Validity and Usefulness of Echography in the Carpal Tunnel Syndrome

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Objective: To evaluate the accuracy and utility of ultrasonography for the diagnosis of carpal tunnel syndrome (CTS).
Material and method: Prospective and blind study of 75 wrists in 42 consecutive patients with suspected CTS. Electrodiagnostic testing (EDT) was used as gold standard. We measure different ultrasonographic parameters and based on a fitted receiver operating characteristic curve, we estimated post-test probabilities for the proximal, middle, and distal cross-sectional area of median nerve. We analyzed interobserver and interreader reliability by 3 different explorers and 2 different readers, cost and the patient discomfort.
Results: Mean ultrasound measurements were significantly higher in the EDT positive group. There was a high concordance between sonography and nerve conduction. A cut-off of 9.5 mm^2 resulted in the correct classification of 83% of cases (sensitivity 88% and specificity 67%). Conversely, a cut-off of >14 mm^2 or <7 mm^2 had excellent power to rule in CTS, with a post-test probability of 100% of specificity and sensitivity respectively. The interobserver acquisition ICC was 0.915-0.980, and the inter-reader ICC was 0.912-0.987. Ultrasound cost savings in this study were €3217.59 (€42.9 per symptomatic wrist) and the discomfort perceived by the patient was significantly lesser 6.3 versus 56 in EDT (P<.0005).
Conclusions: Ultrasound median nerve crosssectional area is reliable and may be used to accurately rule in or rule out CTS. Sonography as a first-line test is cost-effective and is more satisfactory to the patients.

Keys words: Sonography. Carpal tunnel syndrome. Imaging diagnostic. Reliability.

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Validez y utilidad de la ecografía en el síndrome del túnel carpiano

Objetivo: Evaluar la validez y la utilidad de la ecografía en el síndrome del túnel carpiano (STC).
Material y método: Estudio ecográfico ciego y prospectivo en 75 carpos de 42 pacientes consecutivos con sospecha de STC. Se utiliza la electromiografía (EMG) como prueba de referencia. Se miden distintos parámetros ecográficos y mediante curvas ROC se estiman las probabilidades tras la prueba para los diferentes cortes del área de sección transversal del mediano (AST). Se analiza la fiabilidad entre explorador y lector con tres exploradores diferentes y dos lectores. Finalmente se efectúa un estudio de costes y de satisfacción del paciente.
Resultados: Las medias de los parámetros ecográficos son significativamente mayores en el grupo con STC. Hay una alta concordancia entre la ecografía y la conducción nerviosa. Un punto de corte del AST en 9,5 mm^2 clasifica correctamente el 83% de los casos (sensibilidad del 88% y especificidad del 67%). Un punto de corte mayor de 14 mm^2 o menor de 7 mm^2 tiene una probabilidad tras la prueba para el STC del 100% de especificidad y sensibilidad respectivamente. Los coeficientes de correlación intraclase (ICC) entre observadores fueron 0,915-0,980, y entre lectores, 0,912-0,987. La ecografía puede resultar más económica y ahorrar en el estudio 3.217,59 euros (42,9 euros por muñeca sintomática). El malestar percibido por los pacientes fue significativamente menor: EVA, 6,3 con ecografía frente a 56 con el EMG (p < 0,0005).
Conclusiones: La ecografía es fiable y válida para definir si hay o no STC. La ecografía como prueba de primera línea es coste-efectiva y más satisfactoria para los pacientes.

Palabras clave: Ecografía. Síndrome del túnel carpiano. Diagnóstico por imagen. Fiabilidad.

Introduction

Carpal tunnel syndrome (CTS) is the most frequent neuropathy in upper extremities and is due to the compression of the median nerve in the carpal tunnel. The diagnosis is based mainly on clinical and electromyographic (EMG) findings. Although EMG is very specific,[1] its diagnostic precision is 80%-90% with a percentage of false negatives of around 10%-20%.[1-4]

In the past years, median nerve echography has started being used as a diagnostic technique due to its potential benefits over EMG in the diagnosis of CTS, among them: lower cost and examination time, better tolerance on the part of the patient, etiologic information, and the possibility of treatment through a guided intervention.

