Does Ultrasonography, In Conjunction with Nerve Conduction Study, Plays Any Role in The Diagnosis and The Evaluation of Severity in Patients with Clinically Diagnosed Carpal Tunnel Syndrome? A Prospective Study

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ABSTRACT

Background: Although nerve conduction study (NCS) represents the commonly performed test to functionally confirm the presence of carpal tunnel syndrome (CTS) in the daily clinical practice, the value of ultrasonography (U/S) is well established as a diagnostic tool for structural evaluation of CTS. The purpose of this study was to compare U/S and nerve conduction velocity in patients with clinically diagnosed CTS, for assessing the usefulness of U/S in determining CTS severity.

Material and Methods: A cross-sectional study with prospective data collection was carried out. 71 patients (100 hands) with clinically diagnosed idiopathic CTS were included in this study. The protocol was comprised of a NCS and an U/S where the cross sectional area (CSA) and the flattening ratio (FR) of the median nerve at the carpal tunnel inlet (level of the pisiform) were measured.

Results: In 94 hands (65 patients) out of 100 hands (71 patients), CTS was electrophysiologically confirmed. The CSA increase of the median nerve was proportional to the electrophysiological severity of the CTS. ROC analysis demonstrated good diagnostic value in both CSA and FR (CSA: AUC = 0.974, p<0.001, FR: AUC = 0.928, p <0.001). The CSA at the tunnel inlet with a threshold of 10.5 mm^2 had the best diagnostic accuracy with a sensitivity of 94.7% and a specificity of 92.5%, as well as the FR with a threshold of 3.1 had the best diagnostic accuracy with a sensitivity and a specificity of 78.7% and 98.8%, respectively. Furthermore, ROC curve analysis for CTS electrophysiological severity showed a superior performance of the CSA (AUC=0.911, p<0.001) compared to the FR (AUC=0.647, p=0.023). The optimal cut-off point of 15.5 mm^2 for CSA at the carpal tunnel inlet was defined to determine severe CTS, which yielded a sensitivity of 82.8% and a specificity of 92.3%.

Conclusions: The U/S of the median nerve combined with electrodiagnostic study, increases significantly the sensitivity and reliability of the patient's diagnostic approach suffering from CTS. It can also be used for the assessment of CTS severity, replacing NCS, as its benefits such as low cost, non-invasive procedure, less time and patient's convenience are remarkable.

Keywords: *Carpal Tunnel Syndrome, Nerve Conduction Study, Ultrasonography, Electrodiagnostic Study, Cross Sectional Area, Flattening Ratio, Median Nerve*

Introduction

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy (Demino and Fowler, 2021; Yoshii *et al*., 2020; Aseem *et al*., 2017). Many authors claim that the diagnosis for most patients is exclusively clinical by the use of special diagnostic tools (Yoshii *et al*., 2020; Fowler, 2017; Graham, 2008). The AAOS Evidence-Based Guideline on Management of CTS strongly recommends the use of physical signs for CTS diagnosis. It also classifies the nerve conduction study (NCS) and the ultrasonography (U/S) as low grade of recommendation for CTS diagnosis (Graham *et al*., 2016). Nonetheless, some physicians insist that the diagnosis is mainly based on NCS or U/S. In fact, the majority of medical doctors diagnose the CTS clinically and confirm it, when necessary, by the use of the aforementioned complimentary examinations (Yoshii *et al*., 2020).

Over the last years, there is a debate about the efficacy and specificity of NCS and U/S in the carpal tunnel diagnosis. The diagnostic accuracy of these examinations varies among several studies. The NCS constitutes the most commonly used examination for CTS diagnosis while the U/S is being increasingly adopted (Aggarwal *et al*., 2020). The purpose of this study was to compare U/S and NCS in patients with clinically diagnosed CTS, for assessing the usefulness of U/S in determining CTS severity.

Material and Methods

Patient Selection

A cross-sectional study with prospective data collection was carried out. The study was approved by Democritus Medical Center Institutional Review Board and all participants signed an informed consent at the inclusion visit.

71 patients (100 hands) with a clinical diagnosis of idiopathic CTS who were referred to our department from Orthopedic outpatients' clinics, between October 2018 and January 2020 were included in this study. The patients' demographic data included sex, age, weight, height and body mass index (BMI). In case of bilateral CTS, every wrist was counted as a separate patient to avoid demographic bias. Medical history and clinical examination were also carried out. All patients underwent nerve conduction study and U/S examination by the same neurologist and radiologist, respectively.

