Diagnostic Utility of Ultrasonography Versus Nerve Conduction Studies in Mild Carpal Tunnel Syndrome

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Objective. To prospectively compare high-resolution ultrasonography (US) and nerve conduction velocity (NCV) in clinically diagnosed mild carpal tunnel syndrome (CTS).

Methods. Eighty-five patients (70 women and 15 men, mean age 46.8 years) reported symptoms compatible with classic/probable CTS. The protocol included NCV of the median and ulnar nerves (distal motor latency [DML], sensory conduction velocity [SCV] from the third [M3 SCV] and fourth fingers [M4 SCV] to the wrist for the median nerve); electrophysiologic severity scale; self-administered Levine/Boston questionnaire (BQ); and cross-sectional area (CSA) measurement of the nerve at the tunnel inlet (CSA-I), at the middle (CSA-M), and at the outlet (CSA-O). Relationship between age, body mass index, duration of symptoms, CSAs, NCV, electrophysiologic severity scale, and BQ scores was calculated. Concordance between CSAs and NCV, sensitivity of NCV and US was also evaluated.

Results. The mean values of CSA-I, CSA-M, and CSA-O were 10.3, 9.8, and 8.7 mm², respectively. Relationships were found between CSA-I and M3 SCV (r = -0.45), M4 SCV (r = -0.56), and median nerve DML (r = 0.29). Anomalous CSA-I, CSA-M, and CSA-O were found in 48, 25, and 26 patients, respectively; 55 (64.7%) had \geq 1 abnormal CSA. NCV abnormalities were found in 67%. The sensitivity increased to 76.5% if US and NCV were considered together. The highest concordance to detect absence/presence of abnormalities was between CSA-I and NCV (77.6%; $\kappa = 0.52$).

Conclusion. In mild cases of CTS, US did not detect more anomalies than NCV and vice versa, and no anomalies were detected with either diagnostic instrument in 23.5% of mild cases.

INTRODUCTION

Carpal tunnel syndrome (CTS) is the most frequent entrapment mononeuropathy, due to the compression of the median nerve at the wrist. The clinical examination, consisting of history, physical examination, and provocative tests, has been considered sufficient for CTS diagnosis. In moderate and severe stages of CTS, when abduction and opposition of the thumb are weak, hypotrophy/atrophy of the thenar eminence and hypoesthesia in the hand territory supplied by the median nerve are evident, and common provocative tests are positive, clinical examination may be sufficient for CTS diagnosis. In contrast, in mild stages when clinical examination is normal, history and topographic distribution of the symptoms may be insufficient for CTS diagnosis. Moreover, the symptoms fre-

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quently extend to the area innervated by the ulnar nerve and more rarely to other areas of the upper limb (1,2). This problem is particularly evident in older patients who have more difficulty describing with precision their hand symptoms, because the symptoms may be confused or associated with those of other musculoskeletal disorders of the hand or upper limb such as osteoarthritis of the carpometacarpal joints (especially the first), metacarpophalangeal joints, and interphalangeal joints, flexor tenosynovitis, trigger finger, and elbow degenerative disease. Moreover, provocative clinical tests (Phalen's sign and Tinel's sign) have a low positive predictive value (3). In these mild or suspected CTS cases an instrumental confirmation of clinical diagnosis may be really helpful. The most reliable method to confirm clinical diagnosis of CTS is electrodiagnostic testing, but false negatives and false positives may occur, even when the most sensitive methods are used (4-6). Magnetic resonance imaging and ultrasonography (US) have been shown to be useful diagnostic tools in CTS, providing information on the median nerve and surrounding structures (7,8). In the last few years, many reports have appeared that agreed that US has high sensitivity and specificity in CTS diagnosis, but many of these articles considered the anomalous electrodiagnostic tests as the

gold standard for inclusion criteria. The goal of the present prospective study was 1) to calculate the sensitivity of nerve conduction velocity (NCV) study and US in a consecutive sample of patients with mild, clinically diagnosed CTS, and 2) to analyze the relationship between US and demographic, clinical, and NCV findings.

PATIENTS AND METHODS

A total of 101 consecutive patients (83 women and 18 men, mean \pm SD age 45.4 \pm 14.2 years, range 17–80 years) were clinically diagnosed with CTS for the first time at the EMG service of Local Health District no. 7 of Siena from March 2003 to February 2004. This EMG service admitted only unselected outpatients. The patients were referred by general practitioners or specialists because of upper limb symptoms.

The CTS diagnosis was made according to American Academy of Neurology criteria (9), which include clinical history and symptoms. According to the hand diagram by Katz et al modified by consensus criteria of the classification of CTS (10,11), only patients with paresthesia or pain in at least 2 of the first 3 fingers (classic/probable cases) were included in the study. Physical examination consisted of evaluating muscular strength and trophism, sensory function, and provocative clinical tests (Phalen's and Tinel's signs). For this study only patients with mild CTS were enrolled; mild cases were defined as those patients who reported only symptoms without objective motor deficit of thenar eminence muscles and normal objective sensory function in the median nerve territory of the hand. The mild cases belonged to stages 1 (nocturnal symptoms and morning symptoms on awakening) and 2 (diurnal symptoms) of a validated historical-objective clinical severity scale (12).

