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Diagnosing Carpal Tunnel Syndrome: Diagnostic Test Accuracy of Scales, Questionnaires, and Hand Symptom Diagrams—A Systematic Review

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OBJECTIVE: To summarize and evaluate research on the accuracy of clinical diagnostic scales, questionnaires, and hand symptom diagrams/maps used for diagnosis of carpal tunnel syndrome (CTS).

DESIGN: Systematic review of diagnostic test accuracy.

LITERATURE SEARCH: A comprehensive literature search of the MEDLINE, CINAHL, and Embase databases was conducted on January 20, 2020.

STUDY SELECTION CRITERIA: Studies that assessed at least 1 diagnostic accuracy property of the scales, questionnaires, and hand symptom diagrams used for the diagnosis of CTS.

DATA SYNTHESIS: The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines were followed. Risk of bias and applicability concerns were assessed using the revised Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) tool. Diagnostic accuracy properties were summarized.

RESULTS: Out of 4052 citations after removing duplicates, 21 articles met the inclusion criteria. Twelve articles reported on the diagnostic accuracy of scales and questionnaires, including the Bland questionnaire, Kamath and Stothard questionnaire, 6-item carpal tunnel syndrome symptoms scale (CTS-6), Boston Carpal Tunnel Questionnaire, Wainner clinical prediction rule, and Lo clinical prediction rule. Positive likelihood ratios ranged from 0.94 for the Boston Carpal Tunnel Questionnaire to 10.5 for the CTS-6, and negative likelihood ratios ranged from 1.04 to 0.05 for the same diagnostic tools, respectively. Nine studies reported the diagnostic accuracy of the Katz and Stirrat hand symptom diagram. Positive and negative likelihood ratios ranged from 1.42 to 8 and from 0.78 to 0.05, respectively. Only 4 studies had high methodologic quality.

CONCLUSION: Limited evidence supports high accuracy of the CTS-6, Kamath and Stothard questionnaire, and Katz and Stirrat hand symptom diagram. Other scales have lesser and more conflicting evidence. Further high-quality studies are necessary to examine the diagnostic accuracy of these tests to assist ruling in or ruling out CTS. *J Orthop Sports Phys Ther 2020;50(11):622-631. Epub 16 Sep 2020. doi:10.2519/jospt.2020.9599*

KEY WORDS: *carpal tunnel syndrome, diagnostic accuracy, diagnostic scales and questionnaires, hand symptom diagram/map, systematic review*

Carpal tunnel syndrome (CTS) is caused by compression of the median nerve in the carpal canal and is the most prevalent type of compression neuropathy of the upper extremity.[3] An important barrier to treating CTS is the lack of a diagnostic gold standard.[1] In clinical decision making, an ongoing process of gathering enough information to decide on the optimal plan of care,[21] diagnosis is a central feature. Clinical examination tests are quick, inexpensive, and give an immediate answer, which makes them appealing for diagnosing CTS.

Carpal tunnel syndrome can be diagnosed with a variety of clinical examination tests and by the patient's history.[1] However, the final confirmation is often made based on neurophysiological tests assessing median nerve conduction velocity.[13] The most recent CTS management guideline of the American Academy of Orthopaedic Surgeons (AAOS) concludes that only limited evidence supports the use of handheld nerve conduction studies (NCS), ultrasound, and magnetic resonance imaging in CTS diagnosis.[1] Advanced diagnostic testing can be expensive and painful in some cases (eg, NCS). Electrodiagnostic studies report higher false-positive and false-negative results compared to studies of clinical examination tests.[1]

According to a previous systematic review[29] and the AAOS guideline,[1] clinical examination tests for diagnosing CTS can be categorized into 4 major groups: (1) provocative maneuvers (eg, Phalen test, Tinel sign), (2) sensory and motor

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tests (eg, 2-point discrimination, thenar weakness test), (3) diagnostic scales (eg, the 6-item carpal tunnel syndrome symptoms scale [CTS-6]) and questionnaires (eg, the Kamath and Stothard questionnaire), and (4) hand symptom diagrams/maps (the Katz and Stirrat hand symptom diagram). In this systematic review, we focused on diagnostic scales, questionnaires, and symptom diagrams/maps. Systematic reviews addressing the 2 other categories (provocative and sensory/motor tests) will be presented in 2 separate systematic reviews.[11]

The last systematic review on diagnostic test accuracy for CTS[29] is outdated. The purpose of our systematic review was to appraise and synthesize the evidence on the diagnostic accuracy of diagnostic scales, questionnaires, and hand symptom diagrams for diagnosing CTS.

METHODS

We registered this study with the International Prospective Register of Systematic Reviews (PROSPERO) on December 20, 2018 (CRD42018109031). The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) and Cochrane Collaboration guidelines were followed.[12,27]

Information Sources

We conducted a literature search in 3 electronic databases—MEDLINE (through Ovid, from 1946), Embase, and CINAHL—from their inception to January 20, 2020. The search strategy was designed to identify studies of diagnostic test accuracy of at least 1 clinical diagnostic test for the diagnosis of CTS. We reported the results for diagnostic scales, questionnaires, and hand symptom diagrams. We developed the search strategy (**APPENDIX A**, available at www.jospt.org) in 2 consecutive meetings with a librarian who specializes in health science research methodology at McMaster University, by combining vocabulary and key words related to the diagnostic accuracy of the clinical examination tests for the diagnosis of CTS.

To identify the names of the clinical diagnostic tests for CTS to be included in the search strategy, we searched previous reviews on this topic and the AAOS guidelines. The terms used in the search were also reviewed by a physical therapist and a hand therapist (A.D. and J.M.) to ensure that all known physical examination tests for CTS were included. We hand searched the reference lists of included articles.

Study Selection

Two reviewers (A.D. and J.Y.) performed the study selection independently in 2 phases. In the first phase, titles and abstracts were reviewed against predetermined inclusion and exclusion criteria. The agreement of the reviewers in this phase was calculated using kappa statistics.[25] Kappa values less than 0.20 indicated poor agreement, and values greater than 0.80 indicated almost perfect agreement in rating.[25] All statistical analyses were conducted using Stata 15 (StataCorp LLC, College Station, TX). In the second phase, full-text articles were retrieved and reviewed. To resolve any disagreement during the first or second phase of the study selection process, a third reviewer (J.M.) moderated a consensus through discussion.

Eligibility Criteria

There were no restrictions on study selection based on sample size, language, or sex. Studies were included in this systematic review when the below criteria were met.

Design Systematic reviews and case-control, cross-sectional, or cohort studies that collected either prospective or retrospective data in a full-report format were included.

Participants Studies that included adults (18 years old or older) diagnosed with or suspected to have CTS and that had a control group of participants with any diagnosis of neurological, musculoskeletal, or vascular conditions of the upper extremity (eg, cervical radiculopathy or tennis elbow) were included. Studies with healthy control groups were excluded.

Diagnostic Test Studies that assessed at least 1 diagnostic accuracy property of the physical examination tests for the diagnosis of CTS (restricted to diagnostic scales, questionnaires, and hand symptom diagrams/maps) were included.

Comparison Because there is no known gold standard for the diagnosis of CTS, we accepted any physical examination test used as a reference standard (eg, NCS, surgical decompression of the carpal canal, other clinical examination diagnostic tests, or a combination of reference standard tests) made by a physician or expert clinician.

Outcome Articles reporting diagnostic accuracy properties, such as sensitivity and specificity or likelihood ratio (LR), or that provided enough data to (re)construct 2-by-2 contingency tables, were included.

Time All time frames reporting the diagnostic accuracy of clinical examination for the diagnosis of CTS were accepted.

We excluded (1) reviews, letters, conference abstracts, editorials, and case reports; (2) studies not using diagnostic scales, questionnaires, or hand symptom diagrams as an index test for the diagnosis of CTS; (3) studies on median nerve conditions other than CTS; and (4) studies not reporting sensitivity, specificity, or other diagnostic accuracy properties or not providing sufficient data to calculate the statistics.

Data Extraction

Two authors (A.D. and J.Y.) independently extracted information from 3 included articles, and the agreement was discussed with a third author (J.M.). Because the agreement was very high, the first author completed data extraction alone, using a predetermined, self-developed data-extraction form. In the case of any uncertainty in data extraction, the other 2 reviewers were contacted and a consensus was acquired through discussion. We extracted author identification,

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publication year, country of study, study design, participant characteristics (age, sex, CTS severity and duration), sample size, inclusion and exclusion criteria, the participant selection process, clinical examination test, reference standard, and all of the available information regarding diagnostic accuracy measures. In the case of any values missing from the articles, the study authors were contacted by e-mail.