The clinical diagnosis of CTS was based on CTS-6 evaluation tool proposed by Brent Graham (Graham, 2008; Graham *et al*., 2006). A score ≥12 points was precondition for all the included patients. The exclusion criteria were 1) a previous surgery due to a fracture or laceration at the wrist, 2) a history of underlying diseases such as generalized inflammatory polyneuropathy, diabetes mellitus, rheumatoid arthritis, autoimmune and metabolic disorders, 3) pregnancy, or 4) other lesions within the carpal tunnel.

Nerve Conduction Study

Electrodiagnostic studies were conducted using Nihon Kohden 4 ME 8 electrode entrance 4 record channel device according to the protocol proposed by the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) (American Association of Electrodiagnostic Medicine, 2002). All participants underwent median and ulnar nerve sensimotor NCS. Standardized NCS was performed by neurologist, using surface electrodes and a constant current stimulator for percutaneous supramaximal stimulation. A ground electrode was placed on the dorsum of the hand. The active electrode was placed over abductor pollicis brevis muscle for the median nerve and over abductor digiti minimi for the ulnar nerve to record motor nerve conduction velocities. The reference electrode was located over the first metacarpophalangeal joint for the median nerve and over the fifth metacarpophalangeal joint for the ulnar nerve. The median and ulnar nerve stimulation was applied 8 cm proximal to the active recording electrode as well as on the elbow (antecubital region for median nerve, ulnar fossa for ulnar nerve). The distal motor latency, the baseline-to-peak amplitude and the motor median/ulnar nerve conduction velocity (MNCV) were measured (American Association of Electrodiagnostic Medicine, 2002).

Ring electrodes were used to obtain sensory nerve conduction velocities (SNCV) ortho-dromically. Electrodes were located over the second finger for the median nerve and fifth finger for the ulnar nerve. The median and ulnar nerves were stimulated at the wrist and elbow. In particularly, for the median nerve the active electrode was attached on the proximal interphalangeal joint of second finger, whereas the reference electrode was attached 4 cm distal to the active electrode. The ground electrode was placed between the stimulus and active electrode. The median sensory nerve was stimulated at 14 cm proximal to active electrode. The latencies, baseline-to-peak amplitudes and SNCV were calculated. In addition, the difference of sensory latencies between ulnar and median nerve was assessed by ring-finger method (RF) and values over 0.5 suggested CTS. Needle electro-myography (EMG) was performed on the abductor pollicis brevis muscle to exclude cervical radiculitis (American Association of Electrodiagnostic Medicine, 2002).

All NCS positive patients were classified into four subgroups on the basis of the electrophysiological severity proposed by Padua, *et al*. (1997):

- Mild: slowing of the median SNCV (<44 m/s) and normal distal motor latency (<4.4 ms).
- Moderate: slowing of the median SNCV (<44 m/s) and prolonged distal motor latency (≥4.4ms).
- Severe: absence of sensory response and prolonged distal motor latency (≥4.4 ms).

- Extreme: absence of motor and sensory responses.

Ultrasonography

Ultrasonography of the carpal tunnel was performed by a radiologist who was blinded to the physical and electrophysiologic findings of the subjects. A Philips IU22 U/S system with a broadband 5-17 MHz linear transducer was used. All participants underwent sonographic examination seated in a comfortable position facing the sonographer, with the forearm resting on the bed, the palm facing up in the neutral position and the fingers semi-flexed. The full course of the median nerve in the carpal tunnel was estimated in longitudinal and transverse planes. The median nerve is located superficial to the echogenic flexor tendons and its changes in shape, size, echogenicity, surrounding structures and overlying retinaculum were assessed.

Using the tracing method, the circumference of the median nerve and its cross-sectional area (CSA) were measured at the carpal tunnel inlet, at the level immediately deep to the proximal edge of the flexor retinaculum. The pisiform bone was used as landmark. The tracing method was involved tracing a continuous line within the hyperechogenic boundary of the nerve. The formula of an ellipsoid area (D1×D2×3.14/4) was used in this measurement (Fig. 1). The measurements were repeated three times, and the mean value was used for statistical analysis. Furthermore, the mean flattening ratio (FR) (defined as the ratio of the major axis of the median nerve to its minor axis) was evaluated at the carpal tunnel inlet (Fig. 2).

Figure 1: Median nerve cross-sectional area (CSA) in mild carpal tunnel syndrome (CTS).