Care was also taken, with extension of neurophysiologic examination in some cases, to exclude patients with cervical radiculopathy, brachial plexopathy, and other upper limb mononeuropathies and polyneuropathies. Duration and bilaterality of symptoms, education (evaluated with a 5-point ordinal scale ranging from 1 to 5, where 1= no formal education, 2= 5 years of primary education, 3= 8 years of primary education, 4= secondary education, and 5= university degree), body mass index (BMI; kg/m²), work (blue collar, white collar, housewife, pensioner), manual hobby (for classification see reference 13), and associated pathologies (diabetes mellitus, connective tissue and thyroid diseases, renal failure, and recent trauma or fractures of the wrist or hand) were also recorded by the neurophysiologist before electrophysiologic study.

For subjective evaluation of symptoms, the Italian version of the self-administered Levine/Boston questionnaire (BQ) was completed by patients before any contact with the neurophysiologist. The BQ is divided into 2 parts. Part I (11 items) assesses severity of hand symptoms (BQ-SYMPT) and part II (8 items) assesses functional status of the hand (BQ-FUNCT). Five answers to each question are possible and are scored 1–5 according to severity of the symptom or difficulty carrying out a certain activity. Each score is calculated as the mean of the responses of the

individual item. Severe impairment is indicated by a high score (14,15).

NCV study included the measurement of motor conduction velocity (MCV), distal motor latency (DML) and compound muscle action potential amplitude (CMAP), sensory conduction velocity (SCV), and sensory nerve action potential amplitude (SNAP) of ulnar and median nerves. Values that differed by at least 2 SDs from the mean of the control group (26 healthy volunteers, mean ± SD age 47.6 ± 16 years, range 19-78 years) were considered abnormal for MCV, DML, and SCV. These median nerve values were 49.2 m/s for MCV (elbow-wrist tract), 4.4 msec for DML, 45.2 m/s for SCV in the third-finger segment, and 41.8 m/s for SCV in the fourth-finger segment (M4). When absolute values of SCV were normal in the digit-wrist segment, comparative and short segment studies were performed. For comparative study, a difference of >10 m/s between SCVs of the ulnar nerve in the fourth-finger wrist segment (U4) and M4 was considered significant. Short segment study consisted of measurement of median and ulnar nerve conduction in the 8-cm palm-to-wrist segment; a difference of >0.4 msec in median-ulnar palmar latency was considered significant. These methods, described in detail elsewhere (16), are in line with the guidelines of the American Association of Electrodiagnostic Medicine (AAEM) (17).

A validated CTS electrophysiologic severity scale, with scores from 0 to 5, was used for statistical analysis. This scale evaluates presence/absence of SNAP and CMAP and normal/abnormal SCV and DML as follows: 0 = normal SCV and DML, including short segment and comparative studies; 1 = normal digit-wrist segment SCV, with abnormal short segment study or abnormal U4-M4 SCV difference; 2 = slowing of the median digit-wrist segment SCV and normal DML; 3 = slowing of the digit-wrist segment SCV and abnormal DML; 4 = absence of SNAP in the digit-wrist segment and abnormal DML; and 5 = SNAP and CMAP absence (18).

High-resolution US was performed by the same rheumatologist, experienced in musculoskeletal US, at the rheumatology section of Siena University Hospital not more than a week after the electrophysiologic study. The operator was blinded to clinical and electrophysiologic CTS severity. A real-time scanner (Esaote Technos Mp; Esaote, Florence, Italy) with a 5-10-MHz linear array transducer was used. Patients were seated in a chair with arms extended, hands resting in a horizontal supine position on the examination couch, and fingers semiextended (19). We performed longitudinal and transverse scans of the median nerve from the distal segment of the forearm to the tunnel outlet. The median nerve cross-section area (CSA) was measured at 3 levels: at the tunnel inlet (just before the proximal margin of the flexor retinaculum), in the carpal canal (at the level of the scaphoid tubercle), and at the tunnel outlet (at the level of the hook of the hamate) (Figure 1). CSA measurements were performed at the inner border of the thin hyperechoic rim of the nerve (perineurium) using the manual tracing technique. The weight of the probe was applied without additional pressure. We considered CSA values >2 SDs of the mean of the control group (28

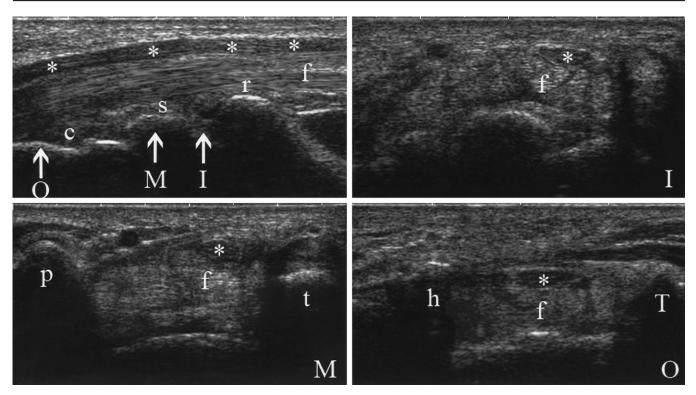


Figure 1. The top left photo shows a longitudinal scan of the median nerve; the **arrows** indicate the 3 levels where the median nerve was measured (I = tunnel inlet, M = in the middle, O = tunnel outlet). Photos marked with I, M, and O represent the aspect of the carpal tunnel and median nerve in a transverse scan at these levels. * = Median nerve; f = flexor digitorum tendons; r = radium; r = r

healthy volunteers, mean \pm SD age 46.9 \pm 13.8 years, range 28–76 years) to be abnormal. These abnormal values of CSA measurements of the nerve at the tunnel inlet (CSA-I), at the middle (CSA-M), and at the outlet (CSA-O) were 10.5 mm², 12.2 mm², and 10.1 mm², respectively. The intraobserver agreement was assessed during the US study in the control group and was very high (κ = 0.99), consequently only one measurement of CSA at each measurement site was performed in the patients.