Data Synthesis and Analysis

Where possible, we extracted sensitivities, specificities, positive and negative predictive values, as well as positive likelihood ratios (+LRs) and negative likelihood ratios (−LRs). When data were not provided, we tried to calculate values using the information reported about true positives, false positives, false negatives, and true negatives.[19] We then created 2-by-2 contingency tables and calculated the sensitivity, specificity, +LR, and −LR, including the 95% confidence interval for each physical examination test if possible.[19] The sensitivity of a diagnostic test is the ability of the test to truly label people (ie, true positive) with a given medical condition, and specificity of a diagnostic test is defined as the identification of those without the disease or disorder (true negative).[19]

Likelihood ratios are diagnostic accuracy properties that are independent of the prevalence of the disease.[33] We calculated +LR [sensitivity/(1 − specificity)] and −LR [(1 − sensitivity)/specificity].[33] Positive likelihood ratio values of greater than 10 and −LRs less than 0.1 comprise one of the most useful measures in diagnostic decision making.[33] Values between 5 and 10 (+LR) and between 0.1 and 0.2 (−LR) suggest that the test has a moderate ability to change the probability of having a condition.[1] Last, +LR and −LR values of less than 5 or more than 0.5, respectively, suggest that the test has a small ability to change the probability of a diagnosis.[1] Data heterogeneity (eg, different index tests, different sample characteristics, different cutoff points for positive test results) precluded meta-analysis.

Assessment of Risk of Bias and Applicability Concerns

Two authors (A.D. and J.Y.) independently rated the risk of bias and applicability concerns using the revised Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2[37]) tool. To resolve discrepancies, we reached a consensus through discussion with a third author (J.M.). The QUADAS-2 tool rates the risk of bias of articles in 4 domains: participant selection, index test, reference standard, and flow and timing.[37] The applicability concerns regarding articles are rated for all of the domains in the QUADAS-2 tool except for the flow and timing of the participants.[37] Each domain has a set of signaling questions that can be answered as "yes," "no," or "unclear."[37]

If the answers to all of the signaling questions were yes, then that domain was considered to have a low risk of bias or applicability concerns. If the answer to any of the signaling questions of a domain was no or unclear, then the risk of bias or applicability concerns of that domain were rated as high or unclear. To generate an overall rating of the risk of bias or applicability concerns of an article, studies rated as low on all of the domains were defined as "low risk of overall bias" or "low applicability concerns." Ratings of high or unclear on any of the domains resulted in the overall judgment of the articles as "at risk of bias" or "concerns regarding applicability."

RESULTS

After removing duplicates and evaluating 4052 records, 161 references were assessed in full-text review. Twenty-one articles met the inclusion criteria (**FIGURE 1**): 9 studies assessed the diagnostic accuracy of diagnostic hand symptom diagrams/maps[2,7,10,15,22-24,32,34] and 12 articles reported on the diagnostic accuracy of diagnostic scales and questionnaires.[4-6,8,9,14,18,20,28,30,31,36] The studies were conducted in 6 countries: Austria, Canada, Greece, Spain, the United Kingdom, and the United States. Conflicts of interest of the included studies are available in **APPENDIX B** (available at www.jospt.org). The kappa value of the agreement for title and abstract screening was 0.70 (95% confidence interval: 0.66, 0.74; SE, 0.02). The methodological assessments of all included articles are presented in **FIGURE 2**. Overall, 4 studies had a low risk of bias[18,22,24,28] and 4 had an unclear rating only in 1 domain.[6,7,14,20] Regarding applicability, 12 studies had no concerns (**FIGURE 3**).[5-8,14,18,20,22,24,28,30,31]

The detailed characteristics of the participants in the included studies, as well as the clinical diagnostic tests and the reference standards used in each study, are presented in **APPENDICES C** and **D** (available at www.jospt.org). Eighteen studies had a prospective cross-sectional study design, and the remaining 3 articles[6,14,23] had retrospective study designs. All but 3 studies[7,10,15] recruited participants from persons with suspected CTS referred to orthopaedic, rheumatology, or hand clinics (or similar clinical settings) or nerve conduction labs. Only 3 studies reported the pretest probability of having CTS in their study sample.[14,15,34] High variability among studies (eg, a variety of index tests, criteria for positive test results, and population characteristics) precluded meta-analysis.

Diagnostic Accuracy of the Diagnostic Scales and Questionnaires for CTS Diagnosis

Six different diagnostic tools were used and assessed across all included studies. Of the 12 studies on the diagnostic accuracy of scales and questionnaires for the diagnosis of CTS, the following diagnostic tools were assessed: (1) the Bland questionnaire,[4,5,18] (2) the Kamath and Stothard questionnaire,[6,9,20,36] (3) the CTS-6,[14,30,36] (4) the Boston Carpal Tunnel Questionnaire,[8,31] (5) the Lo clinical prediction rule,[28,36] and (6) the Wainner clinical prediction rule.[36] Thorough descriptions of the CTS diagnostic scales,

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questionnaires, and hand symptom diagrams, as well as their methods of administration and positive result thresholds, are presented in **TABLE 1.** The overall sample size of these studies was 17 768 wrists with suspected CTS; 7488 wrists were diagnosed with true-positive CTS (positive results confirmed by both the index and the reference standard tests). Positive likelihood ratios to diagnose or rule in CTS ranged from 0.94 for the Boston Carpal Tunnel Questionnaire[31] to 10.5 for the CTS-6,[14] and –LRs to exclude or rule out CTS ranged from 1.04 for the Boston Carpal Tunnel Questionnaire[31] to 0.05 for the CTS-6[14] (**TABLE 2**). Only 1 study combined tests, which resulted in high sensitivity (95.9%) and moderate specificity (50%).[6]

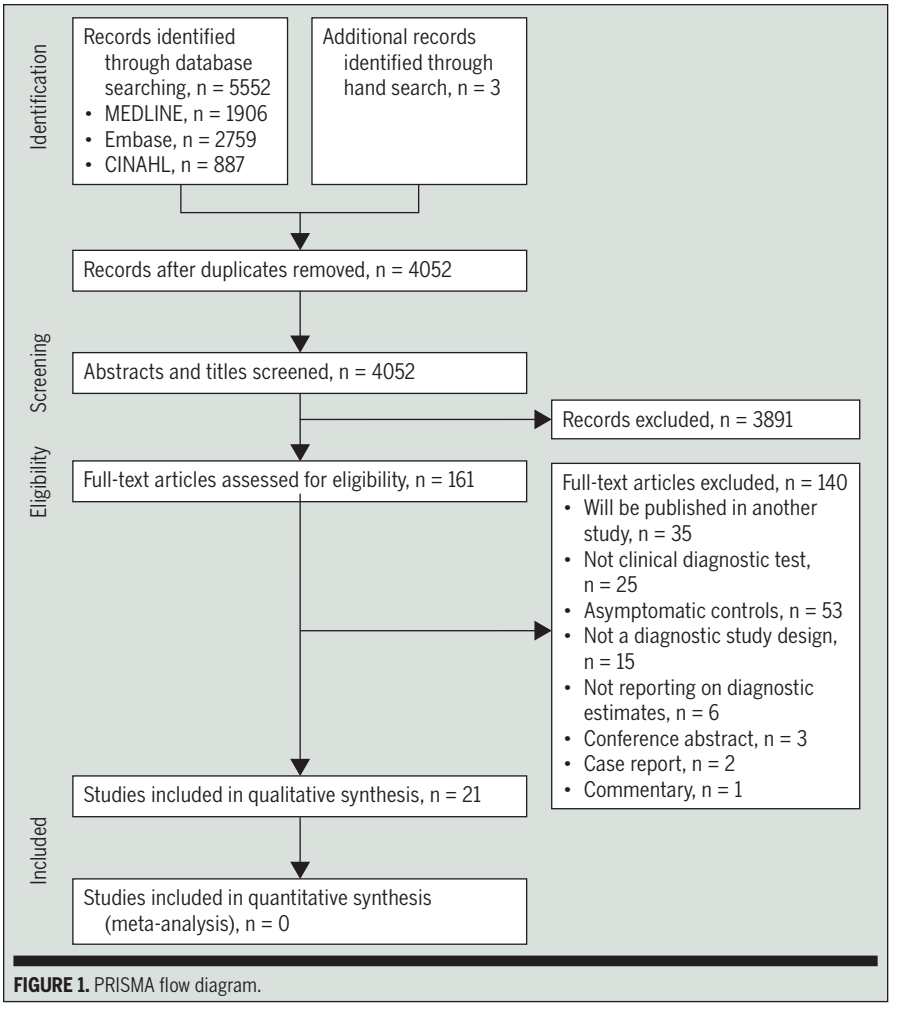

FIGURE 1. PRISMA flow diagram.

