

ARTICLES

Development of a Clinical Prediction Rule for the Diagnosis of Carpal Tunnel Syndrome

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ABSTRACT. Wainner RS, Fritz JM, Irrgang JJ, Delitto A, Allison S, Boninger ML. Development of a clinical prediction rule for the diagnosis of carpal tunnel syndrome. *Arch Phys Med Rehabil* 2005;86:609-18.

Objectives: To develop a clinical prediction rule (CPR) and to assess the reliability and diagnostic accuracy of individual clinical examination items for the diagnosis of carpal tunnel syndrome (CTS).

Design: Prospective diagnostic test study with blind comparison to a reference criterion of a compatible clinical presentation and abnormal electrophysiologic findings.

Setting: Multicenter medical center and community hospital with patient referrals from ambulatory primary care and specialty practice settings.

Participants: Eight-two consecutively referred patients (50% men; mean age, 45 ± 12y) with suspected cervical radiculopathy or CTS referred for electrophysiologic examination.

Interventions: Not applicable.

Main Outcome Measures: Sensitivity, specificity, and likelihood ratios.

Results: The CPR identified in this study consisted of 1 question (shaking hands for symptom relief), wrist-ratio index greater than .67, Symptom Severity Scale score greater than 1.9, reduced median sensory field of digit 1, and age greater than 45 years. The likelihood ratio for the CPR was 18.3 when all 5 tests were positive. Interrater reliability was acceptable for all but 2 clinical examination items.

Conclusions: The CPR identified was more useful for the diagnosis of CTS than any single test item and resulted in posttest probability changes of up to 56%. Further investigation is required both to validate the test-item cluster and to improve point-estimate precision.

Key Words: Carpal tunnel syndrome; Physical examination; Projections and predictions; Rehabilitation.

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CARPAL TUNNEL SYNDROME (CTS) is an important cause of pain, neurologic symptoms, and functional limitation of the hand. It is the most common nerve compression disorder of the upper extremity, with reported prevalence rates of 3% among women and 2% among men. Peak prevalence is among women aged 55 years or older.¹ As many as 2%² to 15%³ of workers in high-risk industries are affected by CTS. In addition to the frequency of occurrence, the percentages of patients experiencing treatment complications or recurrent symptoms are sobering. Approximately 200,000 patients undergo surgical release of the volar carpal ligament annually,⁴ and 7% to 20% of these surgically treated patients may fail to obtain relief.⁵ Clearly CTS has a significant societal impact on both an individual and economic level.

Because the electrophysiologic examination for CTS is highly specific in a clinical setting, reasonably sensitive,⁶ and helps rule out other neuropathic and comorbid conditions as a cause of hand signs and symptoms,^{7,8} both associated symptoms and electrophysiologic findings (nerve conduction, needle electromyography) continue to be the mainstay for the laboratory diagnosis of CTS.⁹⁻¹¹ Furthermore, some third-party payers require electrodiagnostic confirmation of CTS before compensating claims.¹² However, as with many laboratory diagnostic tests,¹³ electrophysiologic procedures are not perfect, and there is continued debate regarding their precise role in the diagnosis and management of CTS.^{11,12,14} Although other laboratory procedures, such as computed tomography scan, magnetic resonance imaging, ultrasonography, and magnetic resonance neurography may be available, the diagnostic accuracy and utility of these procedures have yet to be determined, and they are therefore not considered clinically useful at this time.^{15,16}

The clinical examination, which consists of history, physical examination, and manual test procedures, is once again increasingly relied on in this era of medical cost-cutting.¹⁷ Despite the demonstrated diagnostic value of a clinical prediction rule (CPR) for many disorders,¹⁸⁻²⁰ investigations of the precision and accuracy of the clinical examination have lagged behind similar studies of laboratory tests,²¹ as has the development of CPRs. Although a definitive CPR for the diagnosis of CTS has not been identified, a number of clinical examination items are purported to be useful, with provocative procedures and neurologic findings being the most frequently studied.^{22,23} However, estimates of diagnostic test accuracy vary widely, and in most cases, rater reliability for test measurements is unknown. Other tests that may be potentially useful, such as the wrist-ratio index^{24,25} and flick sign,²⁶ have not been well studied. Despite the demonstrated value of the history in many conditions,^{27,28} useful data about its diagnostic value for CTS are limited. Considering the findings of 2 recent systematic reviews,^{22,23} it is clear that high-quality studies of the value of individual elements of the clinical examination for CTS are lacking, as is a methodologically sound CPR.

Although a CPR for the diagnosis of CTS is highly desirable and would be extremely useful, the most accurate combination of clinical examination items for diagnosing CTS is currently unknown. A review by D'Arcy and McGee²² suggested that a cluster of test items would offer greater diagnostic accuracy for

the diagnosis of CTS. Unfortunately, these researchers and others who have recommended the development of a CPR for CTS did not offer any prospective data for analysis.^{22,23} Katz et al.⁴ conducted original research and reported the diagnostic measurement properties for selected combinations of the Tinel sign, Phalen test, and a hand diagram rating but did not incorporate other clinical tests.

Currently, no studies have followed recently published guidelines^{29,30} for the development of a CPR for the diagnosis of CTS. A CPR considers multiple factors from the clinical examination to improve a clinician's diagnostic accuracy. The primary purposes of our study were (1) to develop a CPR for the diagnosis of CTS and (2) to assess the reliability and diagnostic accuracy of individual clinical examination findings for the diagnosis of CTS using an electrophysiologic reference criterion. The secondary purpose of this study was to examine the influence of disease severity on diagnostic test accuracy.