Statistical analysis. Kruskal-Wallis test was used to evaluate differences in CSA-I, CSA-M, and CSA-O according to the electrophysiologic severity scale (4 samples, stages 0–3). Mann-Whitney U test was used to examine differences in CSAs between men and women and between the 2 stages of clinical severity (i.e., stage 1: only nocturnal symptoms, stage 2: nocturnal and diurnal symptoms; 2 samples). Chi-square tests were used to test differences in the presence/absence of abnormal CSAs and sex and clinical severity.

Relationships of CSA-I, CSA-M, and CSA-O with age, BMI, education, symptom duration, electrophysiologic severity scale, DML, and SCV of the median nerve were calculated with Spearman's coefficient. Sensitivity of US and NCV anomalies was calculated as the percentage of patients with anomalous CSA and abnormal NCV with respect to the control group. The agreement between NCV and US in showing presence/absence of anomalies was calculated with Cohen's κ coefficient.

RESULTS

Of 101 initially enrolled patients, 14 refused to undergo US and 2 others were excluded because they had a bifid median nerve. Therefore 85 patients were entered into this study (70 women and 15 men, mean \pm SD age 46.8 \pm 14 years, range 18-80). The median symptom duration was 12 months (range 2-360 months). Phalen's and Tinel's signs were positive in 63 (74.1%) and 40 (47.1%) patients, respectively, and at least 1 of these tests was positive in 76 (89.4%). One patient had type 2 diabetes, 1 had rheumatoid arthritis, 3 had hypothyroidism, and 2 had symptoms that began within 3 months after a wrist fracture. No patient had renal failure or other connective tissue diseases, or reported symptoms during pregnancy or lactation. Thirtynine patients had blue-collar jobs, 21 had white-collar jobs, 14 were housewives, and 11 were pensioners; 31 patients had manual hobbies. Symptoms were bilateral in 65 patients (76.5%) and were predominant in 1 hand in 58 (dominant hand in almost all cases); the remaining 7 patients considered the symptom intensity the same in both sides. To avoid overvaluation, only 1 hand was considered in bilaterally affected patients. The hand with the worst symptoms or the dominant hand, if there were no differences between the 2 hands, was selected (20).

The mean \pm SD values of CSA-I, CSA-M, and CSA-O were $10.3 \pm 2.3 \text{ mm}^2$, $9.8 \pm 2.1 \text{ mm}^2$, and $8.7 \pm 2 \text{ mm}^2$, respectively. There were 48, 25, and 26 patients with anomalous values (>2 SDs of the mean values of controls) of CSA-I, CSA-M, and CSA-O, respectively; 55 patients

	Electrophysiologic severity scale						
	All cases (n = 85)	Stage 0 (n = 28)	Stage 1 (n = 11)	Stage 2 (n = 37)	Stage 3 (n = 9)		
Age, years	46.8 ± 14	46.5 ± 14.4	47.3 ± 16	47.6 ± 13.6	46.9 ± 13.7		
BQ-SYMPT score	2.7 ± 0.8	2.79 ± 0.7	2.88 ± 0.9	2.59 ± 0.7	2.61 ± 0.9		
BQ-FUNCT score	1.97 ± 0.7	2.03 ± 0.6	2.16 ± 0.7	1.81 ± 0.7	2.26 ± 0.9		
CSA-I, mm ² †	10.34 ± 2.3	8.77 ± 1.7	10.88 ± 1.5	11.2 ± 2.3	11.06 ± 2.3		
CSA-M, mm ²	9.8 ± 2.1	9.13 ± 1.5	10.2 ± 2.2	9.97 ± 2.5	10.71 ± 1.9		
CSA-O, mm ²	8.7 ± 2.0	8.2 ± 1.4	8.3 ± 1.8	8.91 ± 2.4	9.94 ± 1.7		

^{*} BQ = Levine/Boston questionnaire; CSA = cross-sectional area; BQ-SYMPT = BQ symptoms scale; BQ-FUNCT = BQ function scale; CSA-I = CSA measurement of the nerve at the middle; CSA-O = CSA measurement of the nerve at the nerve at the middle; CSA-O = CSA measurement of the nerve at the middle; CSA-O = CSA measurement of the nerve at the middle; CSA-O = CSA measurement of the nerve at the nerve

had at least 1 abnormal CSA. There were 23 (27.1%), 19 (22.4%), and 13 (15.3%) patients with 1, 2, or 3 anomalous CSAs, respectively. No patients showed mass-occupying space in the canal.

NCVs were anomalous in 57 patients; of these, 11 belonged to stage 1 of the electrophysiologic severity scale, 37 to stage 2, and 9 to stage 3. Eight patients had normal NCVs with abnormal US and 10 had normal US with abnormal NCVs.

Therefore the sensitivities of CSA-I, CSA-M, CSA-O, overall CSAs (i.e., at least 1 abnormal CSA), and NCV to detect mild clinically diagnosed CTS were 56.7%, 29.4%, 31%, 64.7%, and 67.1%, respectively. However, the sensitivity increased to 76.5% if US and NCV abnormalities were considered together, because at least 1 of the CSAs or NCV was abnormal in 65 of 85 patients.

Table 1 shows the mean ± SD CSAs, BQ-SYMPT, and BQ-FUNCT scores; mean ± SD age (for all patients and divided according to electrophysiologic stage); and the statistical differences between electrophysiologic stages using Kruskal-Wallis test. Only CSA-I values were significantly different in various stages of the electrophysiologic severity scale.