Figure 2: Median nerve flattening ratio (FR) in severe carpal tunnel syndrome (CTS).

Statistical Analysis

Statistical analysis of the data was performed by using the Statistical Package for the Social Sciences (SPSS), version 19.0 (IBM). The normality of quantitative variables was tested with Kolmogorov-Smirnov test. All quantitative variables were expressed as the mean ± standard deviation (SD). Categorical variables were expressed as frequencies (and percentage). Student's t test, one-way analysis of variance (ANOVA), followed by Tukey's test, and chi-square test were used to determine differences in demographic and clinical characteristics between groups of patients.

For the evaluation of the significance of the median nerve CSA and FR at the carpal tunnel inlet for CTS diagnosis and its electrophysiological severity, the area under the receiver operating characteristic (ROC) curve (AUC) was calculated. Sensitivity and specificity were also calculated, while Cohen's kappa coefficient was used to assess agreement. The value with the shortest distance from the curve to the point with both maximum sensitivity and specificity, i.e., the point (0.0, 1.0), was selected as the cut-off score to classify CTS patients. All tests were two tailed and statistical significance was considered for p values less than 0.05.

Results

In total, 100 clinically diagnosed wrists with idiopathic CTS were assessed, of which 94 had a positive NCS (sensitivity of 94%), confirming the initial diagnosis. Ninety-four wrists of 65 patients with CTS were included in the study. Mean and standard deviation value of demographic characteristics, Phalen and Tinel sign, ring-finger (RF) method of the ulnar and median nerve, cross-sectional area (CSA) and flattening ratio (FR) of the median nerve, are listed in Table 1. A total of 29 patients had bilateral CTS.

Table 1: Demographic characteristics, clinical signs, electrophysiological and sonographic parameters. BMI: Body mass index, RF: Ring- finger method, CSA: cross-sectional area, FR: flattening ratio.

	CTS patients (n=94)
Gender (M/F)	15/50
Age (years)	55.41 ± 9.71
Height (cm)	169.05 ± 5.43
Weight (kg)	78.34 ± 5.66
BMI (KG/m^2)	27.36 ± 0.88
Tinel, n (%)	75 (79.8)
Phalen, n (%)	85 (90.4)
RF	0.88 ± 0.72
CSA (mm^2)	14.50 ± 3.08
FR	3.88 ± 0.84

According to neurophysiologic study, CTS diseased hands were divided into three groups: mild (27 hands, 28.7%), moderate (38 hands, 40.4%) and severe (29 hands, 30.9%) ones. None of the affected wrists was diagnosed as extreme CTS. Regarding to the demographic characteristics, on the basis of the NCS severity, there were statistically significant differences only in height (p=0.003) (Table 2).

Table 2: Distribution of CTS patients' demographics, clinical signs, ultrasonography and nerve conduction study data according to electrophysiological severity. Statistical significance obtained by means of [a]ANOVA and [b] chi-squared test. BMI: Body mass index, RF: Ring- finger method, CSA: cross-sectional area, FR: flattening ratio.

	Mild CTS	Moderate CTS	Severe CTS	P value
Age (years)	54.52 ± 11.62	56.21 ± 9.71	55.21 ± 7.84	0.783[a]
Height (cm)	166.22 ± 3.87	170.68 ± 6.17	169.55 ± 4.71	0.003[a]
Weight (kg)	76.63 ± 5.56	79.55 ± 5.93	78.34 ± 5.12	0.122[a]
BMI (kg/m^2)	27.67 ± 1.23	27.27 ± 0.69	27.19 ± 0.63	0.094[a]
Tinel, n (%)	14 (51.9)	34 (89.5)	27 (93.1)	<0.001[b]
Phalen, n (%)	18 (66.7)	38 (100.0)	29 (100.0)	<0.001[b]
RF	1.07 ± 0.40	1.43 ± 0.49	1.51 ± 0.51	0.011[a]
CSA (mm^2)	12.25 ± 1.40	13.92 ± 2.85	17.34 ± 2.30	<0.001[a]
FR	3.14 ± 0.42	4.16 ±0.74	4.20 ± 0.82	<0.001[a]

Phalen sign was positive in all moderate and severe CTS diseased hands; similarly, Tinel sign was positive in the majority of moderate (34 hands, 89.5%) and severe (27 hands, 93.1%) ones. Positive Phalen and Tinel signs were statistically significantly (both p<0.001) more frequent in moderate and severe compared to mild CTS diseased hands (positive Phalen sign in 18 hands, 66.7%; positive Tinel sign in 14 hands, 51.9%). Furthermore, according to RF method, the difference of sensory latencies between the ulnar and the median nerve was statistically higher in moderate and severe compared to mild CTS diseased hands (p=0.011).