METHODS

Participants and Design

A total of 82 patients were enrolled in the study from December 1998 to April 2000 from 4 medical facilities: University of Pittsburgh, Wilford Hall USAF Medical Center, Brooke Army Medical Center, and Blanchfield Army Community Hospital. Consecutive patients between the ages of 18 and 70 years were recruited directly from the primary care clinic, from the orthopedic department, and from patients referred to the electrophysiologic laboratories of participating facilities. All had suspected cervical radiculopathy or CTS. Participants were informed about the study by laboratory personnel. Only patients judged by the electrophysiologic laboratory provider to have signs and symptoms compatible with cervical radiculopathy or CTS were eligible to participate. The more symptomatic limb was considered the involved limb for patients with bilateral symptoms. Patients with the following conditions were disqualified from study participation: (1) systemic disease known to cause a generalized peripheral neuropathy, (2) primary complaint of bilateral radiating arm pain, (3) history of conditions involving the affected upper extremity that resulted in a reduced level of function, (4) off work for more than 6 months because of the condition, (5) history of surgical procedures for pathologies giving rise to neck pain or for CTS, (6) previous needle electromyography and nerve conduction study (NCS) testing of the symptomatic limb for cervical radiculopathy and/or CTS, and (7) subjects receiving workers' compensation or with pending litigation for their condition. All subjects gave informed consent for participation as approved by the respective facilities' institutional review boards.

Patient Self-Report Items

Before undergoing a standardized electrophysiologic examination, each patient completed the following self-report instruments.

Visual analog scale. Patients rated their hand and/or upper-extremity pain on a 10-cm visual analog scale (VAS). Each patient made 3 VAS ratings: worst pain over the last 24 hours, least pain over the last 24 hours, and current pain. Although the VAS has been used extensively as an outcome measure,³¹⁻³³ its use for diagnostic purposes has not been reported.

Brigham and Women's Hospital Hand Symptom Severity Scale and Function Status Scale. The Brigham and Women's Hospital Hand Symptom Severity Scale (SSS) and Function Status Scale (FSS) are condition-specific scales developed by Levine et al.³⁴ The SSS consists of 11 statement items related to 6

domains thought critical for the evaluation of CTS. The FSS consists of 8 items related to a variety of activities commonly performed by a broad spectrum of patients (ie, young and elderly, workers inside and outside the home). Both scales are scored by calculating the mean of the individual items. A higher overall SSS score represents more severe symptoms. A higher overall FSS score represents greater disability. The psychometric properties of both the SSS and FSS are acceptable.³⁴⁻³⁶ Although the SSS and FSS have been used extensively as outcome measures, their use for diagnostic purposes has not been reported.

Hand diagram. The hand diagram developed by Katz and Stirrat^{4,37,38} was used in this study and graded by classifying the patient as having "classic," "probable," "possible," and "unlikely" CTS based on the areas of the diagram that were marked. Results from the hand diagram were then dichotomized by classifying "classic" and "probable" as a positive result and "possible" and "unlikely" as a negative result.⁴ Intrarater and interrater reliability have been reported as a percentage agreement of 91% and 84%, respectively.³⁸ Prospective studies assessing the diagnostic accuracy of the hand diagram alone and in combination with other diagnostic tests have reported sensitivities that range, respectively, from .61⁴ to .64³⁸ and specificities that range from .71⁴ to .73,³⁸ respectively.

Standardized Electrophysiologic Examination Procedure

A diagnosis of a compatible clinical presentation and abnormal electrophysiologic findings as determined by a neurologist or physiatrist served as the reference criterion for CTS. All subjects underwent a standardized electrophysiologic examination that was conducted by board-certified personnel. NCSs consisted of palmar sensory³⁹ and routine motor NCSs for both the median and ulnar nerves.⁴⁰⁻⁴² All median nerve NCS abnormalities were based on relative and absolute latency findings.³⁹ Median and ulnar nerve F-wave responses (minimum latency) were also obtained. If abnormalities were observed in the median and ulnar nerves of the same limb, nerves in the opposite upper limb and/or 1 lower limb were performed to rule out a generalized peripheral neuropathy.^{6,43} All NCS procedures were performed in accordance with guidelines for measurement, temperature, safety precautions, and electrode placement.⁴²

After the NCS, needle electromyography of the following muscles was performed at rest and during contraction using a monopolar needle electrode: middle and lower cervical paravertebral muscles, deltoid, triceps brachii, extensor carpi radialis longus and brevis, flexor carpi radialis, abductor pollicis brevis, and first dorsal interosseous. In addition, electromyography and NCS providers sampled additional cervical and limb muscles when indicated by a patient's clinical presentation. For each muscle site sampled, the tester applied the standard quadrant/level method for a total of 12 electromyographic observations at each sampling site.⁴² Observations of insertional activity, normal and abnormal spontaneous activity, and motor unit firing frequency were recorded during needle electromyography.⁴²

All NCS and electromyography test results were judged and graded using published criteria.^{6,40,42,44} A board-certified physiatrist or neurologist diagnosed all patients based on compatible symptoms and electrophysiologic examination findings and categorized them into 6 classifications according to established criteria (table 1).^{6,45-47} To examine the influence of disease severity on diagnostic test accuracy, all patients with CTS (classifications 2-4 and 6) were further categorized according to the severity of their respective electromyographic