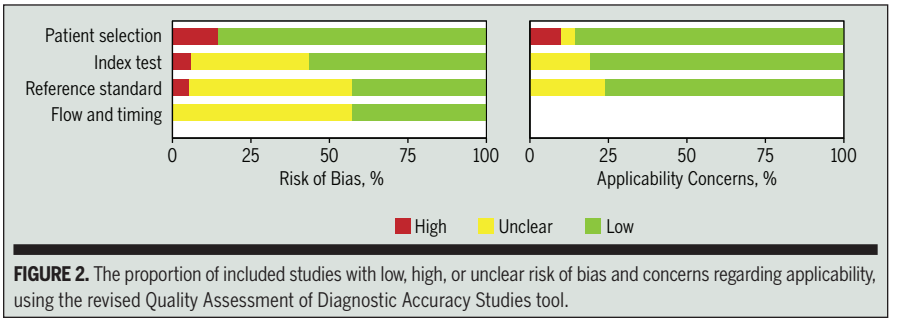

FIGURE 2. The proportion of included studies with low, high, or unclear risk of bias and concerns regarding applicability, using the revised Quality Assessment of Diagnostic Accuracy Studies tool.

Diagnostic Accuracy of Hand Diagrams/Maps for CTS Diagnosis

Nine studies evaluated the diagnostic accuracy of the Katz and Stirrat[23] hand symptom diagram.[2,7,10,15,22-24,32,34] The sample size was 1796 wrists with suspected CTS and 930 true-positive CTS wrists. Positive likelihood ratios to diagnose or rule in CTS ranged from 1.42[7] to 8,[23] and –LRs to exclude or rule out CTS ranged from 0.78[15] to 0.05[24] (**TABLE 3**).

Reference Standards for CTS Diagnosis

Seventeen studies[2,4-10,15,18,22,24,28,30-32,34] used electrodiagnosis as the reference standard, although the methodology and criteria for positive test results varied between the studies. Two studies performed clinical diagnosis[23,36] and 1 study[20] used carpal tunnel release surgery as the reference standard. One study did not have a reference standard and compared the results of the CTS-6 to NCS and diagnostic ultrasound findings, using a statistical method called latent class analysis.[14]

DISCUSSION

The purpose of our systematic review was to summarize and assess the quality of the diagnostic scales, questionnaires, and hand symptom diagrams/maps for the diagnosis of CTS. We found 12 clinical studies reporting on 6 different diagnostic scales and questionnaires, and 9 studies reporting on the Katz and Stirrat[23] hand symptom diagram. Among these tests, the CTS-6, the Kamath and Stothard[20] questionnaire, and the Katz and Stirrat[23] hand symptom diagram (when used with the classical categorization) had the greatest accuracy in deciding whether to rule in or rule out CTS.

Accurate diagnosis is the key to establishing appropriate treatment plans and prognosis. Given the high prevalence of CTS, the clinical diagnosis tends to be an important concern for clinicians. No other condition seen by hand therapists seems to have this variety of available clinical diagnostic tests.[29] The consider-

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FIGURE 3. Risk of bias and applicability concerns of the included studies, using the revised Quality Assessment of Diagnostic Accuracy Studies tool.

able number of available studies on the clinical diagnosis of CTS also reflects the prominent emphasis on diagnosing CTS.

The lack of a gold standard for CTS diagnosis contributes to heterogeneity of diagnostic methods. The diagnostic approaches used for people with suspected CTS vary in different settings, determined by the clinical background of the treating clinician.[16] A classic approach is to first gather information from patient history and physical examination tests and create a list of possible diagnoses, then to determine further ancillary testing to confirm one of these diagnoses.[16] In some clinical settings, electrodiagnostic tests are almost always performed for CTS diagnosis. In other settings, these tests are rarely administered.[16]

Only 3 studies reported the prevalence of CTS in their sample.[14,15,34] Settings with a higher prevalence of CTS (eg, hand clinics or electrodiagnosis labs) have higher pretest probability of CTS. It is important to consider the setting in which the study is being conducted. Although the results from the studies done in a clinical setting tend to be closer to what a clinician might encounter, higher pretest probability of CTS in these settings leads to inflated estimates of the diagnostic accuracy properties of the tools.[16,36] Only 3 studies recruited their sample from a nonclinical population, where the probability of having CTS was still high, because the inclusion criteria consisted of workers with current hand symptoms.[7,10,15] To eliminate the effect of pretest probability of CTS in the sample population on diagnostic accuracy measures, we extracted (or calculated) +LRs and −LRs, as these values are independent of the prevalence of the condition.

Clinicians are often presented with clients who have similar upper extremity signs and symptoms but different diagnoses. Therefore, a healthy control group does not reflect the clinical setting and might decrease the applicability of this systematic review. A case-control design, where the controls are healthy individuals, risks erroneous estimates

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of (inflated) specificity and negative predictive values.[19] To avoid bias, we excluded studies with solely asymptomatic (ie, healthy) control groups.

Due to the lack of a diagnostic gold standard for CTS,[1] different reference standards were used in the included studies. We included studies regardless of their choice of reference standard.[11] The most common reference standard test used in the included studies was electrodiagnosis; however, this comparison is flawed because electrodiagnosis has false-positive and false-negative results.[1] Only 1 study used latent class analysis,[14] which is a statistical technique that can be used when there is no established gold standard.

Classifying CTS Diagnostic Tools

The available clinical examination tests for diagnosing CTS can be categorized into 4 main groups, each test having limited capability of being used alone as

TABLE 1 Description of Scales, Questionnaires, and Hand Symptom Diagrams for CTS

Diagnostic Test	Method	Positive Result Threshold
6-item CTS symptoms scale[17]	Six criteria are assessed and scored: 1. Numbness in the median nerve distribution (3.5 points) 2. Nocturnal numbness (4 points) 3. Thenar musculature weakness/atrophy (5 points) 4. Positive Tinel sign (4 points) 5. Positive Phalen test (5 points) 6. Loss of 2-point discrimination (4.5 points)	A score of 12 points (46%)[9,14,20,30,36] A score of 18 points[36]
BCTQ[26]	It comprises 2 subscales: the symptom severity scale (11 questions) and the functional status scale (8 questions of hand function during daily activities)	Scores of 1.95 or greater[8] Scores of 3 or greater[31]
Bland questionnaire[4]	It has 2 sections: 1. Background information, including age, occupation, hand dominance, and diabetes, is recorded. There is an open question regarding the type of symptoms experienced by the patient 2. Questions 6-12 cover details of symptoms, including the location of paresthesia in the hand, nocturnal pain, relief of paresthesia by shaking the hand, relief by the use of a wrist splint, impairment of manual dexterity, and duration of symptoms	A score of 7 or greater[18] A cutoff probability of 0.5[4] A score of 40% or greater[5]
Lo clinical prediction rule[28]	Nine clinical variables are assessed and scored: 1. Sex 2. Duration of symptoms 3. Presence of wrist pain (negative predictor) 4. Presence of neck pain (negative predictor) 5. Nocturnal symptoms 6. Presence of thenar atrophy 7. Abductor pollicis brevis weakness 8. Median sensory symptoms 9. Pinprick sensation examination	A score of 10 or greater[36]
Wainner clinical prediction rule[35]	Five items are assessed and scored: 1. Shaking hand for symptom relief 2. Wrist ratio index 3. BCTQ symptom severity scale 4. Reduced median sensory field of digit 1 5. Age greater than 45 y	A score of 3 or greater[36]
Katz and Stirrat hand symptom diagram[23]	A self-administered hand symptom diagram that depicts both hands with dorsal and palmar views. Patients are asked to mark areas on the diagram corresponding to the location of their symptoms and to indicate the quality of their discomfort	Classic CTS: tingling, numbness, or decreased sensation with or without pain in at least 2 digits (1, 2, or 3); symptoms in the dorsa and palms of the hands excluded; fifth-finger symptoms, wrist pain, or radiation proximal to the wrist allowed Probable CTS: same as classic, except palmar symptoms are allowed unless confined solely to the ulnar aspect Possible CTS: tingling, numbness, and/or decreased sensation in at least 1 digit (1, 2, or 3) Unlikely CTS: no symptoms in digits 1, 2, or 3[23]
Kamath and Stothard questionnaire[20]	It has 9 questions about signs and symptoms of CTS, with "yes," "no," and "not applicable" response options	Scores greater than 6 and below 3[9] Score greater than 5[9,20,36]

Abbreviations: BCTQ, Boston Carpal Tunnel Questionnaire; CTS, carpal tunnel syndrome.