Due to the great diffusion generated by echography in our country's units and that previous studies have shown that the validity of the transverse section area (TSA) of the median nerve in the diagnosis of CTS,[5-15] we set out to analyze its utility from 3 perspectives: *a)* the physicians, due to its validity in our environment and other, less studied aspects such as trustworthiness and the degree of previous training necessary; *b)* the patients (satisfaction); and *c)* health costs.

Material and Method

Prospective study of 75 wrists of 42 consecutive patients referred to the neurophysiology unit with a suspicion of CTS. All of the patients gave informed consent and the hospitals' ethics committee approved the protocol.

The following parameters were evaluated in an independent manner: age, gender, swelling, paresthesias in the median nerve distribution, Tinel and Phalen's signs. The following exclusion criteria were applied: *a)* a history of wrist swelling (including carpal tunnel infiltration) or fracture; *b)* clinical or electromyographic evidence of conditions that may simulate CTS or that interfere with its evolution such as proximal neuropathies, cervical radiculopathy or polyneruopathy; *c)* a history of CTS related underlying disease such as diabetes mellitus, rheumatoid arthritis, acromegaly, hypothiroidism, or pregnancy; and *d)* an anatomical variant of the median nerve such as a proximal bifurcation at the entrance of the tunnel.

The diagnosis of CTS was based on the criteria of the American Academy of Neurology,[16] and the EMG was considered as the reference test.

The EMG was carried out in a standardized mannerin order to regiter the following parameters: sensory conduction velocity (m/s), distal motor latency (ms), and sensory distal latency (ms). The final evaluation of the neurophysiologist was also considered (normal, mild, mild-moderate, and severe). The echographic examination was carried out in the 72 hours after the EMG; a General Electric Logic 5 Pro machine, with a 12 MHz linear probe was employed. The acquisition of images was carried out by 3 rheumatologists in a consecutive, blinded, and independent manner, one of them experimented in osteo-muscular echography, and 2 fourth year rheumatology residents with basic notions of echography and a specific 6-hour training. Images of all of the representative cuts were archived. Patients were asked not to comment on their symptoms during the examination. This was carried put with the patient seated while facing the echographer, with the forearm on the table, and the palm facing upward. The median nerve was examined in all of its extension through the carpal tunnel in a transversal and longitudinal manner. Images were obtained in 3 topographical areas: at the radio-ulnar joint, at the capitate bone, and distal to it (proximal, medial, and distal levels, respectively). In each one of these regions the following were measured: TSA, calculated with digital markers that trace the nerve margin internal to the perineurium; the degree of swelling (medial TSA/distal TSA); the palmar displacement, measured as the distance between a line that joins the upper edge of the trapezium and the hamate and the apex of the flexor retinaculum, and the major and minor transverse axis. The results of each examination were employed to estimate the agreement between observers and the images stored were used to evaluate the agreement between readers. Two of the participating rheumatologists carried out an evaluation among readers 1 month after obtaining the images that consisted in re-reading all of the images obtained by the 3 examiners.

To carry out the satisfaction study the lack of comfort perceived by the patient, both in the echography and the EMG was evaluated through visual analog scales (VAS) from 0 (no pain or lack of comfort) to 100 (unbearable pain). The costs of EMG and echography were calculated according to those published in the Boletín Oficial del Estado Español (BOE 2006; 62:10.172-86).

The results are shown as a mean (standard deviation [SD]). The relation between echography and EMG was evaluated using lineal regression analysis. The association between the values of the echography and the diagnosis of CTS was measured with logistical univariate or multivariate models, and the ROC curves were employed to determine the cutpoints of larger sensitivity and specificity. Interclass correlation coefficients (ICC) were used to determine the agreement between observers and readers. Means of perceived lack of comfort between the EMG and the echography were compared using the Student's *t* test for paired studies. A P value lesss than .05 was considered significant.