Table 1: Descriptive Statistics for Study Subjects by Diagnostic Classification

Diagnosis Based on EMG/NCV	Sex (n)		Age (y) (mean $\pm$ SD)	Symptom Duration (d)	
	Male	Female		Median	Range
Normal	17	23	40 $\pm$ 11.7	176	21–1439
Unilateral CTS	3	4	48.7 $\pm$ 14.7	184.5	93–7220
Bilateral CTS	6	9	45.7 $\pm$ 10.6	262	31–5415
CTS with ulnar neuropathy	0	1	NA	NA	NA
Cervical radiculopathy	12	2	51 $\pm$ 7.4	74.5	21–2555
Cervical radiculopathy with peripheral neuropathy	3	2	58.7 $\pm$ 6.1	60	42–80

Abbreviations: EMG, electromyography; NCV, nerve conduction velocity; NA, not applicable.

and NCS findings using a modified classification system⁴⁸ as shown in appendix 1.

Seven different electromyography and NCS providers performed the NCSs, needle electromyography procedures, and subsequent diagnostic classification of patients. At 1 center, 3 different evoked potential technicians performed nerve conduction procedures only.

Standardized Clinical Examination Procedure

A standardized clinical examination consisting of 21 items was performed by a physical therapist (examiner 1) after the standardized electromyography and NCS examination was completed and after a 15- to 30-minute rest period. The examination was repeated by a second physical therapist (examiner 2) after a 10-minute rest period to assess interrater reliability. Both examiners were blinded to the patient's suspected diagnosis, electromyography and NCS test results, and diagnostic classification. Nine different physical therapists performed the standardized clinical examination procedures.

History. All patients were asked 9 questions thought to be diagnostic of CTS; examiner 2 obtained responses to the same questions 1 to 2 days later by telephone. The questions and their respective response options are listed in appendix 2.

Conventional neurologic examination. Strength of the abductor pollicis brevis muscle was tested as described by Kendall and McCreary⁴⁹ and was graded as markedly reduced, reduced, or normal, compared with the uninvolved extremity. Pinprick sensory testing of the median nerve cutaneous distribution was done using the end of a straightened paper clip. Palmar cutaneous sensation of the pads of the thumb and index and middle fingers each were compared with the proximal cutaneous sensation of the thenar eminence. The result of each sensory test was graded as absent, reduced, normal, or hyperesthetic, in comparison to the thenar eminence.

Wrist-ratio index. The wrist-ratio index described by Johnson et al⁵⁰ is purported to be an indicator of carpal canal volume, with larger ratios ($>.70$) suggested to be a predisposing factor for CTS. A single pair of sliding calipers was used to measure both anteroposterior (AP) and mediolateral (ML) wrist width in centimeters. Caliper jaws were aligned with the distal wrist crease for both measurements. The wrist ratio index was computed by dividing the AP wrist width by the ML wrist width.

Provocative tests. The following provocative tests were used in this study: carpal compression test (CCT), Phalen test, Tinel sign (parts A, B), and the upper-limb tension test (parts A, B). The tests along with their operational definitions are listed in appendix 2. The reliability and validity of both conventional neurologic examination items and provocative tests used in this study have been summarized and previously reported.^{22,23}

Examiner Training

A videotape of all clinical examination procedures and handbooks detailing the performance of each clinical examination and electrophysiologic measure were distributed to each participating center before data collection. All examiners viewed the tape and read the handbooks to familiarize themselves with the procedures. All examiners practiced all clinical examination measures at least twice. Using a pinch gauge, examiners practiced applying the specified amount of compression force required for the CCT.

Data Analysis

Reliability was computed for each neurologic and provocative clinical examination measure using dichotomized findings from the involved limb obtained by 1 rater pair that examined 50 patients. Sensation and muscle test results were dichotomized into normal or abnormal findings because of low observed base rates for responses of "increased" or "markedly reduced." Reliability for neurologic and provocative tests was assessed with a κ statistic.⁵¹ Reliability for the wrist-ratio index was reported as an intraclass correlation coefficient ($ICC_{2,1}$) and corresponding standard error (SE) of measurement.⁵² Ninety-five percent confidence intervals (CIs) were calculated for all reliability coefficients.

The following qualitative interpretation for κ described by Fleiss⁵³ was used in this study: excellent, .75 or higher; fair to good, .40 to .74; and poor, less than .40.

The clinical examination results obtained by examiner 1 were used for all computations of diagnostic test accuracy. Only findings from the involved limb were used. Contingency tables (2 $\times$ 2) were used to calculate sensitivity and specificity for each test item. Patients diagnosed with CTS (classifications 2, 3), including those with concomitant cervical radiculopathy or ulnar neuropathy (classifications 4, 6), formed the disease-positive group, and patients classified as normal or as cervical radiculopathy (classifications 1, 4) served as the disease-negative group. When a zero cell value was encountered, .5 was added to all cell values in the table to permit calculation of likelihood ratios and their 95% CI. Receiver operator characteristic (ROC) curves were used to determine cutoff values for self-report, age, and wrist-ratio index variables.⁵⁴ Positive and negative likelihood ratios and their associated 95% CIs were computed for all clinical examination items.⁵⁵ For multilevel response items (questions 1–3) and the CPR, likelihood ratios were reported for each response level.⁵⁶ The positive likelihood ratio was calculated as sensitivity/(1–specificity) and the negative likelihood ratio as (1–sensitivity)/specificity. Likelihood ratios are convenient summary measures of diagnostic test performance and indicate by how much a given diagnostic test or CPR will raise or lower the pretest probability of the target disorder of interest.^{56,57} The diagnostic accuracy of individual clinical examination variables was considered useful if the positive likelihood