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the diagnostic criterion to rule in or rule out CTS. In practice, diagnosis is often a triangulation of a representative test from several of the 4 main categories, that is, provocative tests, sensorimotor tests, and the self-reported questionnaires of symptoms or clinician-based evaluations. Following is a discussion of the available scales, questionnaires, and hand symptoms/maps.

Scales and Questionnaires

The 2 tests most frequently studied were the CTS-6 and the Kamath and Stothard[20] diagnostic tests. The CTS-6 test comprises 6 criteria, as ranked by a Delphi consensus of expert clinicians.[17] Based on the results of 1 study with unclear risk of bias[14] (in only 1 domain), the CTS-6 has a strong ability to change the pretest probability of having CTS (+LR = 10.50 and −LR = 0.05). These findings are opposed by the findings of 2 other papers, which indicate that the CTS-6 has a small ability to change the pretest probability of having CTS.[30,36] We believe that more studies are needed to confirm the diagnostic accuracy of the CTS-6 test.

Kamath and Stothard[20] stated that they developed a questionnaire based on the previous work of Levine et al[26]; however, a clear description of this process is lacking.[20] Despite this shortcoming in validation, 1 low-quality paper[9] and 2 papers[6,20] with unclear ratings in only 1 domain have assessed the diagnostic accuracy properties of this tool. Originally, Kamath and Stothard[20] only included persons with a definite diagnosis of CTS (determined by carpal tunnel release surgery). Therefore, specificity, negative predictive values, and +LRs and −LRs could not be calculated.[20] Good diagnostic accuracy values have been reported in 2 studies[9,20] (sensitivity, 85%-87%; specificity, 87%). The +LR of 6.70 and −LR of 0.15 of the Kamath and Stothard[20] questionnaire from 1 study with high risk of bias[9] indicate that the Kamath and Stothard[20] questionnaire has moderate to good utility to change the pretest probability of having CTS. Further validation of the Kamath and Stothard[20] questionnaire might improve the diagnostic ability of this test.

The Boston Carpal Tunnel Questionnaire, a tool most frequently used as an outcome measure for CTS treatment, was assessed in 2 studies.[8,31] According to the LRs of these 2 studies, the Boston Carpal Tunnel Questionnaire had a small value in deciding whether to rule in or rule out CTS in the clinical setting. Clinicians should also be aware that the Boston Carpal Tunnel Questionnaire has different names across studies (eg, Levine's questionnaire[20]); however, all of these names refer to the same diagnostic test.[26]

The Bland questionnaire was evaluated in 3 studies, 2 with large samples[4,5] and 1 high-quality paper.[18] Compared to NCS as the reference standard, the Bland questionnaire had moderate sensitiv-

TABLE 2 Diagnostic Accuracy of Scales and Questionnaires for CTS Diagnosis

Study/Examination Tool	Sensitivity, %[a]	Specificity, %[a]	PPV, %[a]	NPV, %[a]	+LR	−LR
Bland[4]						
Bland questionnaire	79.1	55.6	69[b]	67[b]	2.66[b]	0.56[b]
Bland et al[6]						
Combined KSQ and CTS-7[c]	95.9	50	NR	NR	1.92[b]	0.08[b]
Bland et al[5]						
Bland web-based questionnaire	78	68	NR	NR	2.43[b]	0.32[b]
Bougea et al[8]						
Greek version of the BCTQ	75.5	68.3	NR	NR	2.38[b]	0.35[b]
Bridges et al[9]						
KSQ	87 (80, 94)	87 (80, 93)	NR	NR	6.70[b]	0.15[b]
Fowler et al[14]						
CTS-6	95 (86, 99)	91 (74, 99)	NR	NR	10.50	0.05
Hems et al[18]						
Bland questionnaire	82 (72, 90)	67 (41, 87)	91	48	2.48	0.26
Kamath and Stothard[20]						
KSQ	85	NR	90	NR	NR	NR
Lo et al[28]						
Lo clinical prediction rule	76	68	NR	NR	2.37[b]	0.35[b]
Makanji et al[30]						
CTS-6	87	60	89	55	2.17[b]	0.27[b]
Naranjo et al[31]						
BCTQ functional status scale	35.1	62.5	NR	NR	0.94	1.04
BCTQ symptom severity scale	48.6	60	NR	NR	1.22	0.86
Wang et al[36]						
CTS-6	56 (50, 62)	71 (62, 79)	83 (76, 88)	40 (33, 47)	1.93[b]	0.62[b]
KSQ	74 (68, 79)	64 (54, 72)	83 (78, 87)	50 (42, 58)	2.05[b]	0.41[b]
Lo clinical prediction rule	66 (59, 71)	56 (47, 65)	78 (72, 83)	40 (33, 48)	1.50[b]	0.78[b]
Wainner clinical prediction rule	70 (64, 75)	64 (54, 72)	82 (77, 87)	47 (39, 55)	1.94[b]	0.47[b]

Abbreviations: BCTQ, Boston Carpal Tunnel Questionnaire; CTS, carpal tunnel syndrome; CTS-6, 6-item carpal tunnel syndrome symptoms scale; CTS-7, 7-item carpal tunnel syndrome symptoms scale; KSQ, Kamath and Stothard questionnaire; −LR, negative likelihood ratio; +LR, positive likelihood ratio; NPV, negative predictive value; NR, not reported; PPV, positive predictive value.

[a] *Values in parentheses are confidence interval.*

[b] *Values calculated by the authors of this study.*

[c] *Only questionnaire segments were included for the analysis in the original study. The authors called this test the CTS-7; however, the rationale behind this naming is unclear, and they referenced the CTS-6 paper.*[17]

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ity and strong positive predictive values (82% and 91%, respectively)[18]; therefore, we suggest that it might be a good tool to rule in CTS, but that it is not very specific in ruling it out. The Bland questionnaire had +LRs ranging from 2.43 to 2.66 and –LRs ranging from 0.56 to 0.26. These findings indicate that the Bland questionnaire has a small ability to predict the pretest probability of having CTS.

Two clinical prediction rules (the Lo and Wainner rules), reported in the included studies by Lo et al[28] and Wang et al,[36] were used in the included articles. The reference standard of Wang et al[36] was not well defined, and the extracted information is at unclear risk of bias.[36] In addition, the Lo clinical prediction rule was assessed in a high-quality study, showing that only moderate sensitivity (76%) and specificity (68%) are predictable when electrodiagnostic studies serve as the reference standard.[28] According to the results of this systematic review, we do not recommend clinicians to use the Lo clinical prediction rule or the Wainner clinical prediction rule until future high-quality studies with larger sample sizes establish their diagnostic accuracy.

Hand Symptom Diagrams/Maps

Three different criteria for positive test interpretation were identified in the included studies. Six studies categorized people with suspected CTS into 4 groups of classic, probable, possible, and unlikely (**TABLE 1**), which is the original categorization method suggested by Katz and Stirrat in 1990.[23] This categorization resulted in the highest +LR and lowest –LR among all of the included studies.[23,24] Two studies interpreted people in classic or probable categories as having a positive, and those in possible or unlikely categories as having a negative, CTS diagnosis.[10,32] One study interpreted those with classic, probable, and possible results according to the diagram as having CTS, and those in the unlikely category as not having CTS; this categorization led to the small ability of this test to indicate CTS diagnosis.[7] Our results suggest that the Katz and Stirrat[23] hand symptom diagram is a valuable clinical tool for diagnosing CTS. We recommend clinicians to use the classic categorization method (classic, probable, possible, and unlikely CTS) for the most accurate results.

Clinical Implications

The CTS-6 and the Kamath and Stothard[20] questionnaire had the highest accuracy in diagnosing CTS. The Boston Carpal Tunnel Questionnaire and the Bland questionnaire had a small ability to change the pretest probability of having CTS. The evidence on diagnostic accuracy of the Lo clinical prediction rule and the Wainner clinical prediction rule was inadequate and inconclusive. The Katz and Stirrat[23] hand symptom diagram had the highest accuracy in diagnosing CTS when interpreted by the classical method of categorization: classic, probable, possible, and unlikely CTS.

