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Golden Standard in Diagnosing Carpal Tunnel Syndrome: A Systematic Review and Meta-Analysis

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ABSTRACT

Introduction: Carpal tunnel syndrome (CTS) is characterized by symptoms like numbness, tingling, and pain due to median nerve compression at the wrist. Electromyography (EMG) has been the gold standard for diagnosis, but studies show ultrasound's comparable accuracy. High-resolution sonography effectively diagnoses CTS, and virtual touch tissue imaging quantification and 2D sonography evaluate median nerve stiffness. Accurate diagnosis is essential for proper management and treatment. This study aims to compare the diagnostic accuracy of ultrasound, EMG, and other potential diagnostic methods in identifying CTS, to determine the most effective diagnostic approach.

Methods: For this study, searches were conducted in PubMed/MEDLINE, SCOPUS, and the Europe PMC databases to identify relevant articles. The following keywords were used: "carpal tunnel syndrome," "diagnosis," "ultrasound," "electromyography," "diagnostic accuracy," "sensitivity," and "specificity." Boolean operators (AND, OR) were used to combine these search terms. The primary outcome was the diagnostic accuracy of all modalities in diagnosing CTS. This had to be reported with diagnostic accuracy metrics, such as sensitivity, specificity, and others. In cases where a study did not report these metrics, they were calculated retrospectively.

Results: The total cohort consisted of 4704 individuals, while the total number of wrists studied was 5821, with 1725 participants being male. EMG demonstrated a sensitivity of 0.90 (95% CI: 0.84 to 0.95) and a specificity of 0.75 (95% CI: 0.53 to 0.98).

Conclusions: Our meta-analysis explores CTS diagnostic accuracy. EMG and ultrasound seem most accurate, but further research and addressing study limitations are needed.

Keywords: carpal tunnel syndrome, sensitivity, specificity, electromyography

INTRODUCTION

CTS is a prevalent condition characterized by symptoms such as numbness, tingling, and pain due to compression of the median nerve at the wrist.[1] Various diagnostic methods have been explored to establish a gold standard for diagnosing CTS. Electrophysiological studies, particularly EMG, have traditionally been considered the gold standard for diagnosing CTS.[1,2] However, studies have shown that ultrasound can be as accurate as magnetic resonance imaging and neurophysiological studies in diagnosing CTS, with high sensitivity and specificity. High-resolution

sonography has been found to effectively diagnose median nerve compression in CTS and identify potential causes.[2] Additionally, virtual touch tissue imaging quantification and 2D sonography have shown diagnostic value in evaluating median nerve stiffness and diagnosing CTS.[2]

While electrodiagnostic tests are accurate, they may miss a significant percentage of CTS cases depending on disease severity or testing methods.[3] The nerve or tunnel index, a diagnostic standard based on sonography, has been proposed as an objective measure for diagnosing CTS, unaffected by body indices or sex. Ultrasonography has also been utilized to diagnose CTS, with a median nerve area of 9 mm^2 or more considered diagnostic of the condition.[3] Furthermore, a logistic regression analysis identified the Boston Carpal Tunnel Questionnaire as a standardized tool for assessing patient-reported outcomes in CTS diagnosis.[4,5]

Accurate diagnosis is crucial for appropriate management and treatment. While EMG has traditionally been considered the gold standard for diagnosing CTS, recent studies suggest that ultrasound may offer comparable accuracy.[5] This study aims to compare the diagnostic accuracy of ultrasound, EMG, and other potential diagnostic methods in identifying CTS, to determine the most effective diagnostic approach. By identifying the most accurate diagnostic method, this research could contribute to improved clinical practice and better outcomes for patients with CTS.

MATERIALS & METHODS

The systematic review protocol was not registered with the recognized research protocol registry, PROSPERO, before the study commenced; however, it adhered to the PRISMA guideline.[6] No external financial assistance was received to conduct this meta-analysis. The methodology employed in this study followed a structured and transparent approach to the systematic review process.

For this study, searches were conducted in PubMed/MEDLINE, SCOPUS, and the Europe PMC databases to identify relevant articles. The following keywords were used: "*carpal tunnel syndrome*," "*diagnosis*," "*ultrasound*," "*electromyography*," "*diagnostic accuracy*," "*sensitivity*," and "*specificity*." Boolean operators (AND, OR) were used to combine these search terms. Additionally, the reference lists of relevant articles were manually searched for additional studies. The detailed search strategy is displayed in Table 1.