The relationships between CSAs, age, and NCV are reported in Table 2. There were relationships between CSAs and all NCV findings; CSA-I demonstrated the highest correlation coefficient. There were also relationships between the number of abnormal CSAs and the electrophysiologic severity scale (r = 0.41, P < 0.001). No relationship

was observed between CSAs and age, BMI, education, symptom duration, and BQ scores. There were no differences in CSAs in relation to sex and clinical severity (stages 1 and 2 of the historical-objective severity scale).

Table 3 shows the concordance between the presence/absence of abnormal CSAs and the presence/absence of abnormal NCV and Cohen's κ coefficients. The only acceptable concordance was between CSA-I and NCV (77.6%; Cohen's κ coefficient = 0.52). The concordance between CSA-I and CSA-M was 63.5% (κ = 0.32), between CSA-I and CSA-O was 61.2% (κ = 0.28), and between CSA-M and CSA-O was 72.7% (κ = 0.41).

DISCUSSION

A PubMed search identified 25 publications containing information on use of US in the diagnosis of CTS; detailed findings are summarized in Table 4. The table shows a very variegated picture of inclusion criteria of CTS cases, US, NCV, statistical methods, and outcome results, making a comparison difficult.

US is useful in CTS diagnosis, providing anatomic images of the median nerve, neighboring structures, and mass-occupying space in the carpal canal. US has a low cost, short duration, and availability; is painless and non-invasive; and may offer dynamic images. US is operator dependent, but shows high reproducibility after adequate training of the operators (7).

Table 2. Spearman's correlation coefficient (r) and 2-code statistical significance*										
	Age	BQ-SYMPT	BQ-FUNCT	Electrophysiologic scale	DML	M3 SCV	M4 SCV	CSA-I	CSA-M	CSA-O
CSA-I	0.16 (NS)	-0.14 (NS)	0.15 (NS)	0.46†	0.29‡	-0.45†	-0.56†		0.52†	0.47†
CSA-M	0.11 (NS)	-0.14 (NS)	-0.06 (NS)	0.25§	0.3‡	-0.25§	-0.24§	0.52 †		0.52†
CSA-O	0.08 (NS)	-0.15 (NS)	-0.09 (NS)	0.26§	0.26§	-0.22§	-0.21 (NS)	0.47 †	0.52 †	
Electrophysiologic scale	0.07 (NS)	-0.12 (NS)	-0.09 (NS)		0.62†	-0.76†	-0.81†	0.46†	0.25§	0.26§

^{*} There were no relationships between CSAs and duration of symptoms, body mass index, and education (data not shown in this table). DML = distal motor latency; M3 = third finger; M4 = fourth finger; SCV = sensory conduction velocity; M3 = not significant; see Table 1 for additional definitions. P < 0.001.

[†] Significant differences between electrophysiologic severity stages.

 $[\]ddagger P < 0.01.$

[§] P < 0.05.

Table 3. Number of cases and percentage of concordance between presence/absence of abnormal CSAs and presence/absence of abnormal NCV*							
	CSA and NCV both normal	CSA and NCV both abnormal	Concordance, no. (%)	Cohen's κ coefficient			
CSA-I CSA-M CSA-O Overall CSAs	23 25 22 20	43 22 20 47	66 (77.6) 47 (55.3) 42 (49.4) 67 (78.8)	0.53 0.22 0.11 0.53			

* Values are the number unless otherwise indicated. NCV = nerve conduction velocity; see Table 1 for

The US measurement used in CTS diagnosis is the CSA of the nerve at various levels of the carpal canal, the flattening ratio, the swelling ratio, and the increased palmar bowing of the flexor retinaculum. In some studies CSA was performed at a single level (21–27), mostly at the proximal carpal tunnel. In several studies CSA was measured by ellipsoid formula (21,27–31), but a more accurate measure is obtained by using continuous boundary trace of the nerve, because the nerve does not always have a perfect ellipsoid shape (Figure 2). However, some studies demonstrated that similar results are obtained by both methods (21,24,25,32).

additional definitions.

The sensitivity and specificity of US measures vary widely among studies. Many authors demonstrated that the increase in CSA at the tunnel inlet had the highest sensitivity and specificity (21,22,26,27,33,34); moreover, the measurement at this level was easier to perform. There was also disagreement about the exact localization of tunnel inlet. Most authors considered the proximal edge of the flexor retinaculum, approximately at the level of the distal radioulnar joint, as the tunnel inlet, while others considered the pisiform bone and tubercle of the navicular bone as the landmarks (35). The sensitivity of the CSAs ranged from 48% to 89% (18,21,22,24,26-31,33,34,36-41) and the CSA cutoff at which the value was considered abnormal varied from 9 mm² (21,34,38) to 15 mm² (29). Sensitivities of increased palmar bowing of the flexor retinaculum varied from 40% to 81% (27,28,30,31,38), and sensitivities of flattening ratio ranged from 37% to 100% (21,24,27,28,42).

These discrepancies result from many factors: selection criteria of patients and controls, gold standard for diagnosis of CTS, electrodiagnostic methods, levels of CSA measurement, and US cutoff values. Because there was no agreement between various US studies, consensus criteria for standardization in US measurement techniques are required; only in this way can future studies be comparable. A bias of the results may also be due to incorrect selection of the control group. For example, sometimes the asymptomatic wrist of CTS cases was included in the control group (24,30).

