Commentary

Consensus Criteria for the Classification of Carpal Tunnel Syndrome in Epidemiologic Studies

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ABSTRACT

Criteria for the classification of carpal tunnel syndrome for use in epidemiologic studies were developed by means of a consensus process. Twelve medical researchers with experience in conducting epidemiologic studies of carpal tunnel syndrome participated in the process. The group reached agreement on several conceptual issues. First, there is no perfect gold standard for carpal tunnel syndrome. The combination of electrodiagnostic study findings and symptom characteristics will provide the most accurate information for classification of carpal tunnel syndrome. Second, use of only electrodiagnostic study findings is not recommended. Finally, in the absence of electrodiagnostic studies, specific combinations of symptom characteristics and physical examination findings may be useful in some settings but are likely to result in greater misclassification of disease status. (*Am J Public Health*. 1998;88:1447–1451)

Carpal tunnel syndrome is a clinical disorder resulting from compression of the median nerve at the wrist.[1,2] The syndrome is common, with an estimated population lifetime cumulative incidence rate of 8%, and it can be associated with substantial disability.[3–5] The diagnosis of carpal tunnel syndrome can be made confidently in patients who present with the characteristic history, physical examination findings, and electrodiagnostic abnormalities, but confidence diminishes as the presentation deviates from these characteristic findings.

Current controversy surrounding occupational risk factors for carpal tunnel syndrome stems, in part, from debate regarding an acceptable case definition. Some studies have employed case definitions based on symptoms and physical exam criteria,[6,7] others have employed only electrodiagnostic study findings,[8] and still others have employed combinations of symptoms and physical examination findings with electrodiagnostic study findings.[9–12]

Case definitions with the greatest possible sensitivity and specificity are preferred for epidemiologic research as well as clinical applications. However, such "gold standard" case definitions often require procedures that are impractical for use in epidemiologic settings because they are costly, time consuming, uncomfortable, or result in undesirable complications. Case definitions with lower sensitivity or specificity than those of the gold standard may be useful for research when they are based on rapid, easy to administer, safe, and acceptable procedures. Whether such case definitions are sufficiently accurate for a particular epidemiologic study depends on the effect size to be observed, the sample size available for study, the prevalence of the disorder in the target population, and the specific purposes of the study. Therefore, no single "epidemiologic case definition" can be created; different case definitions are appropriate for different settings.

With these considerations, an ad hoc group of experienced research physicians met with a goal of defining and ranking consensus criteria for the classification of carpal tunnel syndrome in epidemiologic studies. The criteria are not intended for clinical diagnosis or for medical management.

Methods

The participants in the process (the authors of this report) were selected on the basis of their extensive experience conduct-

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ing epidemiologic, clinical, or outcome studies of carpal tunnel syndrome. Participants were also selected to span relevant medical specialties (e.g., epidemiology, hand surgery, internal medicine, neurology, occupational medicine, and rheumatology). The computerized bibliographic database of the National Library of Medicine and the authors' files were searched to identify relevant articles from the literature.

A modified nominal group process[13] was adopted to achieve the best possible consensus while acknowledging major differences of opinion. Prior to the first meeting, each participant prepared case definitions of different likelihoods of carpal tunnel syndrome (definite, probable, possible, unlikely). The first meeting identified areas of agreement regarding these case definitions and highlighted areas of disagreement. Results of this initial consensus underwent iterative modifications via electronic mail. A second meeting, followed by further iteratives via electronic mail, continued this process until consensus was achieved.

The guidelines to the participants were to identify and rank order by degree of confidence case definitions that would be (1) used for epidemiologic studies in various settings but not for clinical case diagnosis, (2) simple and practical, (3) recognizable by and defensible to practicing clinicians, and (4) evidence based.

Results

Based on published and clinical experience, the group reached agreement on the following conceptual issues:

1. There is no perfect gold standard for carpal tunnel syndrome. Although electrodiagnostic study findings are considered the most accurate single test, false negatives and positives are well documented.
2. The combination of electrodiagnostic study findings and symptom characteristics provides the most accurate carpal tunnel syndrome diagnosis. Physical examination findings add little diagnostic value if electrodiagnostic findings and symptom characteristics are available.
3. In the absence of electrodiagnostic findings, combinations of symptom characteristics and physical examination findings provide the greatest diagnostic information.

Two sets of case definitions are proposed. The first set (Table 1) requires both the assessment of symptoms and an appropriate electrodiagnostic study. The second set (Table 2), used when no electrodiagnostic study is available, involves symptoms and physical examination findings. Both sets require a symptom questionnaire instrument that is capable of classifying symptoms as "classic/probable," "possible," or "unlikely," as shown in Table 3.[14–16] Case definitions that include electrodiagnostic study findings are believed to have better specificity than case definitions that do not include electrodiagnostic study.