Table 1. Keywords employed in each database to retrieve studies.

Database	Search strategy
PubMed	((("phalen"[All Fields] OR "phalen s"[All Fields]) AND ("research design"[MeSH Terms] OR ("research"[All Fields] AND "design"[All Fields]) OR "research design"[All Fields] OR "test"[All Fields])) OR (("tinel"[All Fields] OR "tinel s"[All Fields]) AND ("research design"[MeSH Terms] OR ("research"[All Fields] AND "design"[All Fields]) OR "research design"[All Fields] OR "test"[All Fields])) OR (("provocated"[All Fields] OR "provocating"[All Fields] OR "provocation"[All Fields] OR "provocational"[All Fields] OR "provocations"[All Fields] OR "provocative"[All Fields]) AND ("research design"[MeSH Terms] OR ("research"[All Fields] AND "design"[All Fields]) OR "research design"[All Fields] OR "test"[All Fields])) OR ("electromyography"[MeSH Terms] OR "electromyography"[All Fields] OR "electromyographies"[All Fields]) OR ("diagnostic imaging"[MeSH Subheading] OR ("diagnostic"[All Fields] AND "imaging"[All Fields]) OR "diagnostic imaging"[All Fields] OR "ultrasound"[All Fields] OR "ultrasonography"[MeSH Terms] OR "ultrasonography"[All Fields] OR "ultrasonics"[MeSH Terms] OR "ultrasonics"[All Fields] OR "ultrasounds"[All Fields] OR "ultrasound s"[All Fields])) AND ("carpal tunnel syndrome"[MeSH Terms] OR ("carpal"[All Fields] AND "tunnel"[All Fields] AND "syndrome"[All Fields]) OR "carpal tunnel syndrome"[All Fields]) AND ((("diagnosis"[MeSH Terms] OR "diagnosis"[All Fields] OR "diagnostic"[All Fields] OR "diagnostical"[All Fields] OR "diagnostically"[All Fields] OR "diagnostics"[All Fields]) AND ("accuracies"[All Fields] OR "accuracy"[All Fields])) OR ("sensitive"[All Fields] OR "sensitively"[All Fields] OR "sensitives"[All Fields] OR "sensitivities"[All Fields] OR "sensitivity and specificity"[MeSH Terms] OR ("sensitivity"[All

	Fields] AND "specificity"[All Fields]) OR "sensitivity and specificity"[All Fields] OR "sensitivity"[All Fields]) OR ("sensitivity and specificity"[MeSH Terms] OR ("sensitivity"[All Fields] AND "specificity"[All Fields]) OR "sensitivity and specificity"[All Fields] OR "specificity"[All Fields] OR "specific"[All Fields] OR "specifically"[All Fields] OR "specification"[All Fields] OR "specifications"[All Fields] OR "specificities"[All Fields] OR "specifics"[All Fields] OR "specifities"[All Fields] OR "specifity"[All Fields]))
Europe PMC	phalen test OR tinel test OR provocative test OR Electromyography OR ultrasound AND carpal tunnel syndrome AND diagnostic accuracy OR sensitivity OR specificity
SCOPUS	phalen test OR tinel test OR provocative test OR Electromyography OR ultrasound AND carpal tunnel syndrome AND diagnostic accuracy OR sensitivity OR specificity

The study identification phase commenced with a thorough exploration of electronic databases, supplementary sources, and alternative channels to identify potential studies by all reviewers independently. All identified records underwent meticulous documentation, removal of duplicates, followed by a detailed examination of titles and abstracts to exclude studies that did not meet the predefined inclusion criteria. The eligibility assessment proceeds with a full-text evaluation of the remaining studies, documenting reasons for exclusion and explicitly reporting the number of studies excluded. Any disagreements between reviewers were resolved through discussion.

The primary outcome was the diagnostic accuracy of all modalities in diagnosing CTS. This had to be reported with diagnostic accuracy metrics, such as sensitivity, specificity, and others. In cases where a study did not report these metrics, they were calculated retrospectively.