TABLE 3 Diagnostic Accuracy of the Hand Symptom Diagrams/Maps for CTS Diagnosis

Study[a]	Sensitivity, %[b]	Specificity, %[b]	PPV, %[b]	NPV, %[b]	+LR	–LR
Ammer et al[2]	92.6	50	62.5	88.2	1.85[c]	0.15[c]
Bonauto et al[7]	61	58	52	67	1.42[c]	0.67[c]
Calfee et al[10]	38 (28, 50)	81 (73, 87)	54 (41, 67)	69 (61, 76)	1.63[c]	0.76[c]
Franzblau et al[15]	34	84	27	88	2.12[c]	0.78[c]
Katz and Stirrat[23]	80	90	NR	NR	8[c]	0.22[c]
Katz et al[24]	96	73	58	91	3.55[c]	0.05[c]
Katz et al[22]	61	71	59 (48, 68)	73 (66, 80)	2.10[c]	0.54[c]
O'Gradaigh and Merry[32]	92	40	92	14	1.53[c]	0.2[c]
Szabo et al[34]	76 (62, 89)	76 (52, 77)	36	95	3.17[c]	0.32[c]

Abbreviations: CTS, carpal tunnel syndrome; –LR, negative likelihood ratio; +LR, positive likelihood ratio; NPV, negative predictive value; NR, not reported; PPV, positive predictive value.
[a]*All studies used the Katz and Stirrat[23] hand symptom diagram.*
[b]*Values in parentheses are confidence interval.*
[c]*Values calculated by the authors of this study.*

Limitations

Studies had different interpretation criteria, samples, and reference standards, which made comparisons difficult and resulted in a heterogeneity of data that precluded meta-analysis. Three of the included diagnostic tests (the Boston Carpal Tunnel Questionnaire and the Lo and Wainner clinical prediction rules) were only examined in 1 or 2 studies, which limited our conclusions regarding the diagnostic accuracy of these tests. We might have missed studies, due to variations in the terminology of diagnostic tests. Although our search strategy was developed in consultation with a professional health sciences librarian, we cannot be certain that all of the eligible studies were included. There is a risk for potential publication bias, because we only included published literature.

Although some of the diagnostic scales and questionnaires seem promising, they are not supported by high-quality evidence. We recommend that future studies strictly adhere to established guidelines to produce results with low risk of bias and of high quality. There is also a need to compare the clinical triangulation process to electrodiagnosis or NCS.

CONCLUSION

The CTS-6 and the Kamath and Stothard[20] questionnaire had promising diagnostic accuracies for diagnosing CTS. More high-quality papers are necessary to confirm these findings. The Katz and Stirrat[23] hand symptom diagram yielded the most accurate results in

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predicting the pretest probability of having CTS, when used with the classic categorization method (classic, probable, possible, and unlikely CTS). More invasive diagnostic tools for CTS (ie, NCS) might only be necessary when there is concern regarding the certainty of clinical diagnoses.

KEY POINTS

FINDINGS: The 6-item carpal tunnel syndrome symptoms scale (CTS-6), Kamath and Stothard questionnaire, and Katz and Stirrat hand symptom diagram were most able to change the pretest probability of having carpal tunnel syndrome (CTS). We recommend a multifaceted strategy that combines several diagnostic tests (eg, the CTS-6 and the Katz and Stirrat hand symptom diagram) to confirm CTS diagnosis.

IMPLICATIONS: Although the evidence for the diagnostic accuracy of some of the scales and questionnaires is still inconclusive, we recommend that costly and invasive tests for CTS may only be needed when diagnostic scales, questionnaires, and hand symptom diagrams, as the first line of diagnosis, lack conclusiveness.

CAUTION: Our conclusions are mainly based on studies with moderate to high risk of bias and moderate concerns regarding applicability.

STUDY DETAILS

AUTHOR CONTRIBUTIONS: All authors made a substantial contribution to (1) the conception and design of the review, development of the search strategy, and analysis and interpretation of the data; and (2) drafting the article or revising it critically for important intellectual content. All authors assume public responsibility for the work.

DATA SHARING: All data relevant to the study are included in the article or within the online appendices.

PATIENT AND PUBLIC INVOLVEMENT: There was no patient or public involvement in this research.

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APPENDIX A

SEARCH STRATEGIES

Ovid (MEDLINE)

1. Carpal Tunnel Syndrome/
2. Carpal Tunnel Syndrome.mp.
3. Carpal Tunnel Syndrome/ or Nerve Compression Syndromes/ or Median Neuropathy/
4. Carpal Tunnel Syndrome/di [Diagnosis]
5. Median Neuropathy/di [Diagnosis]
6. median nerve entrapment*.mp. [mp = title, abstract, original title, name of substance word, subject heading word, floatingsubheading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
7. compression neuropathy.mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating subheading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
8. Nerve Compression Syndromes/
9. cts.mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating subheading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
10. syndrome, carpal tunnel.mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating subheading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12. diagnostic test*.mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating subheading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
13. clinical test*.mp.
14. diagnostic accuracy.mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating subheading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
15. "Sensitivity and Specificity"/
16. sensitivity.mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating subheading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
17. specificity.mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating subheading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
18. roc curve.mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating subheading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
19. 12 or 13 or 14 or 15 or 16 or 17 or 18
20. 11 and 19
21. ("Symptom diagram" or "hand diagram" or "Flick sign" or "Provocative Test*" or "Phalen's test" or "phalen test" or "wrist flexion test" or "wrist extension test" or "reverse Phalen test" or "carpal compression test" or "Durkan's test" or "Tinel's sign" or "Tourniquet test" or "Gilliat test" or "Sensory test*" or "Motor Test*" or "Touchor vibration threshold" or "Current perception threshold" or "Two-point discrimination Semmes-Weinstein Monofilament Test" or "Thenar weakness" or "Thumb Abduction Weakness" or "thenar atrophy" or "Abductor Pollicis Brevis Manual Muscle Testing" or "CTS-Relief Maneuver" or "CTS-RM" or "Pin Prick Sensory Deficit" or "ULNT Criterion C" or "upper limb neurodynamic test Tethered median nerve stress test" or "Luthy's sign" or "luthy sign" or "scratch collapse test" or "Pinwheel" or "CTS-6 evaluation tool" or "The Alderson-McGall hand function questionnaire" or "Hand elevation test" or "Katz and Stirrat hand diagram" or "katz hand diagram" or "Purdue Pegboard Test" or "Levine's Self-Assessment Questionnaire" or "Dellon-modified Moberg pick-up test" or "Self-administered diagram" or "web-based questionnaire" "Kamath and Stothard questionnaire" or "Lo Carpal Tunnel Questionnaire" or "scratch-collapse test" or "hyperextension test" or "Flinn Performance Screening Tool" or "FPST").mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating subheading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
22. 20 and 21

Ovid (Embase)

1. carpal tunnel syndrome.mp. [mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
2. median neuropath*.mp. [mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
3. median nerve entrapment*.mp. [mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
4. compression neuropath*.mp. [mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]

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APPENDIX A

5. entrapment neuropath*.mp. [mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
6. carpal canal syndrome.mp. [mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
7. carpal tunnel compression*.mp. [mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
8. "neuropathy, median".mp. [mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
9. "syndrome,carpal tunnel".mp. [mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
10. carpal tunnel syndrome/
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12. clinical test*.mp.
13. "sensitivity and specificity"/
14. receiver operating characteristic/
15. differential diagnosis.mp. [mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
16. "diagnostic test*".mp. [mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
17. ("sensitivity" or "specificity").mp. [mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
18. "ROC curve".mp. [mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
19. diagnostic accuracy/ or diagnostic test accuracy study/ or differential diagnosis/ or physical examination/
20. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21. 11 and 20
22. ("Symptom diagram" or "hand diagram" or "Flick sign" or "Provocative Test*" or "Phalen's test" or "phalen test" or "wrist flexion test" or "wrist extension test" or "reverse Phalen test" or "carpal compression test" or "Durkan's test" or "Tinel's sign" or "Tourniquet test" or "Gilliat test" or "Sensory test*" or "Motor Test*" or "Touchor vibration threshold" or "Current perception threshold" or "Two-point discrimination Semmes-Weinstein Monofilament Test" or "Thenar weakness" or "Thumb Abduction Weakness" or "thenar atrophy" or "Abductor Pollicis Brevis Manual Muscle Testing" or "CTS-Relief Maneuver" or "CTS-RM" or "Pin Prick Sensory Deficit" or "ULNT Criterion C" or "upper limb neurodynamic test Tethered median nerve stress test" or "Luthy's sign" or "luthy sign" or "scratch collapse test" or "Pinwheel" or "CTS-6 evaluation tool" or "The Alderson-McGall hand function questionnaire" or "Hand elevation test" or "Katz and Stirrat hand diagram" or "katz hand diagram" or "Purdue Pegboard Test" or "Levine's Self-Assessment Questionnaire" or "Dellon-modified Moberg pick-up test" or "Self-administered diagram" or "web-based questionnaire" or "scratch-collapse test" or "hyperextension test" or "Kamath and Stothard questionnaire" or "Lo Carpal Tunnel Questionnaire" or "Flinn Performance Screening Tool" or "FPST").mp. [mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
23. 21 and 22