In almost all studies the gold standard of CTS diagnosis was based on clinical and abnormal electrodiagnostic tests, and sometimes the most sensitive tests, such as short segment study or comparative test of median-ulnar distal sensory latency, were not performed. In contrast, only a few studies used clinical findings only as the gold standard (22,23,25,38,39). Only this type of study is able to

compare US specificity and sensitivity with those of the electrodiagnostic tests. The few literature data reported different results on NCV specificity (22,37,39,43). In particular, Swen et al (22) reported a very low NCV specificity (19%). They used as the gold standard patients with \geq 90% relief of symptoms after surgery (22) and received many criticisms on their selection criteria of CTS cases (44,45).

In our study, the CTS gold standard was based only on symptoms and we preferred to enroll only mild cases, which were those with classic symptoms and normal neurologic examination, because in these cases instrumental confirmation of clinical diagnosis may be very useful. In the literature, only the study by Altinok et al (38) took into account mild-moderate cases. These authors defined mild cases as wrists with normal NCV and moderate cases as wrists with abnormal NCV, and demonstrated that abnormal US findings were present in 30% of 20 mild cases and in 100% of 20 moderate cases (38). Moreover, Koyuncuoglu et al (25) studied 59 wrists with negative electrodiagnostic tests and showed that CSA-I was abnormal (>10.5 mm²) in 30.5% of wrists with clinically diagnosed CTS.

Concerning grading of CTS, the diagnostic certainty of symptoms in our cases was in the classic/probable categories; possible cases were excluded (11). In our sample, at least 1 of Tinel's and Phalen's tests was positive in 89.4% of patients, but the real utility of provocative clinical tests is uncertain, as they have demonstrated low predictivity (3.46).

In accordance with AAEM electrodiagnostic protocol, when standard methods did not show any conduction anomalies of the median nerve, comparative tests (ulnar/ median distal SCV comparison) or short segment conduction velocity was used. These tests have high sensitivity and high specificity (17). However, some authors consider NCV an "unnecessary luxury" or useless (47,48), and for others NCV causes discomfort and is considered expensive and time consuming (26). We disagree that NCV is time consuming and uncomfortable, because an expert electromyographer can perform NCV for CTS according to AAEM protocol in ~20 minutes, using surface electrodes and small current intensity. Needle electromyography is rarely necessary. Besides DML and SCV of the median nerve, we also used a validated progressive severity scale (18). This scale assigns stages in a nonarbitrary manner based on normality/abnormality of SCV and DML as well as presence/absence of SNAP and CMAP. Thus laboratories can use their own normal reference values, making this scale a valuable tool for comparing electrophysiologic results

Author	CTS gold	VAIniate / 1	US measures/	IIClt	US/NCV	US/NCV
(ref.)	standard	Wrists/patients	statistics	US results	sensitivity, %	specificity, %
Bayrak (32)	Clinical + NCV	41/27	CSA-It, CSA-M, and CSA-O (direct and indirect method); FR, PD. Correlation with NCV.	CSA-I, CSA-M, CSA-O, FR related with electrophysiologic severity scale, CSA-I, CSA-M related with MUNE.		
Hammer (35)	Clinical + NCV	21/12 (all with arthritis)	CSA-I‡ (direct method) differences vs. controls.	CSA-I means differed from control means. Only 1 patient had CSA lower than the highest values of the controls.		
Mallouhi (27)	Clinical + NCV	206/151 (retro- spective study) of whom 171 of 127 affected by CTS	CSA (direct method; within or proximal to carpal tunnel), FR, PD, CDS. Stepwise logistic regression.	CSA >11 mm² predicts CTS.	CSA 91, FR 60, PD 65, CDS 95	CSA 47, FR 76, PD 68, CDS 71
Wiesler (26)	Clinical + NCV + symptomatic relief after surgery	44/26	CSA (direct method) at pisiform bone. Difference vs. controls. Relationship with NGV.	Statistical differences vs. controls. Correlations with NCV. CSA cutoff 11 mm ² .	CSA 91	CSA 84
Ziswiler (41)	Clinical + NCV	101/71 (78 NCV+, 23 NCV-)		For cutoff CSA 9 mm². For cutoff CSA 10 mm². For cutoff CSA 11 mm². Correlation DML/SCV/ CSA.	CSA 9 mm ² 86, CSA 10 mm ² 82, CSA 11 mm ² 54	CSA 9 mm ² 70, CSA 10 mm ² 87, CSA 11 mm ² 96
Keles (31)	Clinical + NCV	35/25	CSA-It, CSA-M, and CSA-O (indirect method); FR, PD. Differences vs. controls, ROC curve.	Statistical differences vs. controls. Optimal cutoff: CSA-M 9.3 mm² and PD 3.7. FR: no optimum cutoff.	CSA-I 80, CSA-M 80, CSA-O 83, PD 71.4	CSA-I 72.5, CSA-M 77.5, CSA-O 70, PD 55
Kotevoglu (40)	Clinical + NCV	44/24	CSA-1+, CSA-M, and CSA-O (method not indicated); FR, PD differences vs. controls. Relationship with clinical test.	Statistical differences for CSAs, PD vs. controls. US correlated with clinical tests.	US (at least 1 pathologic measure) 89	US 100
Koyuncuoglu (25)	Clinical (enrolled patient with normal NCV)	59/43	CSA-I‡ (direct and indirect method), cutoff >10.5 mm². Differences vs. controls. Relationship with SCV.	Significant differences of CSA and SCV vs. controls. No relationship CSA/SCV. CSA-I (direct and indirect method) abnormal in 30.5% and 27.1% of CTS with NCV—.		
Lee (49)	Clinical + NCV + BQ + surgery	96/48	CSA-I+, CSA-M, and CSA-O (direct method); PD. Relationship with NCV and BQ.	CSA-I correlated with CMAP/SCV/SNAP. CSA-O correlated with BQ-SYMP and BQ- FUNCT.		
Yesildag (24)	Clinical + NCV	148/86	CSA-1‡ (direct and indirect method), FR. Differences vs. controls. Relationship with NCV. ROC curve.	Statistical differences vs. controls. No relationship with SCV and DML. CSA-1‡ cutoff 10.5 mm². FR cutoff >3.	CSA-I‡ (direct method) 89.9, CSA-I‡ (indirect method) 86.5, FR 37.2	CSA-I‡ (direct method) 94.7, CSA-I‡ (indirect method) 93.4, FF 85.5
Wong (34)	Clinical + NCV	195/120	CSA proximal to tunnel, CSA-It, CSA-O (direct method). Optimal threshold level.	Right CSA-prox cutoff 9, CSA-O 12 mm², CSA-I was not predictor. Left CSA-prox cutoff 10.	Right CSA 94, left CSA 83	Right CSA 65, left CSA 73
El Miedany (39)	Clinical	96/78	CSA-I (method not indicated), CSA-O (direct method), FR, thickness of ligament at middle carpal canal. Differences vs. controls. Relationship with BQ and electrophysiologic	CSA-I >10.03 mm ² . Significant differences of all US measures vs. controls. Correlation of CSA-I with electrophysiologic scale and BQ. Correlation of CSA-I and thickness of ligament.	CSA-I >10 mm ² 97.9, NCV 94	CSA-I >10 mm ² 100