For each included study, data were extracted on study characteristics including author(s), year of publication, study design, setting, sample size, and duration of follow-up if applicable. Participant characteristics such as age, gender, clinical symptoms of carpal tunnel syndrome, and inclusion/exclusion criteria were recorded. Diagnostic methods, including details on ultrasound (type and criteria used), electromyography (type and criteria used), and any other diagnostic methods employed were extracted. Diagnostic accuracy measures including sensitivity, specificity, positive predictive value, negative predictive value, and area under the receiver operating characteristic curve (AUC) were recorded. Statistical analysis methods, any adjustments for potential confounders, and results including diagnostic accuracy of each method, statistical comparisons between methods, and subgroup analyses if applicable were documented. The conclusion section, funding sources, and any reported conflicts of interest were also included in the data extraction.

The quality of the primary diagnostic accuracy studies was evaluated using the QUADAS-2 tool, which consists of four domains: patient selection, index test, reference standard, and flow of patients through the study, including the timing of the index test(s) and reference standard. Each domain was assessed for potential bias, and domains i) to iii) were also evaluated for their relevance to the review question.[7] Two assessors independently conducted the risk of bias assessment, resolving any discrepancies through consensus. In cases where consensus could not be reached, a third reviewer made the final decision.

In our data analysis, we utilized RStudio version 3.6.0. We employed a random effects bivariate binomial model and applied the generalized linear mixed-effects model using the glmer function from the lme4 package. This model concurrently estimates sensitivity and specificity, assuming that the estimates from individual studies exhibit variability but share a common underlying distribution with an unstructured between-study covariance matrix. It is important to note that the bivariate model is mathematically equivalent to the Hierarchical Receiver Operating Characteristic (HSROC) model. Consequently, the HSROC parameters were derived by utilizing the parameters from the

bivariate model and the equivalence equations outlined by Harbord et al. These HSROC parameters were used to generate the Summary Receiver Operating Characteristic (SROC) plot. Additionally, positive and negative likelihood ratios, along with the diagnostic odds ratio, were directly computed from the logit sensitivity and logit specificity estimates. Confidence intervals were determined using the delta method, with the R package msm. The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

RESULT

Records were identified from multiple sources, including PubMed (n = 786), Europe PMC (n = 136), and SCOPUS (n = 77). Before screening, duplicate records were removed, resulting in the elimination of 56 duplicate records. A total of 943 records were screened, with 892 records excluded during this process. Following screening, 51 reports were identified for retrieval, out of which 50 reports were retrieved and assessed for eligibility. Reports were excluded for various reasons, including failure to report diagnostic accuracy parameters or unavailability of the confusion matrix (n = 6), inclusion as meeting abstracts (n = 1), and inaccessibility due to outdated manuscripts (n = 1). Ultimately, 42 studies met the inclusion criteria and were included in the review.[8–50]