There was a statistically significant association between electrophysiological severity of CTS and CSA of the median nerve (p<0.001). The mean median nerve CSA at the tunnel inlet was 12.25 ± 1.40 mm^2 for mild, 13.92 ± 2.85 mm^2 for moderate and 17.34 ± 2.30 mm^2 for severe CTS. Post-hoc analysis using Tukey's test, demonstrated that the CSA was significantly higher in severe than in mild (by 41.5%, p<0.001) and moderate (by 24.6%, p<0.001) CTS; the CSA was also higher in moderate than in mild (by 13.6%, p<0.001) CTS. The CSA of the median nerve in relation to the electrophysiological severity of CTS is shown in Fig. 3.

The association between the electrophysiological severity of CTS and the FR of the median nerve was also statistically significant (p<0.001). The mean FR of the median nerve at the tunnel inlet was 3.14 ± 0.42 in mild, 4.16 ± 0.74 in moderate and 4.20 ± 0.82 in severe CTS. Post-hoc comparisons demonstrated that the FR at the tunnel inlet was statistically higher in moderate and severe CTS compared to mild CTS (both p<0.001); no statistically significant difference was observed between moderate and severe CTS (p=0.973) (Table 2).

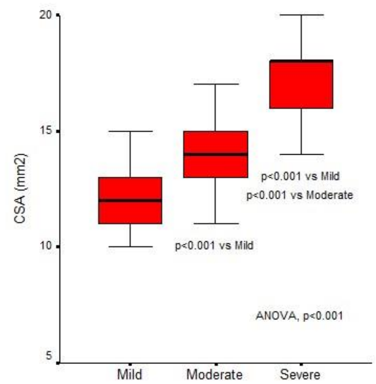

Figure 3: Distribution of median nerve cross- sectional area (CSA) according to nerve conduction study (NCS).

The ROC curve analysis was performed for the evaluation of the diagnostic significance of the U/S measurements in the diagnosis of CTS. The area under the ROC curves (AUC) of the median nerve CSA and FR at the carpal tunnel inlet was very high (CSA: AUC=0.974, p<0.001; FR: AUC=0.928, p<0.001), which indicates high diagnostic significance for both measurements.

Clinically important cut-off points of the median nerve CSA and FR at the carpal tunnel inlet for CTS diagnosis were also determined by the ROC curve analysis. In particular, the optimal cut-off point of 10.5 mm^2 for CSA at the carpal tunnel inlet was determined to classify CTS patients, which yielded a high sensitivity of 94.7% and a specificity of 92.5%. The optimal cut-off point of 3.1 for the FR at the carpal tunnel inlet, yielded substantial sensitivity of 78.7% and a high specificity of 98.8%. The overall agreement of CTS patients according to CSA and FR with the initial NCS was 93.8% and 88.0% respectively, while Cohen's k coefficient indicated very good agreement for both sonographic measurements (CSA: k=0.874, p<0.001; FR: k=0.764, p<0.001) (Fig. 4).

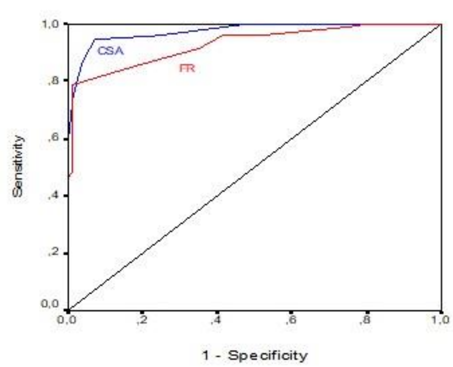

Figure 4: Receiver Operating Characteristic (ROC) Curve for the diagnosis of carpal tunnel syndrome (CTS) according to cross-sectional area (CSA) and flattening ratio (FR).

The ROC curve analysis was also performed for the evaluation of the significance of the U/S measurements for CTS electrophysiological severity. This analysis showed a superior performance of CSA (AUC=0.911, p<0.001) compared to FR (AUC=0.647, p=0.023).