Results

Patient Characteristics

Forty-two patients and 75 symptomatic wrists were examined: 37 (88.1%) women and 5 (11.9%) men, with

TABLE 1. Echographic Measures According to Gender

	Gender	No.	Mean (Standard Deviation)
Mean proximal area	Women	36	11.17 (2.62)
	Men	5	11.95 (5.49)
Mean medial area	Women	37	11.28 (2.91)
	Men	5	13.60 (7.99)
Mean distal area	Women	36	12.06 (4.28)
	Men	5	14.15 (9.08)
Mean major axis	Women	36	62.15 (10.59)
	Men	5	64.35 (21.77)
Mean minor axis	Women	36	22.57 (3.76)
	Men	5	24.40 (8.99)
Mean quotient swelling	Women	11	6.07 (1.22)
	Men	2	4.46 (1.86)
Mean displacement palmar	Women	27	39.60 (10.27)
	Men	3	37.42 (20.49)

TABLE 2. Echographic Measures by Wrist (Right/Left)

	Carpus	No.	Mean (Standard Deviation)
Mean proximal area	Right	41	10.98 (3.22)
	Left	29	10.55 (3.21)
Mean medial area	Right	42	11.39 (3.86)
	Left	29	10.71 (3.25)
Mean distal area	Right	41	12.16 (4.89)
	Left	29	11.61 (5.01)
Mean major axis	Right	41	61.09 (12.76)
	Left	29	60.78 (11.87)
Mean minor axis	Right	41	22.99 (4.60)
	Left	29	21.42 (3.62)
Mean quotient swelling	Right	13	5.87 (1.58)
	Left	6	5.78 (0.83)
Mean displacement palmar	Right	30	39.59 (11.53)
	Left	23	35.23 (9.38)

a mean age of 47.5 (12.1) (21-74) years. Seventy one carpus were examined, 29 (40.8%) were bilateral. Four carpus were excluded due to bifurcated median nerves. Sixty seven point six per cent of the studied carpus had CTS compatible signs.

Association of Echographic Measurements and Descriptive Variables

Although superior measurements were found in males and on the right side, these differences were not statistically significant (Tables 1 and 2).

Validity Study

Echographic measurements in patients with and without CTS are presented on Table 3. In it one can observe that the means of all of the echographic parameters evaluated were significantly higher in the EMG positive group, excepting the swelling index that does not reach statistical significance.

With the object of studying if there was a grading of the echographic findings, compared to the CTS diagnosis made through EMG, these were regrouped as: mild CTS and >mild CTS (any degree of severity over mild). The findings showed significant increments in the proximal area, medial area, distal area, and major axis measurements ($P<.001$), and palmar displacement ($P<.05$). Through logistical bivariate models we calculated the odds ratio for patients with and without CTS: proximal area, 1.629 (95% confidence interval [CI], 1.247-2.127); medial area, 1.582 (95% CI, 1.235-2.028); distal area, 1.700 (95% CI, 1.280-2.258); maximum area, 1.680 (95% CI, 1.287-2.197); major axis, 1.120 (95% CI, 1.048-1.197); minor axis, 1.176 (95% CI, 1.015-1.361). Or, to explain it another way, in mild CTS an increase of 1 mm^2 in the area (or 1 mm in the axis) corresponds to an increase in the risk of mild CTS from 12% for the major axis to 70% for the distal area.

We then studied the correlation between echographical and electromyographical measures, finding a significant negative association between the area determined by echography (proximal, medial, or distal) and the conduction velocity, sensitive latency, and motor latency. Spearman's rho, always with a $P<.0001$, was: *a)* for the proximal area versus the conduction velocity −0.608, versus the mean sensitivity latency 0.575 and versus the mean motor latency −0.579; *b)* for the medial area versus the conduction velocity −0.633, versus the mean sensitive latency 0.624 and versus the mean motor latency −0.585; *c)* for the distal area versus the conduction velocity −0.658, versus the mean sensitive latency 0.627 and versus the mean motor latency −0.597.