Table 2: Reliability of Clinical Examination Items

Variable	κ (95% CI)	ICC (95% CI)	SE
Question 1 (Most bothersome symptoms . . .)	.74 (.55–.93)	NA	NA
Question 2 (Where most bothersome . . .)	.82 (.68–.96)	NA	NA
Question 3 (Symptom behavior . . .)	.57 (.35–.79)	NA	NA
Question 4 (Hand fat/swollen . . .)	.85 (.68–1.0)	NA	NA
Question 5 (Fumbling/dropping . . .)	.95 (.85–1.0)	NA	NA
Question 6 (Entire limb numb . . .)	.53 (.26–.81)	NA	NA
Question 7 (Night symptoms wake . . .)	.83 (.60–1.0)	NA	NA
Question 8 (Hand shaking improves . . .)	.90 (.75–1.0)	NA	NA
Question 9 (Worse with hand use . . .)	.72 (.49–.95)	NA	NA
Median sensory field 1	.48 (.23–.73)	NA	NA
Median sensory field 2	.50 (.25–.75)	NA	NA
Median sensory field 3	.40 (.12–.68)	NA	NA
MMT abductor pollicis brevis	.39 (.00–.80)	NA	NA
Upper-limb tension test A	.76 (.51–1.0)	NA	NA
Upper-limb tension test B	.83 (.65–1.0)	NA	NA
Tinel Part A	.47 (.21–.72)	NA	NA
Tinel Part B	.35 (.10–.60)	NA	NA
CCT	.77 (.58–.96)	NA	NA
Phalen test	.79 (.59–1.0)	NA	NA
Wrist AP	NA	.77 (.62–.87)	2.1mm
Wrist ML	NA	.86 (.75–.92)	2.1mm

Abbreviations: MMT, manual muscle testing.

ratio was 2.0 or greater or if the negative likelihood ratio was .50 or less.⁵⁸ Based on the prevalence or pretest probability for CTS of 34% in this sample, positive likelihood ratio values greater than 2.0 and negative likelihood ratio values less than .5 result in posttest probability changes of at least 14%.

A stepwise binary logistic regression model was used to determine a CPR for the diagnosis of CTS.⁵⁹ Other than age, only variables with useful accuracy (≥ 2.0 , or negative likelihood ratio $\leq .50$)⁵⁸ were entered into the model. Age was included in the model because CTS is associated with increased age.^{4,60} A backward stepwise selection procedure was used to select variables, with *P* values of .15 to exit the model and .10 to enter it. The method of entry and liberal *P* values were chosen to prevent potentially useful variables from being excluded from the model.⁶¹ The Hosmer-Lemeshow summary goodness-of-fit statistic was used to assess the fit of the model to the data and test the hypothesis that the model fits the data.⁶² Variables retained by the regression model were used to develop a CPR for the diagnosis of CTS. The sensitivity, specificity, and positive likelihood ratio for the number of positive findings in the CPR were calculated as previously described for other dichotomous variables. Because all patients had at least 1 positive CPR finding, diagnostic values were only calculated for 2 or more CPR findings. According to Jaeschke et al,⁵⁸ positive likelihood ratio values between 2.0 and 5.0 would generate small shifts in probability, values between 5.0 and 10.0 would generate moderate shifts, and values greater than 10.0 would generate large and often conclusive shifts in probability. We chose to focus on the positive likelihood ratio instead of the negative likelihood ratio because we were interested in the diagnosis of CTS based on positive test results.

Patients with CTS were subclassified based on severity of electromyography and NCS findings as mild/moderate CTS or as pronounced/severe CTS, and diagnostic accuracy was computed for both CTS subgroups in the same manner previously described for the entire CTS cohort. Each subgroup was analyzed independently of the other.

RESULTS

The descriptive statistics for age and duration of symptoms of the 82 patients (41 men, 41 women; mean age, 45 ± 12 y) who participated in the study are listed by diagnostic classification in table 1. The prevalences of CTS and cervical radiculopathy were 34% ($n=28$) and 23% ($n=19$), respectively. The mean age and median symptom duration of patients with CTS (mean age, 48.4 ± 11.5 y; symptom duration, 183.5d) did not differ significantly ($\alpha < .05$) from patients without CTS (mean age, 43.2 ± 11.7 y; symptom duration, 123d). The right extremity was involved in 17 patients. Of the 28 patients with CTS, 15 had bilateral involvement. Based on severity of the electromyography and NCS findings, 14 patients were classified as having mild/moderate CTS (mean age, 46 ± 12 y) and 14 were classified as having pronounced/severe CTS (mean age, 50 ± 11 y). One patient, classified as having cervical radiculopathy with concomitant CTS and ulnar neuropathy at the elbow, dropped out of the study after the standardized electrophysiologic examination and was not included in the analysis of test measurement properties.

Reliability

The 32 subjects not included in the reliability analysis did not differ from the rest of the sample with regard to age, SSS score, FSS score, or pain ratings ($P > .05$). Seventeen of the 19 dichotomous variables had κ values of at least fair or better ($\kappa \geq .40$). The interrater reliability coefficients for items of history and clinical examination are in table 2.