TABLE 1—Estimated likelihood of Carpal Tunnel Syndrome (CTS) for Case Definitions of CTS that Include Electrodiagnostic Studies (EDS)

Symptom	EDS	Ordinal Likelihood of CTS
Classic/probable	Positive	+++
Possible	Positive	++
Classic/probable	Negative	+/–[a]
Possible	Negative	–
Unlikely	Positive	–
Unlikely	Negative	– –

Note. The criteria also require symptom classification (see Table 3).
[a]No consensus achieved on whether likelihood should be – or +.

Within each set, the case definitions are rank ordered by estimated likelihood of disease or calculated positive predictive value (assuming a disease prevalence of 10%). For case definitions that include electrodiagnostic studies (Table 1), empirically derived sensitivities and specificities cannot be calculated, since in such studies electrodiagnostic findings are also used, alone or in combination with other findings, as the gold standard. Therefore, only a qualitative ranking can be provided for these definitions. The group consensus was, however, that the positive predictive value of an abnormal electrodiagnostic study and classic/probable symptoms is likely to be very high. For case definitions that do not include electrodiagnostic studies (Table 2), empirically determined sensitivities and specificities are provided on the basis of the gold standard case definition used by the investigator. As noted subsequently, the use of electrodiagnostic findings alone as the gold standard for testing other case definitions is problematic and may result in a lowering of the apparent test performances shown in Table 2. With a disease prevalence of 10%, negative predictive values are, by definition, in excess of 90% and are therefore not shown.

The likelihood of carpal tunnel syndrome was judged greatest for classic or probable symptoms in combination with positive electrodiagnostic study results (Table 1). When symptoms were "unlikely," the likelihood of carpal tunnel syndrome was judged to be low, regardless of the results of the electrodiagnostic study. Consensus could not be reached for subjects with classic or probable symptoms in combination with a negative electrodiagnostic findings.

Among the case definitions not including electrodiagnostic findings (Table 2), the greatest positive predictive value (0.44) was observed for the combination of classic/probable symptoms, a physical examination abnormality compatible with carpal tunnel syndrome, and nocturnal symptoms. The positive predictive value was poorest (0.16) for a positive physical examination result alone.

Characterization of Symptoms

No single best scheme has emerged for assessing symptom qualities. A recommended classification scheme, modified from Katz and colleagues[14,15] and Franzblau et al.,[16,17] is presented in Table 3. It requires documentation of symptom location and character (numbness, tingling, burning, or pain). Little information is available on the predictive value of symptom duration or frequency.

Electrodiagnostic Studies

The goal of the electrodiagnostic is to determine whether median nerve function is impaired at the wrist. There is currently no consensus regarding which electrodiagnostic study technique is best for detecting carpal tunnel syndrome.[18] We recommend the selection of one or more simple and acceptable measures in order to allow cross-study comparisons.[10,19–21] The most sensitive of these tests are the median sensory conduction measured over a short distance (8 cm) and techniques comparing median with ulnar or median with radial distal sensory conduction in the same hand.[22] The value of some types of electrodiagnostic studies has not been established (e.g., median motor residual latency, median F wave, sensory amplitude measurements). If population norms are used to interpret the electrodiagnostic study findings, investigators should determine whether the range of "normal" values used in their testing procedures was derived from a control population appropriate to the population

TABLE 2—Sensitivity, Specificity, and Positive Predictive Value (PPV) for Case Definitions of Carpal Tunnel Syndrome That Do Not Include Electrodiagnostic Studies

Criteria Evaluated in Workplace Studies	Sensitivity	Specificity	PPV
Classic/probable and PE and night symptoms[a]	0.07	0.99	0.44
Classic/probable and PE[a]	0.12	0.97	0.31
Classic/probable and night symptoms[a]	0.12	0.96	0.25
Classic/probable[a]	0.22	0.90	0.20
Possible[b]	0.34	0.84	0.19
PE[c]	0.41	0.76	0.16

Note. Electrodiagnostic study findings alone were used as the gold standard. See Table 3 for symptom classification. PPV was calculated assuming a disease prevalence of 0.10. PE = positive physical examination (Tinel's test, Phalen's test, 2-point discrimination, or carpal compression test).
[a]Data from 822 workers (Homan et al., unpublished data, 1998).
[b]Study of 408 workers.[16]
[c]Study of 130 workers.[17]

studied. Electrodiagnostic studies should be performed according to the current and future guidelines prepared by the American Academy of Neurology, the American Association of Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation.[22–24] Investigators must monitor and control for skin temperature and should also control for age, height, and other potential covariates when interpreting the results of electrodiagnostic studies or constructing models with electrodiagnostic study results as a dependent variable.[25,26]