eonard (23) Eele (37) Jakamichi (36,43)	Clinical only mild/moderate cases (excluded patients with atrophy or requiring surgery) Clinical (NCV not performed) + relief after surgery Clinical	40/26: 20 mild wrists (normal NCV) and 20 moderate wrists (abnormal NCV) 20/20, then 1 excluded because ganglion 110/77	CSA-It, CSA-M, and CSA-O (direct method); FR, SR, PD. Differences vs. controls. CSA-It (method not indicated), FR, PD. Differences vs. controls. Multiple logistic regression to combine the 3 US measures. QC, CSA-It, CSA-prox (at pisiform), CSA-O (direct method). Differences vs. controls. Relationship with clinical severity and NCV. CSA-It, CSA-M (hook of the hamate), CSA distal (distal edge of flexor	All US measure had significant differences vs. controls. Cutoff CSA-M >9 mm². Cutoff PD >2.5 mm. Cutoff SR ≥1.3. Significant differences vs. controls. Significant differences vs. controls for CSA-I, CSA-prox. No relationship with NCV and clinical severity. Cutoff all CSA >11 mm². Significant differences vs. controls.	CSA mild 30, PD mild 40, SR mild 55, CSA moderate 100, PD moderate 85, SR moderate 90 All 3 measures 72 QC 55, CSA-I 48, CSA-prox 73.6, CSA prox or QC 89, NCV 90, US or NCV 98.2 CSA-I 43, CSA-M 44, CSA distal	CSA mild 92.5, PD mild 90, SR mild 92.5, CSA moderate 92.5, PD moderate 90, SR moderate 92.5 All 3 measures 90 QC 100, CSA-I 96.1, CSA-prox 98, CSA-prox or QC 98
Tele (37) Jakamichi (36,43)	not performed) + relief after surgery Clinical	excluded because ganglion	indicated), FR, PD. Differences vs. controls. Multiple logistic regression to combine the 3 US measures. QC, CSA-I+, CSA-prox (at pisiform), CSA-O (direct method). Differences vs. controls. Relationship with clinical severity and NCV. CSA-I+, CSA-M (hook of the hamate), CSA distal (distal edge	Significant differences vs. controls for CSA-I, CSA-prox. No relationship with NCV and clinical severity. Cutoff all CSA >11 mm ² . Significant differences vs. controls. Cutoff CSA-I	QC 55, CSA-I 48, CSA-prox 73.6, CSA prox or QC 89, NCV 90, US or NCV 98.2 CSA-I 43, CSA-M 44, CSA distal	QC 100, CSA-I 96.1, CSA-prox 98, CSA-prox or QC 98
Jakamichi (36,43)	Clinical		prox (at pisiform), CSA-O (direct method). Differences vs. controls. Relationship with clinical severity and NCV. CSA-I+, CSA-M (hook of the hamate), CSA distal (distal edge	controls for CSA-I, CSA-prox. No relationship with NCV and clinical severity. Cutoff all CSA >11 mm². Significant differences vs. controls. Cutoff CSA-I	CSA-prox 73.6, CSA prox or QC 89, NCV 90, US or NCV 98.2 CSA-I 43, CSA-M 44, CSA distal	96.1, CSA-prox 98, CSA-prox or QC 98
(36,43)		414/275	CSA-It, CSA-M (hook of the hamate), CSA distal (distal edge	controls. Cutoff CSA-I	44, CSA distal	
Vong (33)	Olimin 1 + MON		retinaculum) (direct method). Differences vs. controls.	11 mm ² . Cutoff CSA distal 13 mm ² . Cutoff CSA of mean (multilevel) CSA 12 mm ² .	57, mean CSA 76, NCV 73, NCV or mean CSA 84	97, CSA distal 97, mean CSA 97, NCV 96, NCV or mean CSA 84
	Clinical + NCV	35/54	CSA-prox, CSA-I (proximal edge of retinaculum), CSA-O (distal edge of retinaculum) (direct method); PD, FR, thickness of ligament. Differences vs. controls. Relationship with NCV. ROC curve.	All CSA and FR at inlet differed from controls. Relationship NCV and right CSA-I and PD. Relationship NCV and left CSA-O. Cutoff CSA-prox >8.8 mm². Cutoff CSA-I >9.8 mm². Cutoff CSA-O >8.5 mm².	CSA-prox 74, CSA-I 89, CSA-O 80	CSA-prox 63, CSA- 83, CSA-O 51
wen (22)	Clinical, improvement postsurgery ≥90% of initial symptoms (VAS)	Of 63 surgical patients, 47 included because improved ≥90%	CSA-I‡ (indirect method). ROC curve.	$Cutoff~CSA>10~mm^2.$	CSA-I 70, NCV 98	CSA-I 63, NCV 19
arria (30)	Clinical + NCV	64/40	CSA-It, CSA-M, and CSA-O (indirect method); FR, PD. Differences vs. controls. Relationship with NCV. ROC curve.	Significant differences vs. controls for all CSA and PD. Significant relationship CSA-I/SCV and CSA-M/SCV/DML. Cutoff for all CSA >11 mm². Cutoff PD 2.5 mm.	CSA-I 73.4, CSA-M 73.4, CSA-O 74, PD 81.3	CSA-I 57.1, CSA-M 57.1, CSA-O 57.1 PD 64.3
Teberle (42)	Clinical + NCV	15	FR and SR. Differences vs. controls. Relationship with MRI and NCV.	Significant differences of FR and SR vs. controls. Cutoff FR >3.4, cutoff SR >1.3. Relationship with NCV and MRI.	FR 100, SR 100	
duncan (21)	Clinical (NCV was performed in 74 of 102 and was abnormal in 62)	102/68	CSA-I‡ (direct and indirect method), FR. Likelihood ratio.	Significant differences for CSA-I (direct method), CSA-I (indirect method), and FR. Cutoff CSA-I >9 mm ² . Cutoff FR >3.3 mm.	CSA-I (direct method) 82.4, CSA-I (indirect method) 76.5, FR 38.2, CSA-I (direct method) or FR 88.2	CSA-I (direct method) 97.1, CSA-I (indirect method) 88.2, FR 75, CSA-I (direct method) or FR 72.1
ee (29)	Design in 3 phases (the 1° in cadaver and normal, the 2° in 16 CTS subjects)	3° phase (100/50 with abnormal NCV)	CSA within carpal canal (at scaphoid and capitate bones) (indirect method). Relationship with ordinal severity NCV scale and ANOVA. Linear regression analy- sis.	CSA cutoff >15 mm². Relationship and significant ANOVA CSA/NCV severity scale.	CSA 88	CSA 96