Diagnostic Accuracy

The sensitivity, specificity, and likelihood ratios for each variable, and their associated 95% CIs, are listed in tables 3 and 4. Because the ROC curve for the VAS pain scale showed no potentially useful cutoff points, no further analyses of VAS pain ratings were performed. The following 7 variables were found to have useful diagnostic accuracy: question 3 (Which of the following best describes the behavior of your symptoms?), question 5 (Do you have trouble with fumbling or dropping objects from

Table 3: Validity of Historical Questions

Question*	Sensitivity (95% CI)	Specificity (95% CI)	NLR (95% CI)	PLR (95% CI)
1 (Most bothersome symptoms . . .)	.04 (−.04–.11)	.91 (.83–.98)	1.1 (.94–1.2)	.42 (.05–3.4)
2 (Where most bothersome . . .)	.35 (.16–.53)	.40 (.27–.54)	1.6 (1.1–2.5)	.58 (.33–1.0)
3 (Symptom behavior . . .)	.23 (.07–.39)	.89 (.81–.97)	.87 (.69–1.1)	2.1 (.74–5.8)
4 (Hand fat/swollen . . .)	.38 (.20–.57)	.63 (.50–.76)	.98 (.68–1.4)	1.0 (.57–1.9)
5 (Fumbling/dropping . . .)	.73 (.56–.90)	.57 (.44–.71)	.47 (.24–.92)	1.7 (1.2–2.5)
6 (Entire limb numb . . .)	.38 (.20–.57)	.80 (.69–.90)	.77 (.55–1.1)	1.9 (.92–3.9)
7 (Night symptoms wake . . .)	.73 (.56–.90)	.31 (.19–.44)	.86 (.41–1.8)	1.1 (.79–1.4)
8 (Hand shaking improves . . .)	.81 (.66–.96)	.57 (.43–.70)	.34 (.15–.77)	1.9 (1.3–2.7)
9 (Worse with hand use . . .)	.77 (.61–.93)	.37 (.24–.50)	.62 (.28–1.4)	1.2 (.91–1.6)

NOTE. Useful likelihood ratios are in bold.

Abbreviations: NLR, negative likelihood ratio; PLR, positive likelihood ratio.

*See wording of entire question in appendix 2.

your affected hand?), question 8 (Do your symptoms improve with moving, “shaking,” or positioning your wrist or hands?), median sensory field 1, wrist-ratio index greater than .67, an SSS score greater than 1.9, and an FSS score greater than 2.5.

Clinical Prediction Rule

The 7 variables listed above and age were entered into the regression model as potential predictors for CTS. After list-wise deletion, a total of 78 subjects (26 CTS, 52 control) were used in the analysis. The results of the Hosmer-Lemeshow test indicated that the model fit the data ($P=.65$) and the Nagelkerke R^2 equaled .56. The following 5 test variables were

chosen by the model and are therefore considered the best CTS clinical prediction rule: a single question (shaking hands for symptom relief), wrist-ratio index greater than .67, SSS score greater than 1.9, diminished sensation in median sensory field 1 (thumb), and age greater than 45. The 5 test variables and their diagnostic properties according to the number of abnormalities required for a positive test are listed in table 5. For 4 or more positive test findings, the positive likelihood ratio was 4.6; when all 5 test findings were positive, the positive likelihood ratio was 18.3. Twenty CTS patients had 4 or more positive test results and 4 CTS patients had positive results for all 5 tests. All 81 patients had at least 1 positive CPR test result.

Table 4: Validity of Physical Examination and Self-Report Measures

Test Item	Sensitivity (95% CI)	Specificity (95% CI)	NLR (95% CI)	PLR (95% CI)
Age	.64 (.47–.82)	.59 (.47–.72)	.60 (.35–1.0)	1.58 (.46–2.4)
Median sensory field 1 (thumb)	.65 (.47–.84)	.70 (.47–.84)	.49 (.28–.46)	2.2 (1.3–3.6)
Median sensory field 2 (index finger)	.52 (.32–.72)	.67 (.32–.72)	.72 (.52–1.1)	1.6 (.92–2.7)
Median sensory field 3 (middle finger)	.44 (.26–.63)	.74 (.26–.63)	.75 (.86–1.1)	1.7 (.92–3.2)
MMT abductor pollicis brevis	.19 (.04–.34)	.89 (.81–.9)	.91 (.74–1.1)	1.7 (.58–5.2)
Wrist-ratio index >.67	.93 (.83–1.0)	.26 (.14–.38)	.29 (.07–1.2)	1.3 (1.0–1.5)
Hand diagram (classic or probable)	.75 (.58–.92)	.13 (.04–.22)	1.9 (.72–5.1)	.86 (.67–1.1)
SSS score >1.9	.89 (.77–1.0)	.36 (.23–.49)	.31 (.10–.96)	1.4 (1.1–1.8)
FSS score >2.5	.37 (.19–.55)	.81 (.71–.92)	.77 (.56–1.1)	2.0 (.95–4.2)
Upper-limb tension test A	.75 (.58–.92)	.13 (.04–.22)	1.9 (.72–5.1)	.86 (.67–1.1)
Upper-limb tension test B	.64 (.45–.83)	.30 (.17–.42)	1.2 (.62–2.4)	.91 (.65–1.3)
Tinel Part A	.41 (.22–.59)	.58 (.45–.72)	1.0 (.69–1.5)	.98 (.56–1.7)
Tinel Part B	.48 (.29–.67)	.67 (.54–.79)	.78 (.52–1.2)	1.4 (.84–2.5)
CCT	.64 (.45–.83)	.30 (.17–.42)	1.2 (.62–2.4)	.91 (.65–1.3)
Phalen test	.77 (.61–.93)	.40 (.26–.53)	.58 (.27–1.3)	1.3 (.94–1.7)

NOTE. Useful likelihood ratios appear in bold.