Through the regression analysis we quantified the reduction in the conduction velocity for each mm^2 of increment in each one of the studied areas and therefore, a reduction in 1.7 m/s corresponded to an increase of 1 mm^2 in the proximal area and 0.994 m/s to an increase of 1 mm^2 in the distal area. Changes in the velocity of conduction, the mean sensitive latency and the mean motor latency for an increase of 1 mm^2 of area are shown accompanied with the 95% CI in Table 4.

For the sensitivity and specificity analysis and taking into account the result of the previous regression, ROC curves have been constructed for each one of the measures in

TABLE 3. Echographic Measures in Patients With or Without CTS in EMG[a]

	CTS by EMG					
	No		Yes			
	No.	Mean (SD)	No.	Mean (SD)	t	*P*
Mean proximal area	22	8.49 (2.04)	48	11.86 (3.09)	−4.668	.000
Mean medial area	22	8.72 (2.33)	48	12.27 (3.57)	−4.332	.000
Mean distal area	22	8.69 (2.16)	48	13.42 (5.11)	−4.157	.000
Mean major axis	22	53.06 (8.94)	48	64.58 (12.01)	−4.013	.000
Mean minor axis	22	20.59 (3.48)	48	23.15 (4.38)	−2.410	.019
Mean swelling quotient	22	6.40 (1.17)	48	5.44 (1.41)	1.571	.135
Mean palmar displacement	22	30.37 (8.35)	48	40.59 (10.32)	−3.414	.001

[a]CTS indicates carpal tunnel syndrome; EMG, electromyography; SD, standard deviation.

which significant association was found between the measure and the CTS diagnosis (Table 5). Sensitivity and specificity for the different cutpoints of the distal area can be appreciated in Table 6.

Of the localizations studied, the one associated with a larger sensitivity and the same specificity is the distal area and, in second place, the maximum area of the 3 considered. The best cutpoint, established through the ROC curve was 9.5 mm^2 of the distal area, which correctly classifies 81% of patients.

The inclusion into a predictive logistical model of CTS of other areas (proximal, medial, or major of the 3 measurements), or of the symptoms or clinical signs, did not improve the prediction capacity with respect to the distal area by itself.

In the agreement analysis, a study was carried out among the observers and another among the reader, and both results were always excellent. In the study between observers there were 3 persons participating with the following results: the ICC between examiner 1 and 2 was 0.915 (95% CI, 0.836-0.936), of examiners 2 and 3 it was 0.966 (95% CI, 0.911-0.987), and for examiners 1 and 3 it was 0.980 (95% CI, 0.947-0.993). We then analyzed the interclass correlation between readers, in which the agreement between 2 readers who reread all of the obtained images obtained by each one of the 3 examiners, with an agreement among readers of 0.961 (95% CI, 0.930-0.977).

Cost Study

The cost of the electrodiagnostic study in the carpal tunnel syndrome was 86.52 euros, while the cost of an echographic study of a peripheral nerve was 34.39 euros (BOE 2006; 62:10.172-86), making the echographic study 2.5 times cheaper than an electrodiagnostic test. In the 9.5 mm^2 cutpoint, the sensitivity is similar to electrophysiology, though it has a reduced specificity. In the areas near the cutpoint, normally patients with a mild degree of CTS who undergo conservative treatment, a cost-effectiveness study of the echography would be a valid tool. For this cutpoint and if we take into account the sensitivity and specificity as clinically adequate, the savings would be 71×52.13=3701.23 euros, minus the cost of examination of the 4 bifurcated median nerves which would have to be re-explored through EMG, which translates into 3217.59 euros saved.

TABLE 4. Regression Equation Coefficient of the Echographic Findings With the Electromyographic Variables[a]

	Median Conduction Velocity		Mean Sensitive Latency		Mean Motor Latency	
Area	β	95% CI	β	95% CI	β	95% CI
Proximal	−1.691	(−2.348 to −1.034)	.213	(0.124-0.301)	−1.552	(−2.266 to −0.838)
Medial	−1.475	(−2.064 to −0.886)	.190	(0.111-0.268)	−1.153	(−1.809 to −0.496)
Distal	−0.994	(−1.399 to −0.589)	.132	(0.079-0.184)	−0.743	(−1.214 to −0.272)
Maximum area	−1.006	(−1.423 to −0.590)	.135	(0.082-0.189)	−0.785	(−1.262 to −0.308)

[a]CI indicates confidence interval.