Clinically important cut-off points for severe CTS for median nerve CSA and FR at the carpal tunnel inlet were also determined by the ROC curve analysis. In particular, the optimal cut-off point of 15.5 mm^2 for the CSA at the carpal tunnel inlet was determined to classify severe CTS patients, which yielded a sensitivity of 82.8% and a specificity of 92.3%. The optimal cut-off point of 3.9 for the FR at the carpal tunnel inlet for severe CTS patients, yielded a substantial sensitivity of 65.5% and a specificity of 58.5%. The overall agreement of patients' classification for CTS sonographic severity (according to CSA and FR) with NCS severity was 89.3% (84 out of 94 hands) and 60.6% (57 out of 94 hands) respectively, while Cohen's k coefficient indicated good agreement for the CSA (k=0.751, p<0.001) and substantial agreement for the FR (k=0.206, p=0.032) (Fig. 5).

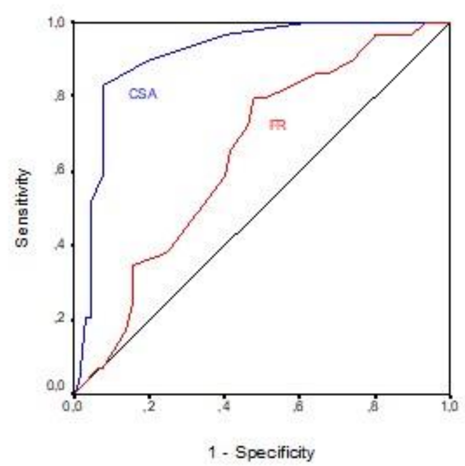

Figure 5: Receiver Operating Characteristic (ROC) Curve for the evaluation of carpal tunnel syndrome (CTS) severity according to cross-sectional area (CSA) and flattening ratio (FR).

Discussion

Although NCS represents the commonly performed test to functionally confirm the presence of CTS, the U/S consists one of the well-established non-invasive methods, providing information about the wrist anatomy and the anatomic variations of the median nerve and the adjacent structures (Yoshi *et al*., 2020; McDonagh *et al*., 2015). The NCS estimates the physiologic condition of the median nerve, excluding the nerve pathology due to cervical radiculopathy, brachial plexopathy, polyneuropathy and other focal mononeuropathies (Fowler, 2017). It also provides information about the level of the lesion and the function of the nerve fibers with larger diameters. Nonetheless, it has the significant shortcomings of increased cost, time requirement and patient discomfort (Aggarwal *et al*., 2020;

Goldberg *et al*., 2016). On the other hand, the U/S constitutes a simple, quick, cost-effective, non-invasive and painless diagnostic procedure (Yoshi *et al*., 2020; Fowler *et al*., 2019). The tissue dynamics can be noticed in real-time imaging (Yoshi *et al*., 2020). The detection of secondary causes like space occupying lesions is also achieved (Chen *et al*., 2012). Nevertheless, one remarkable disadvantage is the inability to evaluate the nerve function and thus, may not be as sensitive in variability as NCSs (McDonagh *et al*., 2015).

The NCS is considered by many authors to be the second most important diagnostic procedure after the clinical examination. The average sensitivity and specificity were calculated 88% and 93%, respectively (Strickland and Gozani, 2011). In particular, the distal sensory latency has a sensitivity of 73.4% and a specificity of 93.6%, while the distal motor latency has 56.2% and 95.8%, respectively (Demino and Fowler, 2021). There is a number of diagnostic scales using the NCS findings to grade the CTS severity (Goldberg *et al*., 2016). The most commonly used are the six-grade diagnostic system by Pedua *et al*. and the Canterbury NCS severity scale by Blant (Padua *et al*., 1997; Bland, 2000). It is considered that a subject with high CTS severity scale has highest probability to have CTS than a subject with low CTS severity scale (Izadi *et al*., 2018). Nonetheless, the isolated use of these diagnostic tools cannot maximize both the specificity and sensitivity (Goldberg *et al*., 2016).

We should not ignore the false-positive and false-negative results of NCS. If the decision for surgical treatment is based only in NCS findings, then 1 of 5 patients will undertake CT release without having CTS (false-positive diagnosis, 20% overtreating). Additionally, if all subjects with normal NCS findings were excluded from CT release, then 1 of 4 subjects will suffer from CTS and will not have the opportunity to be treated (false-negative diagnosis, 25% undertreating) (Fowler, 2017). In another study, 17 out of 40 asymptomatic subjects with a CTS-6 score of 0 had positive NCS (43% false positive diagnosis) (Fowler *et al*., 2019).