Table 5: CPR for the Diagnosis of CTS

Criteria for a Positive Test	Sensitivity (95% CI)	Specificity (95% CI)	Likelihood Ratio (95% CI)	Posttest Probability of CTS (%)
≥2 positive tests	.98 (.14–1.0)	.14 (.23–.23)	1.1 (1.0–1.3)	44
≥3 positive tests	.98 (.14–1.0)	.54 (.40–.67)	2.1 (1.6–2.8)	52
≥4 positive tests	.77 (.61–.93)	.83 (.73–.93)	4.6 (2.5–8.7)	70
All 5 tests positive	.18 (.03–.31)	.99 (.97–1.0)	18.3 (1.0–328.3)	90

NOTE. Five tests are included in the rule: (1) question 8 (hand shaking improves symptoms); (2) wrist-ratio index >.67; (3) SSS score >1.9; (4) diminished sensation in median sensory field 1 (thumb); and (5) age >45 years. Useful likelihood ratios appear in bold. The associated posttest probability values are based on a pretest probability of 34%.

Diagnostic Accuracy for CTS Subclassifications

The diagnostic properties of clinical examination items for mild/moderate and pronounced/severe CTS subclassifications are listed in table 6 along with the results for all 28 CTS patients. There were 12 items with useful likelihood ratios when subclassification analyses were considered. A wrist-ratio index greater than .67, an SSS score greater than 1.9, and the question concerning shaking hands for symptom relief were the only test items with likelihood ratios that remained useful and somewhat consistent when comparing the results of the entire sample with both subclassification categories (table 6).

DISCUSSION

A CPR has been defined as “a tool used by clinicians to assist with medical decision making that provides either a probability of disease or outcome or suggest a diagnostic or therapeutic course of action.”^{29(p488)} Our study is the first to propose a clinically useful CPR for the diagnosis of CTS that meets all major methodologic criteria for a level IV CPR.^{29,30} The rule derived in our study comprises age, a question (shaking hands for symptom relief), SSS score, wrist-ratio index, and median sensory field 1 deficit (see table 5). Of the test items D’Arcy and McGee²² reported to be helpful based on their review, only diminished sensation was represented in our CPR.

The diagnostic usefulness of a CPR is best expressed by likelihood ratio statistics. The positive likelihood ratio of the CPR expresses the change in odds favoring the presence of CTS, depending on the number of positive findings. Before any clinical testing, the probability that a patient had CTS in our sample was 34%. With a CPR criterion of all 5 tests positive (positive likelihood ratio=18.3), the probability of a patient having CTS increases to 90% (fig 1). A CPR criterion of 4 or more positive tests yields a positive likelihood ratio of 4.6 and increases the probability of CTS to 70%. In contrast, the positive likelihood ratio reported by Katz et al⁴ for various combinations of the Phalen test, Tinel sign, and the hand diagram did not exceed 3.5 (calculated from reported data).⁴ The CPR derived in our study represents a reference criterion of provider diagnosis based on both a compatible clinical presentation and electromyography and NCS reference standard, the shortcomings of which have already been discussed. Although a better criterion standard may be found in the future, this is arguably the best currently available.⁹

Our univariate results for the Phalen test, Tinel sign, and night symptoms were very similar to those reported by Katz.⁴ Results for the hand diagram and age were also similar for sensitivity and specificity, respectively. However, specificity of the hand diagram (specificity=.13 in our study vs specificity=.71⁴-.73³⁸) and sensitivity of age (sensitivity=.64 in our study vs .80^{4,38}) differed. These differences may be attributable to spectrum of disease, exclusion criteria, recruitment source (primary care and orthopedic specialty clinic), and use of an ROC curve–specified cutoff for age 45 years or older (vs $\geq 40y^4$). Patients with systemic diseases were excluded in our study, but some of our CTS patients had concomitant peripheral mononeuropathies, as did patients in the comparison group, of whom 49% had normal electromyography and NCS findings.

We assessed several test items that have been infrequently or not previously reported that appeared to be useful for the diagnosis of CTS. These include the SSS score, FSS score, wrist-ratio index, and selected historical questions. All these test items had useful likelihood ratios. Although the SSS and FSS are disease-specific scales commonly used as evaluative instruments for patients with CTS,^{35,36} they appear to have useful diagnostic properties as well (negative likelihood ratio=.21, positive likelihood ratio=.2.0, respectively). Questions related to behavior of symptoms (question 3) and functional limitations (question 5) had a positive likelihood ratio of 2.1 and a negative likelihood ratio of .47, respectively. Question 8, which related to the flick sign, had a negative likelihood ratio of .34. The flick sign, in which a patient shaking his/her hands relieves symptoms, has been reported by Pryse-Phillips²⁶ as being highly sensitive and specific. The wrist-ratio index had much higher sensitivity and lower specificity in our study compared with others,^{24,25,50} but we used an ROC curve to determine an optimal cutoff value, whereas other studies did not. The smallest negative likelihood ratio for any test item in the study belonged to the wrist-ratio index (negative likelihood ratio=.29), which indicates it may be useful for screening purposes. Results for the Phalen test, Tinel sign, and the CCT in this study were comparable to those reported in other studies of higher methodologic quality, as were the results for neurologic tests.²² The exception was the sensitivity of the abductor pollicis brevis manual muscle test, which was low and may be partially explained by disease spectrum and a low index of reliability. Similar to other studies, we found diminished sen-