TABLE 5. Cutpoints Chosen Over the Coordinates of the ROC Curve. Sensitivity and Specificity for the Chosen Cutpoint[a]

		Diagnosis of CTS				
Localization	Cutpoint, mm^2	Sensitivity, %	Specificity, %	Correct Classification, %	Positive LR	Negative LR
Proximal area	9.5	79.59	66.67	75.34	2.3878	0.3061
Medial area	9.5	81.63	65.38	76.00	2.3583	0.2809
Distal area	9.5	87.76	66.67	80.82	2.6327	0.1837
Maximum area	9.5	87.76	61.54	78.67	2.2816	0.1990

[a]CTS indicates carpal tunnel syndrome.

Study of Perceived Quality

In the analysis of comfort of the test on the part of the patient, we compared both procedures: EMG and echography. The mean values of VAS (0-100) for EMG were 56.0 (26.7), and for echography were 6.3 (13.2) (P<.0005).

Discussion

In the past years we have passed from talking about the usefulness of echography in the rheumatology practice to publishing studies in which its validity is adequately analyzed.[3,6,7,9,11-15,17,18]

The validity of echography in CTS agglutinates a group of studies, which lead us to provide this test with a coherent theoretical basis regarding the use that we wish to give it. The validity of the criteria, in other words, is the degree in which the measure that our tests reflect the admitted standards has been investigated for some time. The references employed have been both the electromyographic findings and the clinical findings.[5-15]

In our case we have compared the echographic variables with the electrophysiologic as a standard in many ways. First, we compared patients with a positive and a negative EMG, and compared it finding a statistically significant difference in the measurements studied (Table 3), and then we analyzed the sensitivity and specificity of the test (Tables 5 and 6). In the medical literature there is a great discrepancy regarding the cutpoints that must be applied in the echographic diagnosis of CTS. Because of this we studied the sensitivity and specificity for different parameters and the cutpoint values for the transversal section area of the median nerve that could be used to confirm or rule out CTS through ROC curves. An area of 9.5 mm^2 classifies correctly 81% of our patients, while values <7 mm^2 and >14 mm^2 reach a 100% sensitivity and specificity, respectively. These results coincide with the series and reviews on the literature published by Beekman et al,[19] that show, in a post hoc analysis, critical values that vary from 9 to 15 mm^2, with sensitivities of 0.70-0.88 and specificities of 0.57-0.97.[5-15] Although there are significant differences between patients and healthy controls in numerous studies, there is considerable overlapping in the nerve caliber in patients with mild CTS and normal subjects. The moderate specificity of echography in mild cases reveal the fact that the diagnosis of CTS must not be done in the absence of typical signs and that in these cases the electromyography is probably necessary in the presence of symptoms.

Regarding the validity of the construct, our results are consistent showing a linear relationship between the increase in the area of the median nerve and the alterations in the conduction velocity, the motor and sensitive latency, something seen in other studies.[3,13,14,18]

Another aspect that was analyzed was agreement. In this sense our study is breaking new ground by analyzing aspects seldom studied. In previous studies we found a good correlation with the reader.[17,18] Wong et al[15] analyzed the agreement between the readers in only 8 patients, with coefficients of 0.71-0.90. The present study analyzes the agreement between observers and readers and evaluates whether a strictly standardized technique is enough to reach a good agreement in persons with a basic knowledge