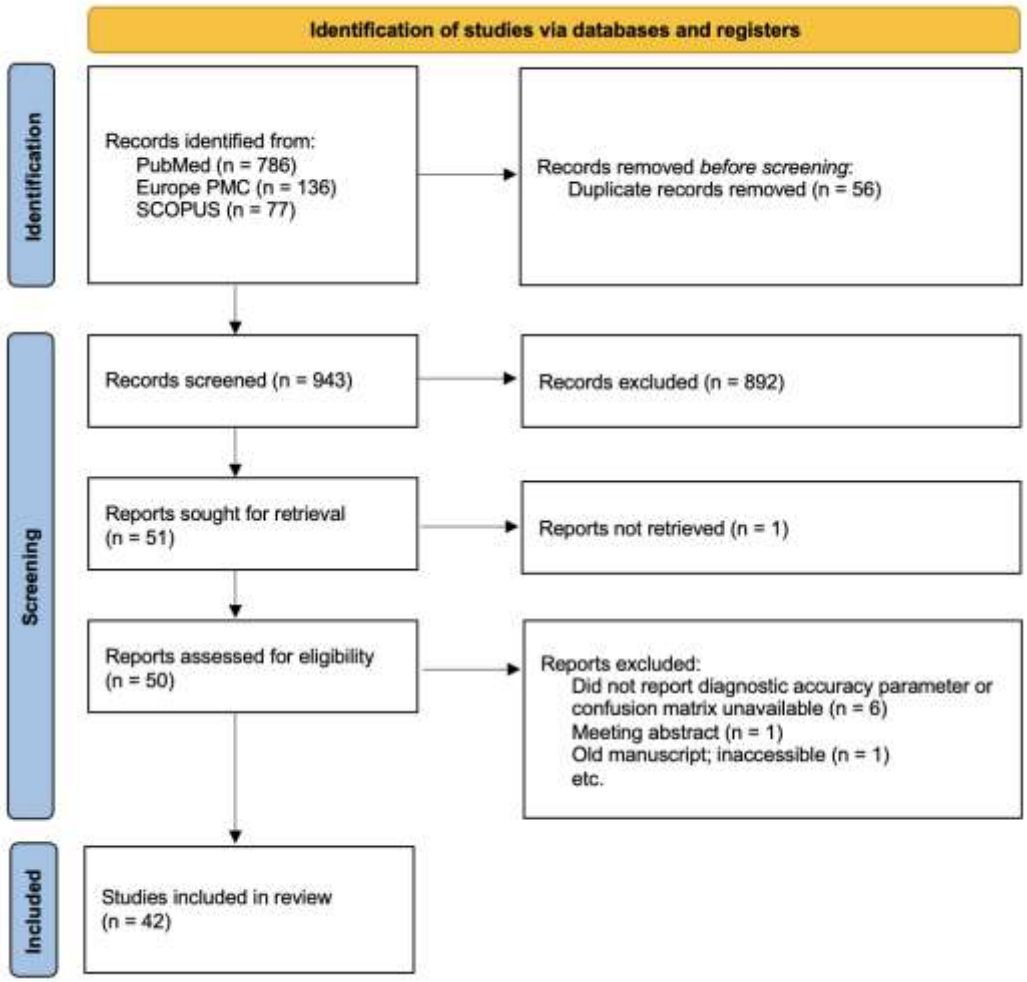

Figure 1. The PRISMA flowchart illustrates the process of study selection from PubMed, Europe PMC, and SCOPUS.

The total cohort consisted of 4704 individuals, while the total number of wrists studied was 5821, with 1725 participants being male. The studies included in the list encompass various research designs. These include one randomized controlled trial, and a mix of retrospective cohort studies, case-control studies, and prospective cohort studies. The diagnostic tests used in the studies included ultrasound, Tinel test, Phalen test, Durkan test, Gilliatt test, Flick test, scratch-collapse test, lumbrical test, tethered median nerve stress test, upper limb tension test, carpal compression test, pressure provocation test, and Hoffman-Tinel test, with electromyography (EMG) and ultrasound being the reference tests.

Table 2. Demographic characteristics of included studies

Study ID	Study design	Total cohort, n	Total wrist, n	Total male, n	Diagnostic test	Reference test
Wainner 2000	Prospective cohort	52	55	n.r.	Carpal compression test and Durkan test	EMG
Martic 2015	Prospective cohort	181	n.r.	100	Tinel test and Flick test	EMG
Naranjo 2007	Prospective cohort	68	105	n.r.	Tinel test and Phalen test	Ultrasound
Walters 2002	Prospective cohort	55	77	n.r.	Tinel test and Phalen test	EMG
El-Shintenawy 2019	Retrospective cohort	40	56	1	Ultrasound	EMG
Swen 2001	Retrospective cohort	63	n.r.	19	Ultrasound	EMG
El Miedany 2004	Case control v	78	96	27	Ultrasound	EMG
Pimentel 2018	RCT	115	n.r.	0	Ultrasound	EMG
Visser 2007	Prospective cohort	168	n.r.	39	Ultrasound	EMG
Filho 2014	Retrospective cohort	56	70	2	Tinel test, Durkan test, and Phalen test	EMG and ultrasound
El Badry 2016	Prospective cohort	100	n.r.	24	Ultrasound	EMG
Kale 2003	Retrospective cohort	77	110	18	Ultrasound	EMG
Azami 2014	Retrospective cohort	90	120	7	Ultrasound	EMG
Fowler 2014	Retrospective cohort	85		31	Ultrasound	EMG
Moran 2009	Prospective cohort	46	70	6	Ultrasound	EMG
Amo 1998	Prospective cohort	57	100	n.r.	Tinel test and Phalen test	EMG
O'Gradaigh 2000	Prospective cohort	105	n.r.	n.r.	Tinel test and Phalen test	EMG
Raudino 2000	Prospective cohort	83	140	n.r.	Tinel test, Phalen test, and tethered median nerve stress test	EMG
Bilkis 2012	Prospective cohort	37	66	11	Phalen test	EMG
Blok 2013	Prospective cohort	41	n.r.	13	Scratch-collapse test	EMG
Buch-Jager 1994	Prospective cohort	112	172	4	Phalen test, Tinel test and Gilliatt test	EMG