Table 6: Validity of Test Items for Subclassifications of CTS

Test Item	Sensitivity				Specificity*	NLR			PLR		
	Total	Mild/ Moderate	Severe	Total		Mild/ Moderate	Severe	Total	Mild/ Moderate	Severe	
Age >45y	.64	.50	.79	.59	.60	.84	.36	1.6	1.2	1.9	
Question 3 (Symptom behavior ...)	.23	.14	.33	.89	.87	.96	.75	2.1	1.3	3	
Question 5 (Fumbling/dropping ...)	.73	.64	.83	.57	.47	.62	.29	1.7	1.5	2.0	
Question 6 (Entire limb numb ...)	.38	.50	.25	.80	.77	.63	.94	1.9	2.5	1.2	
Question 7 (Night symptoms wake ...)	.73	.86	.58	.31	.86	.45	1.3	1.1	1.3	.85	
Question 8 (Hand shaking improves ...)	.81	.86	.75	.57	.34	.25	.44	1.9	2.0	1.7	
Question 9 (Worse with hand use ...)	.77	.86	.67	.37	.62	.39	.90	1.2	1.4	1.1	
SSS score >1.9	.89	.93	.85	.36	.31	.20	.43	1.4	1.5	1.3	
FSS score >2.5	.37	.50	.23	.81	.77	.61	.94	2.0	2.7	1.3	
Median sensory field 1	.65	.50	.83	.70	.49	.71	.24	2.2	1.7	2.8	
Abductor pollicis brevis weakness	.19	.14	.25	.89	.91	.96	.84	1.7	1.3	2.4	
Wrist-ratio index >.67	.93	.93	.92	.26	.29	.28	.30	1.3	1.3	1.3	

NOTE. Useful likelihood ratios appear in bold.

*Specificity remained constant for all 3 comparisons, because the control group did not change.

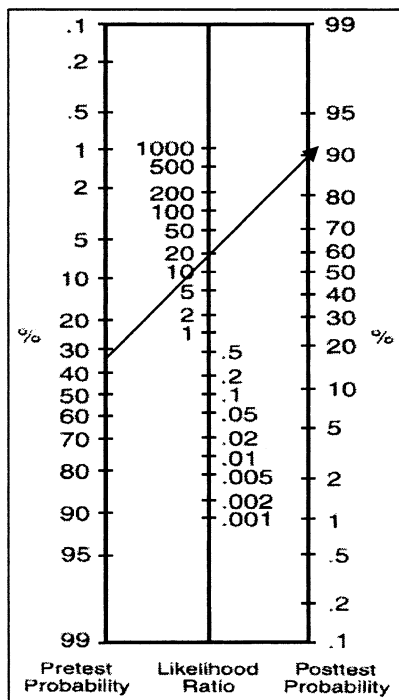


Fig 1. Pretest (34%) to posttest (90%) probability change using the CPR with positive results from all 5 tests.

sation to have useful diagnostic properties.^{25,63} However, our method of testing sensation—by comparing the pad of the thumb with the base of the thenar eminence—has not been previously reported. We did not include sensory threshold tests, because time restraints and training limit their widespread clinical use, nor did we include body mass index as a variable, despite its being a known risk factor for CTS.^{60,64}

The diagnostic values reported for many test items considered useful for the diagnosis of CTS, particularly provocative tests, vary widely. Their diagnostic value is at best mediocre, and interpretation of research findings is confounded by a number of methodologic flaws contained in previous studies. These limitations include lack of a challenging control group, poor or unacceptable test operational definition, and test and diagnosis review

bias.^{22,23,57} However, much of the variation of results between these studies can probably be explained by spectrum bias. The 3 test items (SSS, question 8, wrist-ratio index) that showed somewhat consistent and useful likelihood ratios for the total CTS group and both CTS subgroup classifications (see table 6) have not been well studied or studied at all. Apparently, these items were not affected by the spectrum of disease in our study. All 3 tests were included in the CPR and therefore provide unique information in the diagnosis of CTS.

A common problem with previous studies is that most do not report the reliability of the measures they used.^{22,23} Laupacis et al²⁹ found that, of the 30 reports dealing with CPRs that met their inclusion criteria, only 1 reported indices of reliability for measures used in their study. The reliability of measurements for all items as operationally defined in our study was greater than fair, except the Tinel B and muscle test of the APB, indicating that most common clinical examination items have acceptable reliability for clinical use.

Several factors support the generalizability of our results, including the large number of electrophysiologic laboratory personnel, clinical examiners, multicenter involvement, recruitment of subjects from a primary care setting, and inclusion of a challenging control group. The study was limited by our relatively small sample size, which resulted in wide 95% CIs of our point-estimates and an increased potential for regression model misfit.

Our results suggest that future research assessing the SSS score, wrist-ratio index, and flick sign question is likely to find that these clinical items have useful diagnostic properties. Additional studies of provocative test items such as the Phalen test and Tinel sign, whose values have yet to be clearly demonstrated, are likely to yield more of the same unfruitful results. Future studies should assess and report the influence of disease spectrum on test item performance.

