Comparison of Ultrasound and Electrodiagnostic Testing for Diagnosis of Carpal Tunnel Syndrome

Study Using a Validated Clinical Tool as the Reference Standard

John R. Fowler, MD, Maria Munsch, BS, Rick Tost, MD, William C. Hagberg, MD, and Joseph E. Imbriglia, MD

Investigation performed at the Hand & UpperEx Center, Wexford, Pennsylvania

Background: Ultrasound examination is both accurate and cost-effective for the confirmation of a clinical diagnosis of carpal tunnel syndrome. Previous studies have shown electrodiagnostic testing and ultrasound to be similar with regard to sensitivity and specificity. The purpose of this study was to compare the sensitivity and specificity of ultrasound and electrodiagnostic testing by using a validated clinical diagnostic tool as the reference standard.

Methods: All consecutive patients referred to an upper-extremity practice for electrodiagnostic testing for any reason over a three-month period were recruited to participate in this study. All patients were evaluated with the use of the Carpal Tunnel Syndrome 6 (CTS-6) clinical diagnostic tool, and a score of ≥12 was considered positive for carpal tunnel syndrome. A positive finding on ultrasound was considered to be a cross-sectional area of the median nerve, measured just proximal to the level of the pisiform, of ≥10 mm². A positive finding on electrodiagnostic testing was a distal motor latency of ≥4.2 ms and/or a distal sensory latency of ≥3.2 ms. Sensitivity, specificity, and accuracy were calculated for ultrasound and electrodiagnostic testing with use of the CTS-6 as the reference standard.

Results: With use of the CTS-6 as the reference standard, ultrasound had a sensitivity of 89% and a specificity of 90% in our series of eighty-five patients. Electrodiagnostic testing had a sensitivity of 89% and a specificity of 80%. The positive predictive value of ultrasound was 94% compared with 89% for electrodiagnostic testing. The negative predictive value of ultrasound was 82% compared with 80% for electrodiagnostic testing. Ultrasound was accurate in seventy-six (89%) of the eighty-five cases whereas electrodiagnostic testing was accurate in seventy-three (86%) of the eighty-five cases (p = 0.5).

Conclusions: While ultrasound will not replace electrodiagnostic testing in complicated or unclear cases, in a select group of patients with a positive CTS-6, ultrasound can be used to confirm the diagnosis of carpal tunnel syndrome with better specificity and equal sensitivity as compared with those of electrodiagnostic testing.

Level of Evidence: Diagnostic Level I. See Instructions for Authors for a complete description of levels of evidence.

Carpal tunnel syndrome is the most common compression neuropathy of the upper extremity, with an estimated prevalence of 5% in the general population. Nearly four million patients are evaluated by a physician for carpal tunnel syndrome each year in the United States. Current guidelines recommend obtaining a confirmatory test for patients with a clinical diagnosis of carpal tunnel syndrome for whom surgical treatment is being considered. Electrodiagnostic testing is currently considered the gold standard for confirmation of a clinical diagnosis of carpal tunnel syndrome, but it is uncomfortable for patients, time-consuming, and potentially costly.

Ultrasound measurement of the cross-sectional area of the median nerve at the carpal tunnel inlet has been proposed as an alternative to electrodiagnostic testing for confirmation of

Disclosure: None of the authors received payments or services, either directly or indirectly (i.e., via his or her institution), from a third party in support of any aspect of this work. None of the authors, or their institution(s), have had any financial relationship, in the thirty-six months prior to submission of this work, with any entity in the biomedical arena that could be perceived to influence or have the potential to influence what is written in this work. Also, no author has had any other relationships, or has engaged in any other activities, that could be perceived to influence or have the potential to influence what is written in this work. The complete Disclosures of Potential Conflicts of Interest submitted by authors are always provided with the online version of the article.
carpal tunnel syndrome\textsuperscript{3,4}. A recent cost-effectiveness analysis showed ultrasound to be a cost-effective alternative to electrodiagnostic testing\textsuperscript{5}. In addition, although electrodiagnostic testing continues to demonstrate a significantly higher sensitivity and specificity compared with ultrasound, these differences are not likely of clinical relevance\textsuperscript{6}. Graham\textsuperscript{3} previously developed a validated clinical diagnostic tool, the Carpal Tunnel Syndrome 6 (CTS-6), which combines findings from the history and physical examination to predict the results of electrodiagnostic testing. Graham argued that, for patients with a positive CTS-6, the high pre-test probability makes electrodiagnostic testing unnecessary\textsuperscript{3}.

