patients who had undergone carpal tunnel decompression surgery, no relationship was found between the nature or duration of preoperative symptoms and the severity of the electrophysiologic impairment. Furthermore, no relationship could be identified between preoperative NCS and the outcome of surgery (Longstaff et al., 2001). In a prospective study in 43 patients investigating the predictive value of NCS on clinical outcome after endoscopic carpal tunnel surgery, all electrophysiologic parameters improved after surgery. It was, however, not possible to predict failure in clinical improvement or worsening of NCS in individual cases. Many patients still showing abnormal NCS results were satisfied with the result of the surgery, whereas others reporting of serious symptoms had improved or normal NCS results (Vogt and Scholz, 2002).

However, our observation that all NCS parameters improved significantly after treatment is in line with a number of studies that provide evidence in support of clinical and electrophysiologic relationships. In a large, multicenter study comprising 1,123 hands, highly significant ($P < 0.001$) correlations were found between functional impairment (measured using patient-oriented questionnaires) and NCS, although the exact correlation coefficients were not reported. Interestingly, it was demonstrated that the domains "symptoms" and "pain" behaved differently than the domain "function." Scores for symptoms and pain were higher in patients with normal NCS than in patients with minimal neurophysiologic impairment, increased progressively in patients with moderate and severe neurophysiologic impairment, and decreased in patients with extreme neurophysiologic impairment (Padua et al., 1999). A low pain and discomfort threshold in the first phase of nerve entrapment that later increases was postulated to explain these observations. Giannini et al. (2002) validated a new clinical scale, the historical-objective (Hi-Ob) scale, and reported a significant correlation ($r = 0.42$) between the Hi-Ob score and NCS, divided in six neurophysiologic classes. Correlations with specific domains (symptoms, function, pain) showed only weak correlations, with correlation coefficients ranging from 0.17 to 0.28.

What general lessons can be learned from the results of this randomized controlled trial and those of other studies regarding the usefulness of NCS in evaluating treatment effects in patients with CTS? First, there seems to be no indication to routinely perform NCS in clinical practice to evaluate the treatment effects in CTS. The correlations observed in this study and in the literature are only modest, and cannot be used to predict outcome in individual cases. It remains possible, however, that dividing the results of NCS in different classes or combining NCS parameters to a sumscore will yield stronger correlations. Second, it has become clear that clinical outcome measures derived from validated questionnaires and NCS are complementary. NCS can demonstrate objective evidence of nerve dysfunction, whereas patient-oriented clinical scales are meant to reflect the most important aspects of the success of treatment from the patients'point of view. To objectively compare outcome in various patient series a standardized approach is necessary. Recently, a protocol for the evaluation of outcome was proposed that incorporates the BQ, Hi-Ob scale, and NCS divided in five severity classes. The validity was demonstrated by applying the protocol prospectively on a series of 323 hands (Reale et al., 2003). Hence, studies investigating the effects of treatment for CTS should incorporate both clinical outcome measures and NCS.

Furthermore, NCS can provide additional information to the clinician when treatment effects are unsatisfactory. When NCS performed after surgery show improvement despite persisting complaints, it should alert the clinician to the possibility of a diagnosis other than CTS. However, worsening NCS should raise the question of whether release of the transverse ligament has been properly performed, or lead to the consideration of other disorders with prominent involvement of the median nerve. Various disorders (e.g., radiculopathy, motor neuron disease, spondylotic myelopathy, syringomyelia) can masquerade as CTS, and are sometimes recognized only after carpal tunnel release has been unsuccessful (Witt and Stevens, 2000).

In conclusion, although NCS cannot be considered essential in assessing (individual) outcome in CTS, to discard them completely as an "unnecessary luxury" (Smith, 2002) is also inappropriate. In assessing outcome, clinicians must balance between the strength of NCS in providing objective evidence of nerve dysfunction and their shortcomings. For scientific purposes, it is recommended that clinical questionnaires and NCS be combined in a standardized approach, to cover the spectrum of signs and symptoms in CTS.

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