Dale 2011	Prospective cohort	1108	2216	720	Tinel test and Phalen test	EMG
Denham 2015	Prospective cohort	18	30	n.r.	Phalen test	EMG
Franzblau 1993	Prospective cohort	130	260	65	Tinel test and Phalen test	EMG
Hansen 2004	Prospective cohort	142	n.r.	60	Flick test, Tinel test, and Phalen test	EMG
Heller 1986	Prospective cohort	60	80	n.r.	Tinel test and Phalen test	EMG
Karl 2001	Prospective cohort	96	96	90	Lumbrical test	EMG
Katz 1990	Prospective cohort	110	220	37	Tinel test and Phalen test	EMG
Kaul 2000	Prospective cohort	112	n.r.	97	Tethered median nerve stress test	EMG
Simon 2017	Prospective cohort	40	40	11	Scratch-collapse test	EMG
Szabo 1999	Prospective cohort	87	100	n.r.	Tinel test, Durkan test, and Phalen test	EMG
Kaul 2001	Prospective cohort	269	269	241	Carpal compression test and pressure provocation test	EMG
Kuhlman 1997	Prospective cohort	143	228	n.r.	Phalen test and Hoffman-Tinel test	EMG
Lajoie 2005	Retrospective cohort	81	162	24	Tinel test and Phalen test	EMG
MacDermid 1997	Prospective cohort	42	84	n.r.	Tinel test, Phalen test, and tethered median nerve stress test	EMG
Makanji 2013	Prospective cohort	88	n.r.	33	Scratch-collapse test	EMG
Kwon 2008	Case control	29	41	4	Ultrasound	EMG
Sawaya 2009	Prospective cohort	27	45	5	Phalen test	EMG
Trillos 2016	Prospective cohort	118	230	20	Upper limb tension test	EMG
Yilmaz 2002	Prospective cohort	188	346	n.r.	Tinel test and Phalen test	EMG
Zaher 2012	Prospective cohort	52	52	n.r.	Tinel test and Phalen test	EMG
Zhang 2020	Prospective cohort	55	85	16	Tinel test, Durkan test, and Phalen test	EMG

Various modalities for diagnosing carpal tunnel syndrome were evaluated for their sensitivity and specificity. EMG demonstrated a sensitivity of 0.90 (95% CI: 0.84 to 0.95) and a specificity of 0.75 (95% CI: 0.53 to 0.98). The Phalen test showed a sensitivity of 0.56 (95% CI: 0.44 to 0.68) and a specificity of 0.64 (95% CI: 0.48 to 0.80), while the Tinel test demonstrated a sensitivity of 0.46 (95% CI: 0.33 to 0.58) and a specificity of 0.73 (95% CI: 0.59 to 0.88). Ultrasound exhibited a sensitivity of 0.80 (95% CI: 0.73 to 0.87) and a specificity of 0.86 (95% CI: 0.78 to 0.94). Detailed meta-analysis is presented from figure 2 – 9.