While we concede that electrodiagnostic testing remains the test of choice when the diagnosis is unclear or when there is a desire to grade the extent of nerve dysfunction, ultrasound may be an appropriate confirmatory test for patients who meet certain criteria, such as a positive CTS-6. This algorithm might improve the efficiency of diagnosis, decrease patient discomfort, and result in overall cost-savings for the health-care system\textsuperscript{7}. The purpose of this study is to compare sensitivity and specificity between ultrasound and electrodiagnostic testing by using a validated clinical diagnostic tool as the reference standard.

Materials and Methods

After institutional review board approval was obtained, all consecutive patients referred to an upper-extremity practice for electrodiagnostic testing, for any reason, over a three-month period were prospectively enrolled to participate in this study. Demographic information including age and sex were recorded. Clinical information including the involved extremity, presence of diabetes, and/or presence of peripheral neuropathy was also noted.

A certified electrodiagnostic technician blinded to the results of the CTS-6 and ultrasound examination performed all electrodiagnostic testing according to the standards of the American Association of Electrodiagnostic Medicine\textsuperscript{8}. The patient was seated in a comfortable chair across from the technician, with the arm supinated and the palm up. The skin temperature was kept above 32°C. All testing was performed with use of a Neuro Diagnostics Series 4.0 LBM machine (Philadelphia, Pennsylvania). Motor latencies were measured over a 5 to 6-cm segment, and sensory latencies were measured over a 12 to 13-cm segment. A distal motor latency of \( \geq 4.2 \) ms and/or a distal sensory latency of \( \geq 3.2 \) ms were considered positive for carpal tunnel syndrome.

A hand surgery fellowship-trained surgeon blinded to the results of the CTS-6 and electrodiagnostic testing performed all ultrasound examinations using a 13-6 MHz linear array transducer (SonoSite M Turbo; SonoSite, Bothell, Washington). The patient was seated at a table with the forearm supinated and the wrist in a neutral position. The fingers were positioned in a normal resting posture with mild flexion at the metacarpophalangeal and proximal interphalangeal joints. The ultrasound probe was positioned perpendicular to the long axis of the forearm, and the cross-sectional area of the median nerve was measured just proximal to the level of the pisiform. The electronic ellipse function was used as previous studies have shown this to be the most accurate method and level of measurement\textsuperscript{9,2,4,7,9}. The borders of the median nerve were defined as the area within the hyperechoic epineurium\textsuperscript{8}. Each measurement was performed three times, and the average value was recorded. On the basis of previous studies\textsuperscript{2,3,3}, we chose an a priori cross-sectional area of \( \geq 10 \text{ mm}^2 \) as indicating a positive result.

A hand and upper-extremity fellow not involved in the ultrasound or electrodiagnostic examinations was trained to independently examine the patients and to calculate and record the CTS-6 score. CTS-6 “represents a logistic regression model that estimates the probability of carpal tunnel syndrome on the basis of the presence or absence of six clinical findings” from the history and/or physical examination\textsuperscript{10}. The clinical findings are weighted on the basis of their diagnostic importance\textsuperscript{3}. The CTS-6 diagnostic tool (Table I) was completed for each patient on the basis of his/her history and physical examination. A score of \( \geq 12 \) on the CTS-6 was considered a positive diagnosis for carpal tunnel syndrome and \( < 12 \) was considered a negative diagnosis.