CINAHL

S1. (MH "Carpal Tunnel Syndrome")
S2. "median neuropath*"
S3. "median nerve entrapment*"
S4. "compression neuropath*"
S5. "entrapment neuropath*"
S6. S1 OR S2 OR S3 OR S4 OR S5
S7. "diagnosis or assessment"
S8. "diagnosis"
S9. "diagnostic"
S10. (MH "Diagnosis") OR (MH "Diagnosis, Neurologic") OR (MH "Diagnosis, Musculoskeletal") OR (MH "Exercise Test") OR (MH "Functional Assessment") OR (MH "Patient Assessment") OR (MH "Patient History Taking") OR (MH "Physical Examination") OR (MH "Sensitivity and Specificity")
S11. (MH "Diagnosis, Musculoskeletal") OR (MH "Diagnosis, Neurologic") OR (MH "Functional Assessment") OR (MH "Patient Assessment") OR (MH "Patient History Taking") OR (MH "Physical Examination") OR (MH "Sensitivity and Specificity") OR (MH "Skin Tests")
S12. (MH "Sensitivity and Specificity") OR "sensitivity and specificity" OR (MH "ROC Curve")

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APPENDIX A

S13. "sensitivity"
S14. "specificity"
S15. S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14
S16. S6 AND S15
S17. "Symptom diagram" or "hand diagram" or "Flick sign" or "Provocative Test*" or "Phalen's test" or "phalen test" or "wrist flexion test" or "wrist extension test" or "reverse Phalen test" or "carpal compression test" or "Durkan's test" or "Tinel's sign" or "Tourniquet test" or "Gilliat test" or "Sensory test*" or "Motor Test*" or "Touch"or "vibration threshold" or "Current perception threshold" or "Two-point discrimination" "Semmes-Weinstein Monofilament Test" or "Thenar weakness" or "Thumb Abduction Weakness" or "thenar atrophy" or "Abductor Pollicis Brevis Manual Muscle Testing" or "CTS-Relief Maneuver" or "CTS-RM" or "Pin Prick Sensory Deficit" or "ULNT Criterion C" or "upper limb neurodynamic test" "Tethered median nerve stress test" or "Luthy's sign" or "luthy sign" or "scratch collapse test" or "Pinwheel" or "CTS-6 evaluation tool" or "The Alderson-McGall hand function questionnaire" or "Hand elevation test" or "Katz and Stirrat hand diagram" or "katz hand diagram" or "Purdue Peg-board Test" or "Levine's Self-Assessment Questionnaire" or "Dellon-modified Moberg pick-up test" or "Self-administered diagram" or "web-based questionnaire" or "Kamath and Stothard questionnaire" or "Lo Carpal Tunnel Questionnaire" or "scratch-collapse test" or "hyperextension test" or "Flinn Performance Screening Tool" or "FPST"
S18. S16 AND S17

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APPENDIX B

CONFLICTS OF INTEREST FOR INCLUDED STUDIES

Study	Conflict of Interest
Scales and questionnaires	
Bland[4]	No conflict of interest statement
Bland et al[6]	No conflict of interest statement
Bland et al[5]	No conflicts of interest
Bougea et al[8]	No conflicts of interest
Bridges et al[9]	No conflict of interest statement
Fowler et al[14]	There was no outside funding for this study
Hems et al[18]	No conflict of interest statement
Kamath and Stothard[20]	No conflicts of interest
Lo et al[28]	No conflict of interest statement
Makanji et al[30]	No conflicts of interest
Naranjo et al[31]	No conflict of interest statement
Wang et al[36]	No benefits in any form have been received or will be received related directly or indirectly to the subject of this article
Hand symptom diagrams/maps	
Ammer et al[2]	No conflict of interest statement
Bonauto et al[7]	None declared
Calfee et al[10]	No benefits in any form have been received or will be received related directly or indirectly to the subject of this article
Franzblau et al[15]	No conflict of interest statement
Katz and Stirrat[23]	No conflict of interest statement
Katz et al[24]	Grant support: National Institutes of Health grants AR36308 and AR07530 and the Kellogg Program for Training in Research in Clinical Effectiveness
Katz et al[22]	No conflict of interest statement
O'Gradaigh and Merry[32]	No conflict of interest statement
Szabo et al[34]	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

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APPENDIX C

CHARACTERISTICS OF THE STUDIES ASSESSING DIAGNOSTIC SCALES AND QUESTIONNAIRES FOR THE DIAGNOSIS OF CTS, AND THEIR REFERENCE STANDARDS

Study, Design, Country	Diagnostic Tool	Population Characteristics	Participant Inclusion and Exclusion Criteria	Index Test	Reference Standard Test	Risk of Bias
Bland[4] Prospective cross-sectional United Kingdom	Bland questionnaire	n = 7768 (5392 female) consecutive subjects; CTS cases, n = 3710 TP; age, 10-98 y; symptom duration: 0-3 mo, 5.6%; 3-6 mo, 17.8%; 6-12 mo, 18.0%; >12 mo, 46.1%	All patients with suspected CTS were referred for NCS No exclusion criteria were reported	A small selection of questions, all of which were arranged in multiple choice/checkbox, performed by the participants A cutoff probability of 0.5	NCS of median and ulnar orthodromic sensory conduction from finger to wrist and measures of the motor terminal latency to the APB recorded on both hands, supplemented by either a sensory potential recorded at the wrist on ring finger stimulation, performed by a neurologist Normal values were defined as those within 2.5 SDs of the mean	Unclear (2 domains)
Bland et al[6] Retrospective cross-sectional United Kingdom	Combined KSQ and CTS-7[a]	n = 5860 consecutive subjects; no more detail	Patients who sought medical attention with suspected CTS for the first time Excluded those with previous surgery to either side or recurrence after successful conservative treatment. Did not exclude patients with concomitant pathologies, such as diabetic polyneuropathy or ulnar neuropathy	The CTS-7 includes examination findings (Tinel's and/or Phalen's signs), and the authors aimed to study data that could be collected from the patient without medical intervention	NCS were carried out on both hands of all patients according to AANEM standards	Unclear (1 domain)
Bland et al[5] Prospective cross-sectional United Kingdom	Bland web-based questionnaire	n = 2655 consecutive subjects (67% female); age, 54.2 y; CTS cases, n = 1430 TP	Primary care physicians' referrals of suspected CTS patients Excluded those who already had known CTS prior to visiting the website, those having tests for follow-up purposes, or those who had already had treatment for one hand and were returning for management of the other. No exclusions were made on the grounds of age, sex, or coincident pathology	Patients were asked to visit http://www.carpal-tunnel.net prior to their appointment (takes 20-30 min) Cutoff point of website score of 40% was used to diagnose CTS	NCS according to guidelines published by the AANEM The NCS results were graded using the Canterbury severity scale for CTS, which represents the changes in sensory and motor NCVs and amplitudes as a numeric scale, increasing in severity from 0 (no abnormality) to 6 (extremely severe CTS)	Unclear (2 domains)
Bougea et al[8] Prospective cross-sectional Greece	Greek version of the BCTQ	n = 90 consecutive subjects (75% female); age, 57.3 ± 13.8 y; CTS severity: grade 1, 18.9%; grade 2, 6.7%; grade 3, 42.2%; grades 4-6, 12.2%	Patients referred to the electrophysiology laboratory with symptoms consistent with CTS Included: age, ≥18 y; first-time visitors not previously diagnosed by the investigators; absence of severe intellectual disability or cognitive impairment Excluded: polyneuropathy, systemic diseases potentially associated with polyneuropathy (diabetes mellitus, renal failure, hypothyroidism, or amyloidosis), other diseases that cause hand symptoms (eg, cervical radiculopathy or thoracic outlet syndrome), pregnancy	The overall FSS and SSS scores from the BCTQ were calculated Cutoff point: scores of ≥1.95	EMG based on the AANEM guidelines Used the Canterbury severity scale for CTS, which expresses the modifications of sensory and motor NCVs and amplitudes as a numeric scale for the EMG grading of severity, from 0 (no abnormality) to 6 (extremely severe CTS)	Unclear (2 domains)