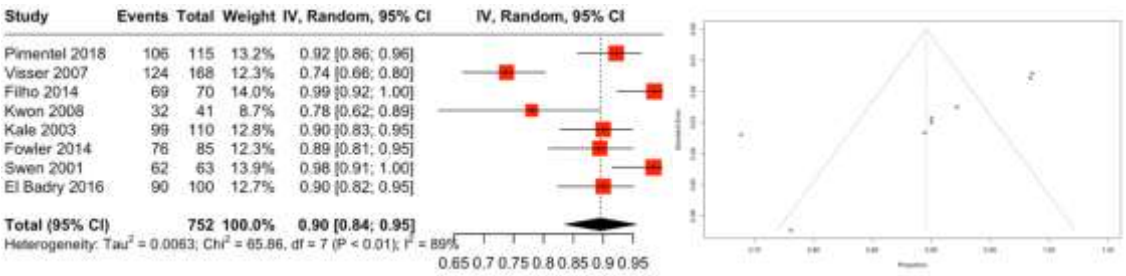

Figure 2. Meta analysis of EMG sensitivity

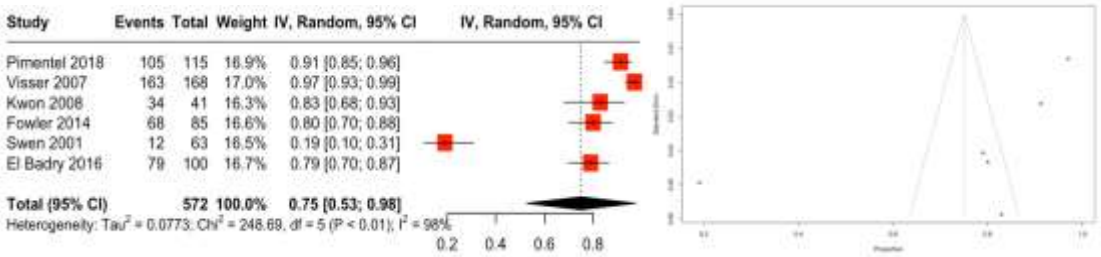

Figure 3. Meta analysis of EMG specificity

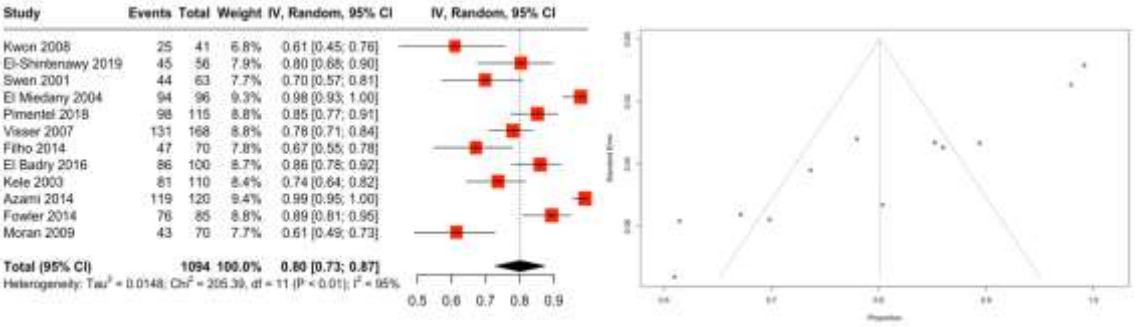

Figure 4. Meta analysis of ultrasound sensitivity

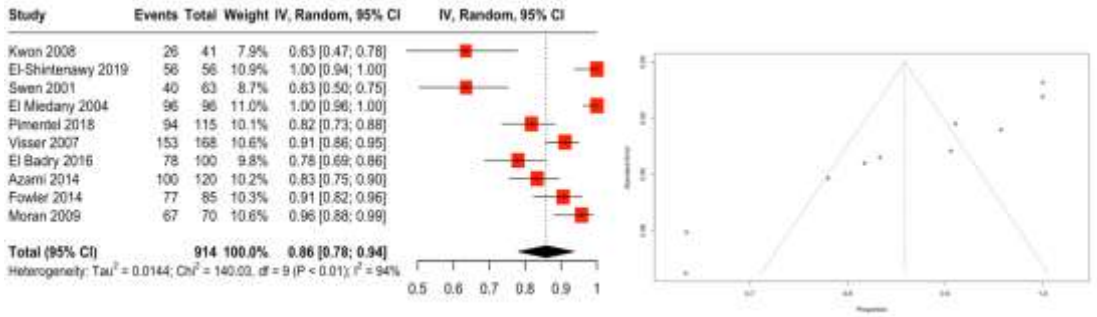

Figure 5. Meta analysis of ultrasound specificity

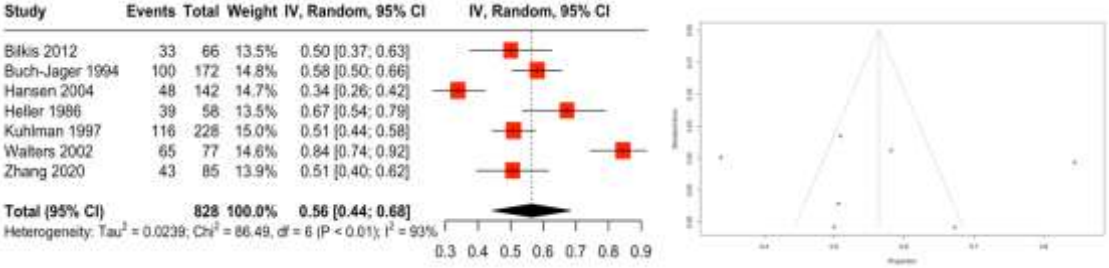

Figure 6. Meta analysis of Phalen test sensitivity