With use of the CTS-6 as the reference standard, true-positive, true-negative, false-negative, and false-positive results were recorded for each test for each patient. The sensitivity and specificity of electrodiagnostic testing and ultrasound were calculated with use of a 2×2 table. The accuracy of the ultrasound and electrodiagnostic testing was defined as the rate of agreement with the reference standard (CTS-6). Statistical comparison was performed by using a chi-square test on the raw data. A prior power analysis (power = 80%, alpha error = 5%, and clinically relevant difference = 10%) showed that approximately seventy-seven patients would be needed.

Source of Funding

There was no outside funding for this study.

Results

Eighty-five patients (fifty-four [64%] female) with an average age of fifty-six years (range, eighteen to eighty-six years) participated in the study (Table II). The CTS-6 validated diagnostic tool was positive for fifty-five (65%) of the eight-five patients, the ultrasound was positive for fifty-two (61%), and the electrodiagnostic testing was positive for fifty-five (65%).

\begin{table}[h]
\centering
\begin{tabular}{|c|c|}
\hline
\textbf{Finding} & \textbf{Points*} \\
\hline
Numbness predominantly or exclusively \textsuperscript{a} in median nerve distribution & 3.5 \\
Nocturnal symptoms & 4 \\
Thenar atrophy or weakness & 5 \\
Positive Phalen test & 5 \\
Loss of 2-point discrimination \((\geq 5 \text{ mm})\) & 4.5 \\
Positive Tinel sign & 4 \\
\hline
\end{tabular}
\caption{CTS-6\textsuperscript{5}}
\end{table}

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|}
\hline
 & \textbf{Positive} & \textbf{Negative} \\
 & CTS-6 & CTS-6 & \textbf{P Value} \\
\hline
No. of patients & 55 & 30 & \\
Mean age (yr) & 59 & 50 & 0.02 \\
No. (%) of men & 19 (35%) & 12 (40%) & 0.6 \\
CTS-6 score* & 15.8 ± 3.4 & 4.8 ± 4.4 & 0.0001 \\
Median-nerve cross-sectional area at carpal tunnel inlet* \text{(mm}^2\text{)} & 12.7 ± 3.8 & 7.9 ± 1.6 & 0.0001 \\
\hline
\end{tabular}
\caption{Demographic Data}
\end{table}

\textsuperscript{a}The corresponding point values for all positive findings are added together to obtain a total score. A score \( \geq 12 \) was defined as positive for carpal tunnel syndrome.

\textsuperscript{*}The values are given as the mean and standard deviation.
With use of the CTS-6 as the reference standard, ultrasound was accurate for seventy-six (89%) of the eighty-five patients whereas the electrodiagnostic testing was accurate for seventy-three (86%) (p = 0.5). The sensitivity and specificity values are reported in Table III. The ultrasound findings correlated with the electrodiagnostic testing findings in seventy-one (84%) of the eighty-five cases. Alternatively, if electrodiagnostic testing was considered the reference standard, ultrasound had a sensitivity and specificity of 85% (95% confidence interval [CI], 72% to 93%) and 83% (95% CI, 65% to 94%), respectively.

**Discussion**

Although ultrasound will not replace electrodiagnostic testing in all cases, in a select group of patients with a positive CTS-6, ultrasound can be used to confirm the diagnosis of carpal tunnel syndrome with better specificity and equal sensitivity as compared with those of electrodiagnostic testing. It is important to recognize that patients with a positive CTS-6 have what most physicians would consider “classic” carpal tunnel syndrome. In order to have enough (12) points to have a positive CTS-6, a patient must have three or four findings (depending on which findings and their point values). The CTS-6 includes findings such as nocturnal symptoms, numbness predominantly or exclusively in the median nerve distribution, a positive Phalen test, a Tinel sign at the wrist, thenar atrophy and/or weakness, and loss of two-point discrimination. It is possible that a patient with a positive CTS-6 does not have carpal tunnel syndrome but rather a different or additional diagnosis, such as cervical radiculopathy or peripheral neuropathy. We are not advocating that ultrasound be the only test used to confirm a clinical diagnosis of carpal tunnel syndrome in all situations. However, it can be an accurate and efficient tool in the correct clinical scenario for patients with a positive CTS-6 and no clinical signs of radiculopathy or polyneuropathy.