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Study, Design, Country	Diagnostic Tool	Population Characteristics	Participant Inclusion and Exclusion Criteria	Index Test	Reference Standard Test	Risk of Bias
Bridges et al[9] Prospective cross-sectional United Kingdom	KSQ	n = 211 consecutive subjects (57% female); age, 52.7 ± 14.0 y	Patients who had been referred for electrophysiological testing with symptoms suggestive of CTS Excluded patients with diabetes	All patients attending a hand clinic routinely fill out the KSQ, which consists of 9 questions relating to possible symptoms of CTS, performed by a rheumatologist Cutoff point: scores of >6 and <3	NCS, performed by a single trained doctor who was also responsible for administering the questionnaire Positive test if: onset motor latency to the APB of >4.2 ms, peak sensory latency to index finger of >4.0 ms, a difference in onset motor latency between the APB and ipsilateral ADM of >1.5 ms, a difference in motor latencies between both APBs of >1.0 ms, or a reduction of median sensory amplitude of >50% of either the ipsilateral ulnar sensory latency or the contralateral median nerve	High
Fowler et al[14] Retrospective cross-sectional United Kingdom	CTS-6	n = 85 consecutive subjects; age, 55 y (range, 28-87 y); pre-exam CTS probability, 6%; CTS cases, n = 55 TP	A data set of patients referred to EDS from an orthopaedic hand surgery practice with a higher prevalence of CTS than that in the general population	The CTS-6 score was calculated by a blinded examiner who was not involved in US or NCS A score of 12 points was considered a positive CTS-6 score	The authors used latent class analysis (Bayesian methods) as their reference standard and compared the scores obtained from the CTS-6 to NCS and US. NCS was conducted according to AANEM guidelines. A DML of 4.2 ms and a DSL of 3.2 ms were used as the cutoffs for a positive diagnosis of CTS. The cross-sectional area of the median nerve was measured at the inlet to the carpal tunnel, using a 13- to 6-MHz linear array transducer, by a blinded hand surgeon. The a priori cutoff of 10 mm^2 was used as the cutoff for a positive US examination	Unclear (1 domain)
Hems et al[18] Prospective cross-sectional United Kingdom	Bland questionnaire	n = 152 consecutive subjects (108 female); symptom duration: >12 mo, n = 125; 6-12 mo, n = 20; 3-6 mo, n = 7	All patients referred to the hand clinic with suspected CTS during the period of the study were asked to consent to participation in the study and to complete the questionnaire	A questionnaire that has 2 parts, filled out by both the participants and clinicians Cutoff point: score of ≥7	NCS: they measured the latency of sensory conduction (positive if thumb to median nerve was 40.5 ms greater than thumb to radial/motor latency, or positive if median nerve to APB was >4.1 ms)	Low
Kamath and Stothard[20] Prospective cross-sectional United Kingdom	KSQ	n = 58 consecutive subjects with definite CTS diagnosis (67 female in the original population before exclusion criteria were applied)	Patients referred with a diagnosis of CTS to a hand clinic Included: definite diagnosis of CTS by a physician Excluded: a possible generalized neuropathy (eg, those with diabetes mellitus), renal transplant patients, pregnant patients	A questionnaire based on the BCTQ, filled out by a hand surgeon Cutoff point: score of >5 on the KSQ	CTR Positive criterion: symptom relief at 2 wk after surgery	Unclear (1 domain)

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Study, Design, Country	Diagnostic Tool	Population Characteristics	Participant Inclusion and Exclusion Criteria	Index Test	Reference Standard Test	Risk of Bias
Lo et al[28] Prospective cross-sectional Canada	Lo CPR	n = 278 consecutive subjects (58.8% female); age, 50 ± 12.7 y; CTS cases, n = 149 TP	Subjects referred to the electrodiagnostic laboratory over a 1-y period with a clinical suspicion of CTS	The subject's point score was determined by a physiatrist, based on the information and clinical findings obtained during history and physical examination	NCS by a blinded electrodiagnostic technologist; AANEM references Positive criteria: a combination of a median-to-ulnar transcarpal latency difference of 0.4 ms and median transcarpal latency of 2.2 ms	Low
Makanji et al[30] Prospective cross-sectional United States	CTS-6	n = 78 consecutive subjects (62% female); age, 55 ± 15 y; CTS severity: mild, n = 16; moderate, n = 46; severe, n = 16	Adult patients in the practice of 3 hand surgeons were prescribed electrophysiological testing and invited to participate Included: patients suspected to have CTS Excluded: prior CTR, injury to the wrist or hand, previous electrophysiological testing of the median nerve, and pregnancy	The instrument assigns varying weights to 6 symptoms and clinical maneuvers and determines the probability of having CTS using a logistic regression equation Cutoff point: score of 50%	NCS and EMG. The median nerve was stimulated at the wrist, and antidromic sensory action potentials were recorded 13 cm distally at the index finger for DSL studies. The median nerve motor action potential was recorded at the APB muscle and stimulated at the wrist 7 cm proximal to the electrodes for DML studies The presence of 1 or both of the following: DSL of ≥3.6 ms and/or DML of ≥4.4 ms based on AANEM	Unclear (3 domains)
Naranjo et al[31] Prospective cross-sectional Spain	BCTQ	n = 68 consecutive subjects (56 female), 105 wrists (54% bilateral); age, 47 ± 11 y; CTS cases, 80 TP wrists; CTS severity: mild, n = 13; moderate, n = 30; severe, n = 37; symptom duration, 21 mo (IQR, 8-36 mo)	Adult patients with suspected CTS referred to the outpatient rheumatology clinic Included: burning pain or numbness aggravated by sustained positions and relief by shaking or moving the hands, sleep disruption by symptoms, and daily complaints over at least a 3-mo period Excluded: surgery or traumatic injuries at the target wrist, hypothyroidism, acromegaly, polyneuropathy or radiculopathy, pregnancy, fibromyalgia, rheumatoid arthritis or crystal arthritis, had received injections or presented ganglions, tenosynovitis, or arthritis	The BCTQ has 2 components: a hand function scale and hand sensitivity (sensory). Filled out by a rheumatologist. Two different diagnostic accuracy measures were calculated for each component Cutoff point: score of >3	NCS, AANEM referenced Performed by 2 neurologists	Unclear (2 domains)
Wang et al[36] Prospective cross-sectional United States	CTS-6, KSQ, Lo CPR, Wainner CPR	n = 408 consecutive wrists of 250 subjects (181 female); wrists with definite CTS, n = 255; age, 52 ± 14 y	Patients were identified and recruited through an orthopaedic hand surgery clinic Included: patients who returned to the office after being previously referred for electrodiagnostic testing for the assessment of CTS Excluded: patients <18 y of age and unable to comprehend English or give consent	Questionnaires were filled out by a hand fellowship–trained surgeon Cutoff points of 18 on the CTS-6, 5 on the KSQ, 10 on the Lo CPR, and 3 on the Wainner CPR	Clinical diagnosis (no further explanations)	Unclear (3 domains)

Abbreviations: AANEM, American Association of Neuromuscular and Electrodiagnostic Medicine; ADM, abductor digitorum minimi; APB, abductor pollicis brevis; BCTQ, Boston Carpal Tunnel Questionnaire; CPR, clinical prediction rule; CTR, carpal tunnel release; CTS, carpal tunnel syndrome; CTS-6, 6-item carpal tunnel syndrome symptoms scale; CTS-7, 7-item carpal tunnel syndrome symptoms scale; DML, distal motor latency; DSL, distal sensory latency; EDS, electrodiagnostic studies; EMG, electromyography; FSS, functional status scale; IQR, interquartile range; KSQ, Kamath and Stothard questionnaire; NCS, nerve conduction studies; NCV, nerve conduction velocity; SSS, symptom severity scale; TP, true positive; US, ultrasound.