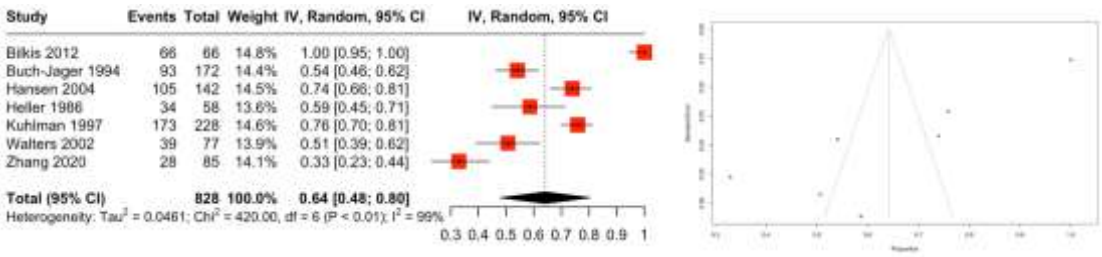

Figure 7. Meta analysis of Phalen test specificity

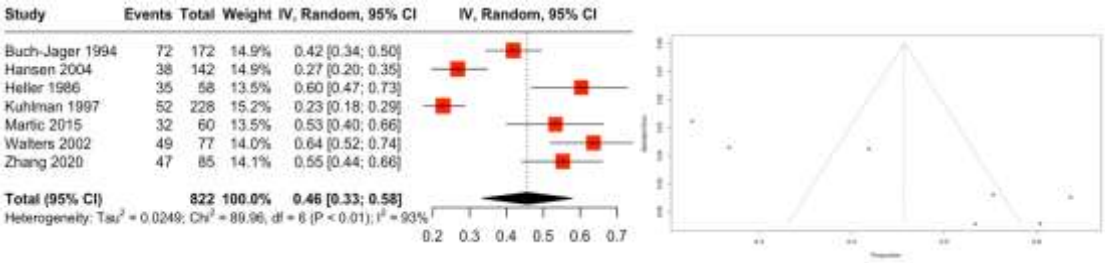

Figure 8. Meta analysis of Tinel test sensitivity

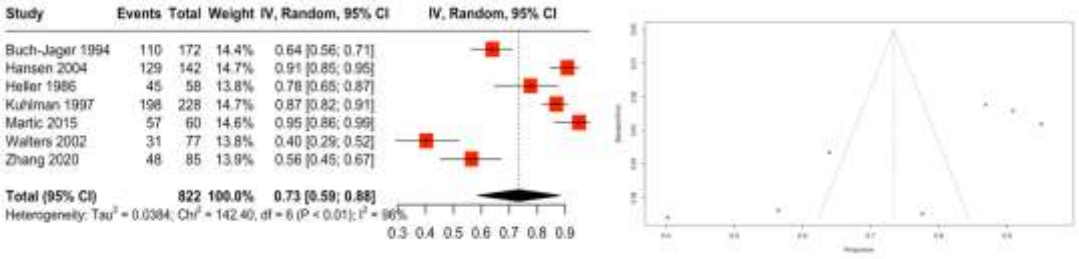

Figure 9. Meta analysis of Tinel test specificity

In terms of QUADAS-2, all included studies were of medium to high risk of bias. Detailed is presented in Figure 10.

Figure 10. QUADAS-2 assessment for risk of bias of included studies.