The most useful U/S parameters of the median nerve in the diagnosis of CTS have been examined by plenty of studies. The median nerve enlargement (CSA at various levels of carpal tunnel) is the most commonly utilized parameter to diagnose CTS using U/S, providing a high sensitivity and a specificity of 77.6% and 86.8%, respectively (Fowler *et al*., 2011). The swelling of median nerve calculated with CSA, reflects the degree of the nerve damage severity (Bang *et al*., 2019). It was demonstrated that the median nerve CSA is significantly greater in patients suffered from CTS compared to healthy controls (Kim *et al*., 2013; Kutlar *et al*., 2017). Bang *et al*. have shown that the CSA of the median nerve is the most sensitive method to diagnose the early-stage CTS (Bang *et al*., 2019). Most studies determined the CSA upper normal limit between 9-10 mm^2 (10.5 mm^2 in our study, with a sensitivity of 94.7% and a specificity of 92.5%) (Goldberg *et al*., 2016). A meta-analysis of 28 published studies showed that the cut-off point in the carpal tunnel inlet of CTS affected patients ranged from 9.0 to 12.6 mm^2, while in the carpal tunnel outlet from 9.5 to 10.0 mm^2 (Torres-Costoso *et al*., 2018). The ideal site of the CSA measurement is of debate. Many studies have showed that the CSA increase at the carpal tunnel inlet provides the highest sensitivity and specificity (McDonagh *et al*., 2015). Other U/S parameters include the flattening ratio, the swelling ratio, the wrist-to-forearm ratio and the palmar bowing ratio of the flexor retinaculum (Dejaco *et al*., 2013; Paluch *et al*., 2018). Nevertheless, we should not skip that a 23% of healthy subjects have positive U/S findings (Fowler *et al*., 2019).

It would be expected that, in patients with mild CTS, the symptoms are better correlated with NCS than sonographic findings. Routine NCS evaluates only the large myelinated fibers rather than the small sensory fibers, which may be responsible for sensory symptoms/deficits in CTS. This would justify the lack of strong correlations between the neurophysiological parameters and symptoms in early stages of CTS (Kaymak *et al*., 2008). Aseem, *et al*. (2017) reported that a large proportion of patients with clinically diagnosed CTS, but normal NCS, had abnormal neuromuscular ultrasound findings. Thus, the importance of ultrasound is related to the mild degree of CTS that cannot detect NCS. In these cases, with normal NCS but a clinical picture of CTS, the CSA on U/S has been shown to be significantly larger than in healthy controls (Koyuncuoglu *et al*., 2005; Klauser *et al*., 2009).

The predominant approach to CTS diagnosis is clinical (Padua *et al*., 2016). The CTS-6 evaluation tool provides a high sensitivity and a specificity of 95% and 91% respectively (Fowler *et al*., 2015). The U/S and the NCS are usually used to determine the diagnosis when the clinical examination is controversial (Sonoo *et al*., 2018). They do not alter the diagnosis in patients with clinically diagnosed CTS, but they confirm it (Fowler *et al*., 2015). In short, U/S and NCS do not constitute isolated diagnostic tools, but complementary tools to clinical examination, providing higher diagnostic accuracy.

There are some limitations and shortcomings in this study. First of all, a control group of healthy subjects was not included. As a result, a comparison between healthy and CTS affected wrists was not held. Secondly, the clinical data of CTS-6 evaluation tool about each separate patient was not collected. Therefore, there was a lack of quantification of clinical severity. As a result, clinical correlation with NCS and U/S findings was not held. Finally, the targeted selection of only 2 U/S parameters measured in this study, also limited its results.

Conclusion

Summarizing the results of the present study, we conclude that the U/S of the median nerve combined with an electrodiagnostic study, significantly increases the sensitivity and reliability of the patient's diagnostic approach suffering from CTS. It can also be used for the assessment of CTS severity, replacing NCS, as its benefits such as low cost, non-invasive procedure, less time and patient's convenience are remarkable.

Footnote- Abbreviations

CTS: Carpal Tunnel Syndrome

NCS: Nerve Conduction Study

U/S: Ultrasonography

MNCV: Motor Nerve Conduction Velocity

SNCV: Sensory Nerve Conduction Velocity

RF: Ring-Finger

EMG: Electro-Myography

CSA: Cross-Sectional Area

FR: Flattening Ratio

ROC: Receiver Operating Characteristic

AUC: Area Under the ROC Curve

Declarations of Interest: None.

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