

A Prospective Comparison of Diagnostic Tools for the Diagnosis of Carpal Tunnel Syndrome

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Purpose Nerve conduction studies (NCS), CTS-6, Wainner, Kamath, and Lo are diagnostic tests that are used to diagnose carpal tunnel syndrome (CTS). To our knowledge, no study has compared the sensitivity and specificity of these 5 tests with one another. The purpose of this study is to compare NCS, CTS-6, Wainner, Kamath, and Lo using clinical diagnosis by a hand fellowship-trained orthopedic surgeon as reference standard.

Methods A hand fellowship-trained surgeon completed the CTS-6, Wainner, Kamath, and Lo diagnostic tools. Cutoff values for a positive test were based on values in the literature, if available. The NCS were performed by a certified electrodiagnostic physician according to the standards of the American Association of Neuromuscular and Electrodiagnostic Medicine and were interpreted using absolute latencies, relative latencies, and combined sensory index. Sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, and negative likelihood ratio were calculated for the tests using clinical diagnosis as the reference standard.

Results A total of 408 wrists from 250 patients were analyzed in the study. The NCS had the highest sensitivity (94%) but also the lowest specificity (50%) of any of the diagnostic tests. Using a cutoff of 18, CTS-6 had the highest specificity (99%). The NCS had the highest area under the curve at 74%, followed closely by the Kamath at 69%.

Conclusions The NCS were traditionally felt to be a strong confirmatory test given their high specificity. However, this prospective series demonstrated that NCS had the lowest specificity of any diagnostic test.

Clinical relevance Consideration should be given to using alternative diagnostic tests/tools based on the results of this study. (*J Hand Surg Am.* 2018;■(■):1.e1-e6. Copyright © 2018 by the American Society for Surgery of the Hand. All rights reserved.)

Key words Carpal tunnel syndrome, CTS-6, Kamath, Lo, Wainner.



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CARPAL TUNNEL SYNDROME (CTS) is a common musculoskeletal disorder, with an estimated prevalence of 6% in men and 9.2% in women.¹ The diagnosis of CTS is generally made through clinical history and physical examination findings. Symptoms include nocturnal paresthesias, numbness, tingling, and pain in the median nerve distribution, decreased grip strength, and thenar muscle atrophy. Although the diagnosis of CTS can be made on history and clinical findings, confirmation of CTS is commonly performed using nerve

conduction studies (NCS) to assess for median neuropathy.^{2,3} The American Academy of Orthopaedic Surgeons Clinical Practice Guidelines indicate that NCS and clinical evaluation using the CTS-6 diagnostic tool and/or Katz Hand diagrams are interchangeable.⁴

The CTS-6, Wainner, Kamath, and Lo are diagnostic tools that use common physical examination and history findings to estimate the probability of CTS (Appendix A; available on the *Journal's* Web site at www.jhandsurg.org). Individually, these tools have been shown to have potential to reasonably estimate the probability of CTS.^{5–7} There have been limited follow-up studies in the literature to test the reliability of these diagnostic questionnaires.^{8–11} Furthermore, there have been no studies in the literature that have directly compared these tools with one another. The purpose of this study is to compare the accuracy of the CTS-6, Wainner, Kamath, and Lo clinical diagnostic questionnaires in diagnosing CTS with clinical diagnosis by a hand fellowship–trained orthopedic surgeon (R.J.G. or J.R.F.) as reference standard.

METHODS

After institutional board review, patients were identified and recruited through an orthopedic hand surgery clinic. We enrolled patients who presented to our hospital orthopedic surgery clinic from October 2014 through March 2017. Our inclusion criteria included patients who returned to the office after being previously referred for electrodiagnostic testing for the assessment of CTS. Our exclusion criteria were patients younger than 18 years of age and the inability to comprehend English or give consent.

The sample size calculation was based on the following assumptions: 2-sided α of 0.05 and β of 0.20 (power of 80%), a predicted sensitivity and specificity of diagnostic tests ranging from 75% to 85%, and a difference in specificity and sensitivity of 20% being considered a clinically important difference. Tables from the study by Bujang and Adnan,¹² a study specifically examining power analyses for diagnostic tests, were utilized and a prevalence of CTS set at 10%. Based on these assumptions, 310 wrists were required with at least 31 having CTS.

A hand fellowship–trained surgeon (R.J.G. or J.R.F.) completed the CTS-6, Wainner, Kamath, and Lo diagnostic tools. The diagnostic questionnaires were completed with the patient during scheduled clinic visits by the treating surgeon. In general, absolute motor and/or sensory latencies, relative

sensory latencies, and the combined sensory index were used to make the diagnosis of CTS using NCS.¹³

Stepwise cutoffs for a positive test were used for the diagnostic tests without a specified cutoff value (Lo, Wainner, CTS-6). Lo was tested at a cutoff value of 10 and 20; CTS-6 tested at 12, 14, 16, and 18; and Wainner tested at 3 and 4. The Kamath has a suggested threshold of 5 or more to replace NCS as a screening tool.¹⁴ Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for each test using clinical diagnosis by a hand fellowship–trained orthopedic surgeon (R.J.G. or J.R.F.) as the reference standard.

RESULTS

A cohort consisting of 408 consecutive wrists from 250 patients consented to the study, of which 69 were men and 181 women. The sample consisted of 219 right wrists and 189 left wrists. The age range was 18 to 90 years, with a mean of 52 years (SD, 14). Diagnosis of CTS was made in 255 wrists (63%).

The NCS had the highest sensitivity (94%) and highest NPV (87%), but also the lowest specificity (50%) of any of the diagnostic tests (Table 1). Using a cutoff of 18, CTS-6 had the highest specificity (99%) and highest PPV (96%). The NCS (74%) had the highest area under the curve (AUC) (Table 2), followed closely by the Kamath (69%).

DISCUSSION

This study has found that commonly used diagnostic tests perform better than NCS when clinical diagnosis is used as the reference standard. The NCS had the lowest specificity of any of the diagnostic tools/tests, meaning it had the most false positives of the diagnostic tools/tests evaluated. This finding is in agreement with a growing body of literature, which has found a high rate of false-positive results for NCS.^{15,16} Proponents of NCS will diagnose these patients with “asymptomatic carpal tunnel syndrome.” However, a syndrome is, by definition, a constellation of signs and symptoms. If the patient does not have the signs and symptoms, then by definition, the patient does not have the syndrome in question.

The CTS-6 diagnostic tool, using a cutoff of 18, had a specificity of 99% and PPV of 96%. This makes sense because CTS-6 was originally designed to offer a probability of having a diagnosis of CTS. As the CTS-6 score increases, the probability of having a diagnosis of CTS increases. Based on the

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