Other Tests

Attempts have been made to develop quantitative measures for detecting carpal tunnel syndrome that are neither uncomfortable, like electrodiagnostic studies, nor purely subjective, like assessment of symptoms. One such measure, which initially produced encouraging results, is the cutaneous vibrotactile threshold (vibrometry). However, when evaluated in working populations or clinical populations that include a range of symptom severity (to avoid spectrum bias), simple vibrometry and other similar tests performed poorly.[20,21,27] One specific vibrometry testing technique has been shown, in 2 studies of clinical populations, to have a test performance similar to that of symptoms instruments combined with physical examination.[21,28] Although this test has a much greater positive predictive value (0.44) than simple vibrometry, it has not been tested in working populations.

Discussion

At present, the combination of a positive electrodiagnostic study and characteristic symptoms (classic or probable) appears to have the best predictive value as a case definition of carpal tunnel syndrome. Case definitions using combinations of symptom characteristics and physical examination findings alone are useful in some study settings but are likely to result in more misclassification of disease status, and thus they require larger study sample sizes than definitions using symptoms and electrodiagnostic findings. Factors affecting selection of a particular case definition include available resources, anticipated effect size, sample size, acceptance by study participants, and purpose of study (i.e., screening, etiologic investigation, etc.).

The electrodiagnostic study alone has been used as a gold standard for carpal tunnel syndrome because it is an "objective" test and because it presumably measures the underlying pathophysiologic process of the condition. In the hands of experienced electromyographers, intraexaminer and interexaminer reliability of measures of median nerve latency and velocity is high.[29,30] However, there are several problems with the use of electrodiagnostic findings as the sole classification criterion.

Carpal tunnel syndrome is, by definition, a clinical syndrome with a characteristic symptom complex and, in severe cases, clear physical examination findings. Case definitions based only on the electrodiagnostic study ignore these additional data that are likely to improve the accuracy of classification.

Studies of patients referred to electrodiagnostic centers estimate the specificity of electrodiagnostic study findings to be 90% or better.[3,31] In a population with a high prevalence of carpal tunnel syndrome (i.e., those referred to an electrodiagnostic center), the positive predictive value associated with this specificity may be acceptable. However, among healthy worker populations, for whom the prevalence of carpal tunnel syndrome is much lower, the false-positive rate will be considerably greater, and the positive predictive value will be reduced. Indeed, in a study of Japanese furniture makers, Nathan et al.[32] found that while nearly 18% had an abnormal electrodiagnostic study, only 2% had carpal tunnel syndrome by symptoms and electrodiagnostic findings. Similarly, in a study of 822 workers (M. M. Homan et al., unpublished data, 1998), 139 had an abnormal electrodiagnostic study (0.5-ms difference between median and ulnar latency), and 103 had carpal tunnel syndrome symptoms (classic or probable). Only 31 of the 139 workers with an abnormal electrodiagnostic study had symptoms of carpal tunnel syndrome. Thus, with the electrodiagnostic study alone, the prevalence of false positives (72/822) greatly exceeds the prevalence of true positives (31/822), yielding a positive predictive value of 33% (31/[31 + 72]). These findings are unlikely to be due to differences in electrodiagnostic techniques; the results of the Homan et al. study did not change when a more restrictive criterion for abnormal electrodiagnostic study was applied (0.8-ms difference). This high prevalence of abnormal electrodiagnostic studies in working populations has been observed by others.[8,33,34]

Furthermore, the natural history of this population of asymptomatic workers with abnormal electrodiagnostic findings was recently investigated, and it appears that they are not at increased risk for becoming symptomatic. In a prospective study, 75 asymptomatic active workers with an abnormal electrodiagnostic study were matched on age, sex, and work site with 75 asymptomatic workers with a normal electrodiagnostic study.[35] After a mean of 17 months of follow-up, there were no differences between groups in occurrence of hand symptoms consistent with carpal tunnel syndrome. Thus, an abnormal electrodiagnostic study in an asymptomatic worker is not predictive of future risk of carpal tunnel syndrome, at least in the short term.