Table 4. Summary of literature findings in US and CTS* (Continued)								
Author (ref.)	CTS gold standard	Wrists/patients	US measures/ statistics	US results	US/NCV sensitivity, %	US/NCV specificity, %		
Buchberger (28)	Clinical + NCV	20/18	CSA-It, CSA-M, and CSA-O (indirect method); FR, PD. Differences vs. controls. ROC curve. US values corresponded well with MRI values.	Significant differences of CSA-M, CSA-O, all FR, PD vs. controls. Cutoff (mean + 2 SD): CSA-I 10.1 mm², CSA-M 10.7 mm², CSA-O 9.9 mm², PD 3.7 mm. At least 1 between CSAs, FR, PD abnormal in 19 of 20.	CSA-I abnormal 16/ 20, distal FR abnormal 13/20, PD abnormal 9/ 20, individual area under ROC curve: FR 0.9, SR 0.86, PD 0.85			

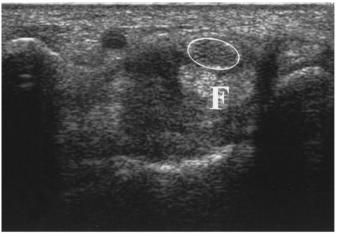
- * Several studies reported positive and negative predictive values, but they are not shown in this table. US = ultrasonography; CTS = carpal tunnel syndrome; NCV = nerve conduction velocity (includes distal motor latency, sensory conduction velocity, and distal sensory latency); CSA = cross-sectional area; CSA-I = CSA at the carpal canal inlet; CSA-M = CSA in the middle carpal tunnel at the level of the pisiform; CSA-O = CSA at the carpal canal outlet at the level of the hook of hamate; FR = flattening ratio (ratio of the nerve's major to its minor axis); PD = palmar displacement (bowing of the flexor retinaculum; determined as the distance from the palmar apex retinaculum to a straight line drawn between the tubercle of the trapezium and the hook of the hamate bone); MUNE = motor unit number estimation; CDS = color Doppler sonography; ROC curve = receiver operating characteristic curve; DML = distal motor latency; SCV = sensory conduction velocity; CMAP = compound muscle action potential amplitude; SNAP = sensory nerve action potential amplitude; CSA-prox = CSA proximal to the tunnel inlet; SR = swelling ratio; QC = qualitative compression sign at longitudinal scan; VAS = visual analog scale; MRI = magnetic resonance imaging; ANOVA = analysis of variance; see Table 1 for additional definitions.
- † CSA-I measured at the radioulnar joint or wrist crease.
- ‡ CSA-I measured between the pisiform bone and the tubercle of the navicular.

from different laboratories that use different techniques and reference values. This scale was also used by other authors in US studies (32,39). In our study protocol, we also considered the patient's point of view about symptoms and functional status of the hand by means of the well-known BQ, which is translated and validated in many languages. Two other US studies also considered the BQ (39,49).