CONCLUSIONS

This study represents a level IV CPR and the first step in developing a clinically sensible CPR for the diagnosis of CTS. Validation is required before this rule can be applied clinically, and it has yet to be determined whether patients presenting in primary care, orthopedic, and other specialty clinic settings will be better off for undergoing these tests.

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APPENDIX 1: CTS SEVERITY CLASSIFICATION SYSTEM

Severity Level	Description
Mild	Abnormal median sensory latency. All other sensory and motor NCS parameters normal.
Moderate	Abnormal sensory and distal motor latency. Sensory nerve action potentials (SNAP) or compound nerve action potentials (CNAP) amplitudes may be diminished but are greater than or equal to 50% of normative values. Motor nerve conduction velocity (NCV) is normal but mild slowing of forearm NCV may be present (≥ 45 m/s).
Pronounced	Abnormal sensory and distal motor latency. SNAP or CNAP amplitudes at 50% or less of normative values. Compound muscle action potential (CMAP) amplitude may be diminished but at 50% or more of normative values. Mild slowing of forearm NCV may be present (≥ 45 m/s) and spontaneous activity may be noted on electromyography examination.
Severe	Absent SNAP or CNAP, abnormal distal motor latency, CMAP amplitude less than 50% of normative values or absent. Mild (> 45 m/s) slowing of forearm NCV may be present and electromyographic abnormalities are present.

APPENDIX 2: QUESTIONS OF HISTORY AND PROVOCATIVE TESTS

Questions of History and Provocative Tests	Responses
1. Which of the following symptoms are most bothersome for you?	Pain, numbness & tingling vs loss of feeling
2. Where are your symptoms most bothersome?	Neck, shoulder or shoulder blade, arm vs hands and/or fingers
3. Which of the following best describes the behavior of your symptoms?	Intermittent, variable (comes and goes) vs constant
4. Does your affected hand feel "fat" or "swollen"?	Yes or No
5. Do you have trouble with fumbling or dropping objects from your affected hand?	Yes or No
6. Does your entire affected limb and/or hand feel numb?	Yes or No
7. Do your symptoms wake you during the night?	Yes or No
8. Do your symptoms improve with moving, "shaking," or positioning your wrist or hands?	Yes or No
9. Are your symptoms made worse when performing tasks that require a lot of grasping or hand and/or finger use?	Yes or No
Provocative Tests	Positive Test Criteria
● Tinel part A was performed and interpreted as a test of neural regeneration as described by Tinel.⁶⁵ With the patient sitting, the elbow flexed 0°–30°, and the forearm in a supinated position, the patient's wrist and hand were supported in a neutral position. A tendon reflex hammer positioned ≈6 inches above the wrist was allowed to fall 4–6 times over the median nerve located between the tendons of the flexor carpi radialis and the palmaris longus at the proximal wrist crease. Part B was performed and interpreted as a provocative measure used to reproduce the patient's symptoms.⁴ The patient was positioned and the test was performed as for part A above, except that the examiner brought the hammer down with mild to moderate force in an attempt to elicit symptoms. ● Carpal compression test (CCT). With the patient sitting, the elbow flexed 0°–30°, and the forearm in a supinated position, the patient's wrist and hand were supported in a neutral position. The examiner placed both thumbs over the transverse carpal ligament and applied approximately 6 pounds of pressure with each thumb. The pressure was maintained for a maximum of 30 seconds.⁶⁶ The patient was questioned with regard to symptoms at 15-second intervals during the 30-second period. ● Phalen test. With the patient sitting, the elbow flexed 0°–30°, and the forearm in a supinated position, the patient's wrist and hand were supported in a neutral position. The examiner placed the patient's wrist in a position of maximal flexion for a maximum of 60 seconds.⁶⁷ The patient was questioned with regard to symptoms at 15-second intervals during the 60-second period.⁶⁸ ● Upper-limb tension test. Part A was performed similar to Elvey's description.⁶⁹ With the patient supine, the examiner sequentially introduced the following movements to the symptomatic upper extremity: (1) scapular depression, (2) shoulder abduction, (3) forearm supination, wrist and finger extension, (4) shoulder lateral rotation, (5) elbow extension, and (6) contralateral then ipsilateral cervical side-bending. Part B. With the patient supine and the shoulder abducted 30°, the examiner sequentially introduced (1) scapular depression, (2) shoulder medial rotation, (3) full elbow extension, (4) wrist and finger flexion, and (5) contralateral then ipsilateral cervical side-bending. In both parts the patient was questioned regarding symptom reproduction throughout the maneuver.	Part A: Nonpainful tingling sensation radiating distally along the course of the nerve. Part B: Discomfort or pain at the wrist or radiating distally along the course of the nerve that is related to the patient's condition. Reproduction of the symptoms in the cutaneous distribution of the median nerve that is related to the patient's condition. Reproduction or exacerbation of paresthesias or anesthesia in the cutaneous distribution of the median nerve in the hand.⁶⁷ Any 1 of the following: (1) patient's symptoms reproduced (2) side-to-side differences (>10°) in elbow extension (part A) or wrist flexion (part B) on completion of all motion sequences (3) symptomatic limb side: contralateral neck side-bending increased symptoms or ipsilateral side-bending decreased symptoms.

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