[a]*Only questionnaire segments were used in this study[6]; the authors called this test "CTS-7"; however, the rationale behind this naming is unclear, and they have referenced the CTS-6 paper.[17]*

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APPENDIX D

CHARACTERISTICS OF THE STUDIES ASSESSING SYMPTOM DIAGRAMS/ MAPS FOR THE DIAGNOSIS OF CTS, AND THEIR REFERENCE STANDARDS

Study,[a] Design, Country	Population Characteristics	Participant Inclusion and Exclusion Criteria	Index Test	Reference Standard Test	Risk of Bias
Ammer et al[2] Prospective cross-sectional Austria	n = 101 consecutive subjects (68 female; 147 wrists); age, 57.7 ± 15.8 y; wrists with classic, probable, or possible CTS, n = 120	Patients suspected to have CTS Asymptomatic hands and patients with normal NCV were excluded from the analysis	Patients were asked to mark pain, tingling, and numbness in the diagram	NCS. All tests were performed with an EMG system Normal values were: distal latency of motor fibers at a distance of 5.5 cm = 2.994 ms + 0.004 × age (SD, 0.392) and antidromic conduction velocity of sensory fibers: Vs = 71.99 m/s − 0.3 × age (SD, 4.86)	High
Bonauto et al[7] Prospective cross-sectional United States	n = 253 subjects with current hand symptoms and n = 179 subjects with numbness, tingling, or pain (48% female); age, 39.5 ± 10.9 y	Workers from 12 work sites in the manufacturing (electronics, automotive parts, windows, cabinets, medical and fitness equipment) and health care (hospitals, excluding direct patient care and health research) sectors Excluded: sudden shoulder injury, part-time workers, temporary workers, workers in a mobile job such as a forklift driver, or with more than 4 job tasks	Workers were asked to complete a body map describing the distribution of pain or discomfort in the neck, shoulder, elbow/forearm, and hand/wrist if they had problems in the past year that either lasted a week or more or had occurred at least 3 times. A classic/probable/possible diagram rating was considered "positive"	NCS, AANEM referenced, performed by nerve conduction technicians. Positive if at least 1 of the following findings present: median motor latency of 4.0 ms and/or median sensory latency of 3.7 ms	Unclear (1 domain)
Calfee et al[10] Prospective cross-sectional United States	n = 221 consecutive subjects (71% male; 216 with DSL analysis); age, 31.8 ± 10.6 y; positive CTS according to Katz scores, n = 59	CTS suspects: workers with hand symptoms from 11 companies or organizations Included: symptoms of burning, pain, tingling, or numbness Excluded: a history of CTS, peripheral neuropathy, current pregnancy, or inability to have nerve conduction testing	The instructions asked subjects to shade in the area of the problem but not to try to represent the type of their symptoms on the diagram Scoring was performed according to the recommendations of Katz and Stirrat,[23] with modification: scores were dichotomized as positive ("classic" or "probable") or negative ("possible" or "unlikely") The scoring of the diagrams was done by 2 physicians and 1 occupational therapist	NCS with an automated device. Positive if a DSL of >3.5 ms, a DML of >4.5 ms, or paired transcarpal median-ulnar sensory difference of >0.5 ms. Transcarpal DSL measurements were recorded in the long finger	Unclear (3 domains)
Franzblau et al[15] Prospective cross-sectional United States	n = 411 consecutive subjects (41.6% male); age, 35.7 ± 10.5 y; pre-exam CTS probability, 15%	At-risk workers from 4 unrelated companies Included: certain jobs were selected on the basis of the frequency of repetitive hand movements ("low," "medium," and "high"), and all workers with at least 6 mo of tenure in those jobs were invited to participate	Similar to the diagram and instructions used by Katz et al[22] Patients were instructed to shade in the distribution of numbness, tingling, burning, or pain in the wrists, hands, or fingers on the hand diagram	NCS performed by physicians certified in EDS medicine and median and ulnar sensory conduction studies in the wrists, using surface electrodes and fixed distances (14 cm, antidromic stimulation) Positive if a difference of at least 0.5 ms between median and ulnar sensory peak latencies in the same wrist	Unclear (2 domains)

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Study,[a] Design, Country	Population Characteristics	Participant Inclusion and Exclusion Criteria	Index Test	Reference Standard Test	Risk of Bias
Katz and Stirrat[23] Retrospective United States	n = 149 random subjects (73% female); wrists with definite CTS, n = 85; age, 45.6 ± 14 y	Patients with UE paresthesia Included: CTS diagnosis based on NCS, unequivocal response to corticosteroid injection in the carpal tunnel, and improvement after CTR Excluded: patients with presumptive diagnoses that were not confirmed by these criteria, diabetes, heavy ethanol use, hypothyroidism, rheumatoid arthritis, renal disease, ulnar entrapment, cartilaginous lesions, dorsal cutaneous nerve injury, C6-7 radiculopathy, symptomatic hamate fracture	Patients were asked to shade in the area of their discomfort on the diagram and indicate their quality of symptoms. Patients with CTS were categorized into 4 categories: classic, probable, possible, unlikely	Clinical diagnosis Diagnoses, comorbid conditions, and demographic data were abstracted from patients' charts without knowledge of their diagram ratings	High
Katz et al[24] Prospective cross-sectional United States	n = 110 consecutive subjects (145 wrists); age, 45.6 ± 14.4 y; CTS severity: classic, n = 18; probable, n = 16; possible, n = 17; unlikely, n = 2	Patients >18 y of age referred to a nerve conduction lab for evaluation of UE discomfort Control group diagnosis: cervical radiculopathy, ulnar neuropathy, brachial plexopathy, polyneuropathy	Patients were asked to complete a diagram before the NCS. Patients with CTS were categorized into 4 categories: classic, probable, possible, unlikely	NCS performed on an EMG apparatus, with skin temperature maintained at 34°C-37°C. Positive if at least 1 of the following findings present: motor latency >4.0 ms, sensory latency >3.7 ms, sensory velocity <50 m/s	Low
Katz et al[22] Prospective cross-sectional United States	n = 110 consecutive subjects (66.4% female; 165 wrists); wrists with definite CTS, n = 44; age, 45.6 ± 14.4 y	Patients >18 y of age suspected to have CTS were referred to a nerve conduction lab for evaluation of UE discomfort Control group diagnosis: cervical radiculopathy, ulnar neuropathy	Patients completed a self-administered hand pain diagram that depicted both hands with dorsal and palmar views. Patients were asked to mark areas on the diagram corresponding to the location of their symptoms and to indicate the quality of their discomfort. Patients with CTS were categorized into 4 categories: classic, probable, possible, unlikely	NCS. The protocol included bilateral median and ulnar sensory and motor testing and EMG recording from the APB on the most symptomatic hand. Testing was done with standard techniques on an EMG apparatus, with skin temperature maintained at 34°C-37°C Positive if patients had median motor latency >4.0 ms, sensory latency >3.7 ms, or sensory velocity <50 m/s. Performed by neurologist	Low
O'Gradaigh and Merry[32] Prospective cross-sectional United Kingdom	n = 105 consecutive subjects	Suspicion of CTS by the refereeing clinician on any grounds Excluded: previously treated for CTS or with recognized associated conditions	Patients outlined their symptomatic areas on the diagram Those with classic or probable distributions were considered positive	NCS. Sensory amplitude <10 μV or motor latency >3.7 ms	Unclear (2 domains)
Szabo et al[34] Prospective cross-sectional United States	n = 100 consecutive subjects; subjects with definite CTS, n = 50 (38 female; 87 wrists); subjects with other diagnoses of the UE, n = 50 (40 female; 90 hands); age (CTS), 20-73 y; age (non-CTS), 28-70 y; symptom duration, 2 mo to 20 y; pre-exam CTS probability, 15%	Patients who were evaluated and treated at an institution for hand, wrist, and forearm problems Included: a clinical history of numbness and tingling in the median nerve distribution and/or night pain relieved by shaking of the hand; results of physical examination, including sensibility and provocative examinations, consistent with CTS; and relief of symptoms after CTR Control group diagnosis: epicondylitis, De Quervain's tenosynovitis and other tendinosis, radiculopathy, and hand pain of unknown etiology	Subjects completed the hand diagram themselves; it was then scored blindly by one of the authors as classic, probable, possible, or unlikely for CTS, according to the criteria described by Katz and Stirrat[23]	NCS. Bilateral median and ulnar motor and sensory nerve conduction tests were the electrodiagnostic parameters considered. Testing was done with standard techniques, with the skin temperature maintained at 34°C-37°C	High

Abbreviations: AANEM, American Association of Neuromuscular and Electrodiagnostic Medicine; APB, abductor pollicis brevis; CTR, carpal tunnel release; CTS, carpal tunnel syndrome; DML, distal motor latency; DSL, distal sensory latency; EDS, electrodiagnostic studies; EMG, electromyography; NCS, nerve conduction studies; NCV, ; UE, upper extremity nerve conduction velocity.

[a]*All studies used the Katz and Stirrat[23] hand symptom diagram.*

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