Figure. *Transverse cut of the median nerve.*

of echography, something important in order to generalize the use of echography as a diagnostic tool in CTS. The excellent results that were obtained of reading by the 2 supposedly inexperienced rheumatologists (residents in their last year of the specialty) probably reflect the trustworthiness of the standardization of measurement techniques. As for the agreement among examiners, CCI varied between 0.912 and 0.987, without finding significant differences in the inexperienced echographers and the expert in image capture. This correlation shows that echography is useful and easily reproduced in the diagnosis of CTS when a standardized training is previously carried out

Another obvious advantage of echography over EMG is that it does not cause pain; no previous studies have examined this though. Our results confirm that

TABLE 6. ROC Curve for the Distal Area[a]

Cutpoint	Sensitivity	Specificity	Correct Classification	LR+	LR–
(≥6.5)	100%	16.67%	72.60%	1.2000	0.0000
(≥7)	97.96%	16.67%	71.23%	1.1755	0.1224
(≥7.25)	97.96%	20.83%	72.60%	1.2374	0.0980
(≥7.5)	95.92%	20.83%	71.23%	1.2116	0.1959
(≥7.75)	93.88%	25.00%	71.23%	1.2517	0.2449
(≥8)	91.84%	29.17%	71.23%	1.2965	0.2799
(≥8.25)	91.84%	37.50%	73.97%	1.4694	0.2177
(≥8.75)	89.80%	45.83%	75.34%	1.6578	0.2226
(≥9)	89.80%	54.17%	78.08%	1.9592	0.1884
(≥9.25)	87.76%	62.50%	79.45%	2.3401	0.1959
(≥9.5)	87.76%	66.67%	80.82%	2.6327	0.1837
(≥9.75)	81.63%	66.67%	76.71%	2.4490	0.2755
(≥10)	77.55%	66.67%	73.97%	2.3265	0.3367
(≥10.25)	73.47%	70.83%	72.60%	2.5190	0.3745
(≥10.5)	73.47%	79.17%	75.34%	3.5265	0.3351
(≥10.75)	69.39%	79.17%	72.60%	3.3306	0.3867
(≥11)	63.27%	79.17%	68.49%	3.0367	0.4640
(≥11.25)	61.22%	83.33%	68.49%	3.6735	0.4653
(≥11.5)	59.18%	87.50%	68.49%	4.7347	0.4665
(≥11.75)	59.18%	91.67%	69.86%	7.1020	0.4453
(≥12)	57.14%	95.83%	69.86%	13.7143	0.4472
(≥12.25)	53.06%	95.83%	67.12%	12.7347	0.4898
(≥12.5)	46.94%	95.83%	63.01%	11.2653	0.5537
(≥13)	42.86%	95.83%	60.27%	10.2857	0.5963
(≥13.25)	34.69%	95.83%	54.79%	8.3265	0.6815
(≥13.75)	30.61%	100%	53.42%	0.6939	
	ROC			Normal Asymptomatic	
Obs	Area		Standard Error		95% CI
73	0.8295		0.0486		0.73420-0.92481

[a]CI indicates confidence interval.

echographic examination is considered as a less painful and more comfortable procedure (VAS 6.3 vs 56 mm) and should be considered at least in those patients who reject EMG.

As for the cost, echography represents an economical saving. One point of criticism is that echography would only absolutely confirm the CTS with an area of ≥13.5 mm^2, and would only rule it out when ≤7 mm^2. In the intermediate values, and with the appropriate clinical findings, patients could be treated in a conservative way because they are normally graded as mild, or they could be referred for an EMG. These results are similar to those by Wong et al[15] and Ziswiler et al.[14] If 100% sensitivity and specificity criteria want to be employed, the number of saved proofs would be less, but even then echography can be used as a rapid screening test.

This study contributes new data on reader and observer agreement, demonstrating that a fast and standardized learning process of the technique reaches good results, confirms validity and economical efficiency data and, finally purveys data on patient satisfaction and test tolerability.

In conclusion, in this study we demonstrate that echographic examination is a useful and valid tool to confirm the clinical suspicion of CTS. The measurement of the transversal surface area is a sensitive, specific, trustworthy and non-invasive method for the diagnosis of carpal tunnel syndrome and it does not depend importantly on experience if a standardized technique is employed.

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