Certainly, some patients with abnormal electrodiagnostic study results and no or trivial symptoms will have clinically demonstrable impairment of median nerve function and thus could be considered patients with silent carpal tunnel syndrome. This may occur in elderly persons who place low functional demands on their hands and have no complaints but who present with thenar atrophy and measurable loss of sensibility. It seems clear, though, from the examples cited, that there exists a significant subset of young, active patients whose electrodiagnostic findings fall outside the normal range but who do not have, and do not later develop, a clinical picture consistent with carpal tunnel

TABLE 3—Classification of Symptom Quality and Location for Use With Hand Diagrams or Focused Questions (Modified From Katz et al.[14,15] and Franzblau et al.[16])

Symptom	Description
Classic/probable	Numbness, tingling, burning, or pain in at least 2 of digits 1, 2, or 3. Palm pain, wrist pain, or radiation proximal to the wrist is allowed
Possible	Tingling, numbness, burning, or pain in at least 1 of digits 1, 2, or 3
Unlikely	No symptoms in digits 1, 2, and 3

syndrome. Given these findings, the absence of symptoms in combination with an abnormal electrodiagnostic study was judged to have poor positive predictive value and was so ranked in Table 1.

No consensus was reached on how to classify subjects with classic or probable symptoms and a normal electrodiagnostic study. In the clinical setting, there are case reports of symptomatic patients with a normal electrodiagnostic study who have responded to carpal tunnel release and, therefore, may have had true carpal tunnel syndrome.[31,36] In the earlier-mentioned study of Homan et al., 72 (70%) of the 103 workers who had classic or probable hand diagrams had a normal electrodiagnostic study. This category of workers is not small and deserves further study.

Current literature shows that the addition of provocative physical examination findings (Phalen's test, Tinel's test, carpal compression test, 2-point discrimination) yielded only modest gains in positive predictive value (0.02–0.11)—and, in some cases, even reduced this value—relative to classification based on symptoms alone.[17,19,37,38] These modest gains in positive predictive value must be considered in light of the loss of sensitivity, extra resources, and time required to collect such information. Likewise, other tests (single or multifrequency vibrometry, Neurometer [Neurotron Inc, Baltimore, Md], pinch grip, hand grip) provide no gain in positive predictive value relative to use of the symptom questionnaire alone.[20,27,39] The exception is vibrometry following 10 minutes of sustained wrist flexion.[21,28] Use of this promising method deserves further evaluation under field conditions in working populations. It has not been determined to what extent physical examination of the upper extremity proximal to the wrist may be useful in identifying other conditions that may also cause symptoms in the hands and, therefore, should be considered in a case definition.

Hand diagrams have been used in slightly different variations encompassing different combinations of symptoms and anatomic distributions of pain. Comparisons of "classic" and "probable" hand diagrams, as defined by Katz and colleagues[14,15] and Franzblau et al.,[16] demonstrate minimal differences in results. The rating system used in the Franzblau studies was essentially identical to that used in the Katz studies except for substitution of "burning" for "decreased sensation." Unfortunately, by using symptoms in combination with electrodiagnostic findings as the gold standard for carpal tunnel syndrome, the possibility of evaluating the independent role of symptom characteristics (e.g., quality, duration, frequency, and location) is limited as a result of the circularity of definitions. However, if symptom characteristics are evaluated with the electrodiagnostic study as the gold standard, the best positive predictive value obtained (assuming a carpal tunnel syndrome prevalence of 10%) using symptoms alone (classic and nocturnal symptoms) was 0.30. Because the electrodiagnostic study alone is not an ideal estimator of true carpal tunnel syndrome case status, this positive predictive value is probably an underestimate of the true value.

In addition to their ease of use, symptom reports are reproducible. One study evaluated the test–retest reliability of symptom reporting, at a spacing of 3 weeks, in 148 workers.[40] For the right hand, the constellation of numbness, tingling, burning or pain in the wrists, hands, or fingers had a kappa value of 0.81, representing an excellent test–retest reliability. For hand diagrams (classic, probable, possible, or unlikely), the test–retest reliability was somewhat lower but still good (weighted $\kappa = 0.52$). For nocturnal awakening, the test–retest reliability was excellent ($\kappa = 0.78$). Interobserver reliability for rating hand diagrams was excellent as well ($\kappa = 0.93$).[16]

There has been considerable concern that workers may provide inaccurate responses to self-report questionnaires, particularly recipients of workers' compensation who might have financial incentives to dissemble. In fact, this issue has been evaluated empirically in the research setting, and the results are reassuring. Katz et al.[41] have shown that self-reported measures of function and symptoms are equally reliable, valid, and responsive to change in workers whether or not these individuals are receiving workers' compensation. These findings are based on data collected in settings where confidentiality can be reasonably assured. In other settings where the employer has access to the same data (e.g., preplacement examinations, routine work-related medical examinations), it is likely that symptoms will be underreported, with a corresponding reduction in their reproducibility.

In conclusion, we have developed criteria for the classification of carpal tunnel syndrome in epidemiologic studies using a modified nominal group process. The criteria must be regarded as preliminary and should be validated in future studies. We encourage other investigators to participate in this validation effort by using these criteria either alone or in addition to other criteria, thereby allowing comparability of findings between studies. □

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