In contrast with all previous US studies that considered the number of wrists for case collection, we preferred to analyze the data at the patient level and not at the hand level, and the worst or dominant hand was included. Statistically, including a bilaterally affected patient as 2 cases may be a source of error, because the results could be overstated if the correlation between the 2 hands is not taken into account (20).

Because CSA and NCV values of the control group had normal distribution, we considered as NCV and US cutoffs the mean values -2 SDs for SCV and +2 SDs for DML and CSAs of the median nerve. Between the 3 levels of CSA measurement, CSA-I (at the proximal edge of the flexor retinaculum) was the most frequently abnormal and our cutoff value (10.5 mm²) was very similar to that reported most frequently in the literature ($\sim 10-11$ mm²) (22,24–28,30,34,37,39,41). The highest concordance in the positive or negative results was between CSA-I and NCV (77.6%).

Our study demonstrated that in mild cases of CTS, there was no difference in sensitivity between US and NCV even when the most sensitive US and NCV parameters were used. If US and NCV are considered together, the sensitivity increases to 76%. The additional value of US has been reported by Nakamichi and Tachibana (43) in a sample of patients with clinically diagnosed CTS: when US was added to NCV study, the sensitivity increased from 76% to 84%, but specificity decreased from 97% to 84%. How-



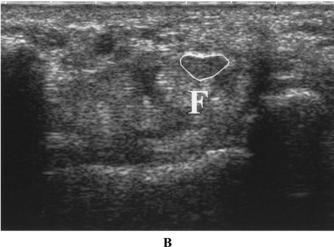


Figure 2. Transverse scan of the median nerve at the level of the pisiform bone. A, The nerve has an oval shape so normal ellipsoid formula could be used. B, The nerve assumes a "heart" shape; in this case the ellipsoid formula could produce a significant measurement error. F = flexor digitorum tendons.

ever, 23.5% of our patients with mild CTS had normal NCV and US findings. It is likely that these patients were in the first stage of nerve compression severity, when acroparesthesia is caused by intermittent ischemia of the sensory axons, unassociated with NCV changes or US evidence of proximal nerve enlargement (50).

All CSAs are related to the electrophysiologic severity scale and with median nerve DML and SCV. Many literature data reported relationships between CSAs and some NCV parameters or the electrophysiologic severity scale, even if NCV and CSA measures differed from study to study (26,29,30,32,39,41,49,51). In particular, El Miedany et al (39) found a strict relationship between electrophysiologic severity, evaluated with Padua's scale (the same scale used by us), and CSA: for CSA 10-13 mm², mild electrophysiologic severity of CTS was found; for CSA 13–15 mm², moderate electrophysiologic severity was found; and for CSA >15 mm², severe electrophysiologic severity was found. Based on the electrophysiologic severity scale and CSA-I findings, these authors suggested an algorithm for evaluation and management of CTS (39). Bayrak et al (32) also found an inverse relationship between the estimation of motor unit number of abductor pollicis brevis muscle and CSA at proximal and middle segments. In contrast, Wong et al (33) reported debatable relationships between CSA-I and distal latency in the right wrist and between CSA-O and distal latency in the left wrist. These relationships suggest that the US findings reflect the severity of the disease. On the contrary, only a few studies did not demonstrate any relationship between CSA and NCV findings (24,25,37).

Two articles reported relationships between the BQ and US (39,49). In contrast, we failed to find a relationship between the BQ and CSA, similar to the finding of a lack of a relationship between the BQ and NCV. The BQ and instrumental findings appeared to be independent measures (52,53). The BQ may be conditioned by many other factors besides severity of CTS such as sex, education, and presence of additional pathologies of the hand other than CTS. Moreover, we selected only patients with mild CTS, and an Italian multicenter study demonstrated that the BQ scores were higher in the first stages of CTS (54).

A limitation of our study was that we did not calculate the specificity of US and NCV in a sample of subjects without CTS symptoms, because the control group should be matched for sex, age, and type of job with the patient group in order to obtain reliable results, as done by Kotevoglu and Gulbahce-Saglam (40) and Wong et al (33). For example, the specificity in the study by Wiesler et al (26) was calculated using a control group with a different age (56 years versus 36 years). In CTS, specificity should be calculated not only in a group without CTS symptoms but also in a sample of patients with upper limb symptoms indicating unlikely or possible CTS cases (11).

In conclusion, US is not an alternative diagnostic tool to electrodiagnostic tests and vice versa in CTS, but they are complementary; one provides anatomic information of the nerve and its surrounding structures while the other provides information on the level of the lesion and the function of the nerve fibers with the largest diameters. However, NCV and classic needle electromyography are essential to

resolve clinical doubts and to rule out cervical radiculopathy, brachial plexopathy, polyneuropathy, and other focal mononeuropathies. In mild cases of CTS, the sensitivity of the 2 diagnostic tools is very similar, but when the most sensitive electrodiagnostic tests and proximal CSA were considered together, at least 1 of the 2 was abnormal in 76.5% of patients with mild CTS. However, that leaves 23.5% of patients with mild CTS with normal NCV and US tests.

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AUTHOR CONTRIBUTIONS

Dr. Mondelli had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study design. Mondelli, Filippou, Gallo, Frediani.

Acquisition of data. Mondelli, Filippou, Gallo.

Analysis and interpretation of data. Mondelli, Filippou, Frediani

Manuscript preparation. Mondelli, Filippou. Statistical analysis. Mondelli.

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