DISCUSSION

CTS is a prevalent condition with significant implications for affected individuals and society as a whole. Accurate and timely diagnosis is essential for appropriate management and to prevent long-term complications. In this meta-analysis, we systematically reviewed studies evaluating the diagnostic accuracy of different tests commonly used in clinical practice for patients with CTS. Our analysis included a diverse range of research designs, including randomized controlled trials, retrospective and prospective cohort studies, and case-control studies. The inclusion of multiple study designs allowed us to comprehensively assess the diagnostic accuracy of various tests commonly used in clinical practice.

It is important to note that other diagnostic tests, such as the Phalen and Tinel tests, showed lower sensitivity and specificity compared to EMG and ultrasound. The Phalen test demonstrated a sensitivity of 0.56 and specificity of 0.64, while the Tinel test exhibited a sensitivity of 0.46 and specificity of 0.73. These findings suggest that while the Phalen and Tinel tests may be useful as screening tools, they may not be as reliable for confirming the diagnosis of CTS. While there is no universally accepted gold standard for diagnosing CTS, provocative tests are essential due to the limitations of electrodiagnostic studies, which have notable false-positive and false-negative rates.[51,52] These tests, such as the Phalen test involving wrist palmar flexion, aid in diagnosing CTS by eliciting characteristic symptoms. Additionally, ultrasonography has been recommended as an initial diagnostic tool for CTS due to its non-invasiveness, with electrophysiologic tests reserved for cases where ultrasonography does not provide clear results. Provocative tests like the Tinel, Phalen, and reverse Phalen tests are valuable in diagnosing CTS, contributing to the overall diagnostic process.[52] These tests, along with nerve conduction studies, are used to provide objective evidence when needed and support the diagnosis, especially in atypical cases. Furthermore, provocative tests have been found to be crucial for confirming the diagnosis, selecting appropriate treatments, and determining the underlying cause of CTS.[52,53] In cases where traditional motor and sensory studies yield normal results in early CTS, provocative electrophysiological tests like the Median versus Ulnar Palmar Mixed Nerve Study (MVR) comparative technique have shown high sensitivity and specificity, aiding in early diagnosis.[54] The use of provocative exercises has also been shown to enhance the sensitivity and specificity of sonographic diagnosis in dynamic CTS cases.

EMG, a technique used to evaluate the electrical activity produced by skeletal muscles, is valuable in assessing the function of muscles innervated by the median nerve, often compromised in individuals with CTS.[55] Several studies have demonstrated its utility in diagnosing CTS, detecting abnormalities in median nerve innervated muscles, highlighting its sensitivity in identifying muscle denervation and assessing the severity of nerve compression.[55] Furthermore, EMG aids in distinguishing CTS from other conditions with similar symptoms, such as cervical radiculopathy, by revealing distinct patterns of muscle denervation. Additionally, EMG can be used to monitor the progression of CTS and assess treatment effectiveness.[35,50,55] For instance, it was utilized to evaluate changes in muscle function following surgical release of the carpal tunnel, demonstrating improvements in muscle activity postoperatively, thus indicating its utility in tracking treatment outcomes.[56] Our findings also indicate that EMG and ultrasound are two of the most accurate diagnostic tests for CTS, with EMG demonstrating a high sensitivity of 0.90 and moderate specificity of 0.75, while ultrasound exhibited a sensitivity of 0.80 and specificity of 0.86, suggesting their value in diagnosing CTS.

Potential limitations of this study include the medium to high risk of bias identified in all included studies according to the QUADAS-2 tool, which could impact the reliability of the findings. The diverse range of study designs, encompassing retrospective cohort studies, case-control studies, and prospective cohort studies, may introduce variability in the results. Furthermore, the variability in diagnostic tests assessed across the included studies, coupled with differences in test protocols and interpretation criteria, may contribute to result variability. The skewed gender distribution within the total cohort, with a higher proportion of female participants, could also potentially affect the generalizability of the results. Finally, as the majority of included studies were conducted in specific clinical settings, the findings may have limited generalizability to other populations or settings.

CONCLUSION

Our meta-analysis provides valuable insights into the diagnostic accuracy of various tests for CTS. While EMG and ultrasound appear to be the most accurate diagnostic modalities, further research is needed to confirm these findings and to identify the most reliable tests for the diagnosis of CTS. Additionally, future studies should aim to address the limitations identified in our analysis, such as the high risk of bias in the included studies, to improve the quality of evidence in this field.

Declaration by Authors

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Source of Funding: None
Conflict of Interest: No conflicts of interest declared.

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