A major limitation of ultrasound is that it cannot be used to grade the severity of carpal tunnel syndrome. To date, there is no literature suggesting that the cross-sectional area of the median nerve on ultrasound correlates with the severity of carpal tunnel syndrome or that nerve recovery after carpal tunnel release correlates with changes in cross-sectional area.

A recent cost-effectiveness analysis demonstrated that ultrasound is a more cost-effective first-line diagnostic test when used by a hand surgeon and improved the accuracy of diagnosis when used in combination with electrodiagnostic testing by primary care physicians. Notably, this cost-effectiveness analysis assumed that patients were referred to a radiologist for the ultrasound examination and thus formal charges were incurred for the testing. However, the ultrasound examinations described in the current study can be performed in the course of daily office hours.

After a learning curve of approximately twenty patients, we were able to perform the ultrasound examinations in less than ninety seconds per patient. This could be reduced to less than thirty seconds if only one measurement is taken instead of three. Electrodiagnostic testing, even performed by an experienced technician, may require thirty minutes. Patient discomfort produced by electrodiagnostic testing is often overlooked. Repeated shocks, albeit minor, are uncomfortable and anxiety producing. Electromyography, although tolerable, remains painful. Ultrasound offers a painless alternative and also allows a teaching moment between the physician and patient, allowing the patient to see the relationship between the tendons and nerve within the carpal tunnel.

This study has several strengths. First, the blinded, prospective design offers a high level of evidence and reduces bias. Second, we used a validated clinical diagnostic tool (the CTS-6) as our reference standard. Third, the sample size was moderately large, which allowed narrowing of our 95% CIs. A limitation of the study, however, is the high-prevalence population that we evaluated as it likely resulted in an overestimation of the true sensitivity and specificity of the diagnostic tests (electrodiagnostic testing and ultrasound). Although the comparison between electrodiagnostic testing and ultrasound likely remains valid because the same sample population was used for both, the numbers are likely inflated. If the same study had been carried out in the general population, the performance of the tests would have likely been much worse. A more ideal situation would have been to recruit healthy volunteers from our hand and upper-extremity practice to serve as our negative controls. Instead, we recruited patients referred for electrodiagnostic testing for carpal tunnel symptoms as well as for other diagnoses, such as cubital tunnel syndrome, cervical radiculopathy, and pronator syndrome. We thought it unnecessary to subject healthy volunteers to the discomfort of electrodiagnostic testing. Using healthy controls would have likely decreased our overall sensitivity and specificity. Another potential limitation is the use of a noncertified ultrasound examiner. Ultrasound studies are criticized in part because of their reliance on the operator’s technique and experience, thereby rendering the findings vulnerable to bias. However, this was an important point of our study—i.e., that a noncertified examiner can also obtain excellent accuracy with a minimal learning curve. Our study was also underpowered, as our a priori power analysis used an expected difference of 10% between the sensitivity and specificity of electrodiagnostic testing and those of ultrasound. It is therefore possible that there is a significant difference between the two groups that was not
detected because of the small sample size. The difference, however, is not likely clinically relevant. Despite a general lack of utilization of ultrasound for the confirmation of a clinical diagnosis of carpal tunnel syndrome, there is a growing volume of literature in support of its use\textsuperscript{2,4,7-9}. The findings of the current study similarly demonstrate that ultrasound has a high sensitivity, specificity, and accuracy in a specific group of patients with a positive CTS-6.  

**Note:** The authors thank Jay Irrgang, PhD, for his statistical expertise in the design and analysis of this study.

John R. Fowler, MD  
Department of Orthopaedics,  
University of Pittsburgh,  
3471 Fifth Avenue, Suite 911, Pittsburgh, PA 15213.

Maria Munsch, BS  
William C. Hagberg, MD  
Joseph E. Imbriglia, MD  
Hand & UpperEx Center,  
6001 Stonewood Drive, Second Floor, Wexford, PA 15090.

Rick Tosti, MD  
Department of Orthopaedics, Temple University Hospital, 3401 North Broad Street, Philadelphia, PA 19140.

References


