Original Article

Correlating symptom severity index, clinical diagnostic criteria of CTS-6 and timed Phalen's test in clinical evaluation of carpal tunnel syndrome

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Abstract

Background: Carpal Tunnel Syndrome (CTS) poses significant diagnostic challenges, especially in resource-limited settings. Reliable tools such as the 6-item Symptom Severity Index, Timed Phalen's Test (TPT) and CTS-6 are promising but under investigated. Correlation between these tools and symptom severity remains underexplored. **Aim:** To correlate the 6-item Symptom Severity Index and CTS-6 diagnostic tool with TPT in clinically diagnosed CTS cases, evaluating their diagnostic performance. **Methods:** Prospective cross-sectional study, conducted in a tertiary care hospital in eastern India. 105 patients were enrolled after fulfilling inclusion criteria, assessing them with the 6-item Symptom Severity Index, CTS-6 diagnostic tool and TPT. Pearson's and Spearman's correlation coefficients were used, and statistical significance was set at $P < 0.05$. **Results:** Of 188 evaluated hands, TPT showed a significant negative correlation with CTS-6 scores ($r = -0.59$, $P < 0.0001$), indicating lower scores with higher TPT values. CTS-6 scores positively correlated with symptom severity ($r = 0.34$, $P < 0.0001$), indicating higher Symptom Severity Indices associated with increased diagnostic probability. Positive predictive value for TPT was 70.1%, with sensitivity of 83.7% and specificity of 61.1%. Symptom Severity Indexing demonstrated higher sensitivity (100%) but lower specificity (3.3%). **Conclusions:** This study highlights the utility of integrating subjective and objective assessment tools in CTS diagnosis. The findings underscore the importance of comprehensive evaluation and suggest the potential value of TPT as an adjunctive diagnostic tool. Further research is warranted to validate these findings and refine diagnostic algorithms for CTS management.

Keywords: 6-item symptom severity index, carpal tunnel syndrome, CTS-6 diagnostic tool, timed Phalen's test

Introduction

Carpal Tunnel Syndrome (CTS) is a common and debilitating condition characterized by the compression of the median nerve within the carpal tunnel at the wrist, leading to symptoms such as pain, numbness and weakness in the hand. It is the most commonly diagnosed site of nerve compression in the upper extremity.[1] Accurate and comprehensive assessment tools are indispensable for diagnosing and evaluating the severity of CTS to guide decision-making in management, such as choosing between conservative therapy and surgical intervention. The prevalence of CTS is estimated between 4% and 5% of the population, affecting patients in the age group 40 to 60 years and more common in women than men.[2] CTS is a clinical diagnosis based on a combination of symptoms and characteristic physical findings; however, its presence may be established by electrodiagnostic and neuromuscular ultrasound. However, because of the constraints on resources and limited accessibility

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of advanced diagnostic tools, clinical assessment and severity grading remain pivotal options in our country.[3,4]

Previous studies have shown that the 6-item CTS symptom severity scale by Atroshi *et al*. has good reliability and validity and can be used to measure symptom severity and treatment outcomes in CTS.[5,6] It considers both subjective and objective aspects of CTS symptoms, providing a well-rounded evaluation. The patient is required to answer 2 main questions, and their response is graded using the scale. The first question is, "How severe are the following symptoms in your hand, such as; pain at night, pain during daytime, numbness or tingling at night and numbness or tingling during daytime?" The scale for grading is likewise: None (0), Mild (1), Moderate (2), Severe (3) and Very severe (4). The second question is, "How often did the following symptoms in your hand wake you up at night, giving the sensation such as pain and numbness or tingling?" The scale for grading is: Never (0), Once (1), 2 or 3 times (2), 4 or 5 times (3) and more than five times (4).

By conventional recommendation, CTS diagnosis in clinics is mainly confirmed by Phalen's test. Phalen's test has a wide range of sensitivity, ranging from 42% to 85%, and specificity, ranging from 54% to 98%.[7] In Phalen's test, flexion of the wrist is provoked in a controlled manner so that symptoms of CTS are reproduced, but the optimum duration of the test is not established. Recently, studies have shown that Phalen's test can be timed, and an optimal cut-off may be more useful than simple Phalen's test. The Timed Phalen's Test (TPT) has emerged as a promising diagnostic tool, particularly for mild CTS cases. Recent evidence suggests that TPT may offer higher accuracy in diagnosing mild CTS compared with traditional Phalen's test (Positive predictive value 96.6% and specificity 96.8%).[8] Hence, Timed Phalen's test is emerging as a more practical and cost-effective tool for the diagnosis of CTS. However, its relationship with the severity of CTS is not yet established.

Graham *et al*. generated a list of six clinical criteria (CTS-6) for the diagnosis of CTS based on a validated statistical analysis of recommendations by an expert panel.[9,10] These include symptoms of numbness predominantly or exclusively over the medial nerve distribution along with nocturnal numbness, clinical examination for thenar hypotrophy, loss of 2-point discrimination, a positive Phalen's test and a positive Tinel's sign. According to these criteria, a score of more than 12 gives an 80% probability of positive CTS; a score of more than 5 gives a 25% probability of positive CTS. CTS-6 criteria focus on the clinical features and functional impact, adding depth to the assessment process. Recognizing the lack of a diagnostic "gold standard," the CTS-6 was created, in part, to standardize clinical diagnostic criteria for CTS, and it can be reliably used as a screening and diagnostic tool for CTS by clinicians with a variety of experience levels.[11] American Academy of Orthopaedic Surgeons (AAOS) evidence-based clinical practice guidelines for CTS have also recommended the criteria mentioned in CTS-6 along with history, other tests and manoeuvres in diagnosing CTS.[12,13]

The 6-item Symptom Severity Index and the CTS-6 diagnostic tool are established instruments for evaluating CTS symptoms and aiding in diagnosis. However, whereas both tools have six items in the components, they assess different aspects of the condition. The former assesses symptom severity, incorporating both subjective and objective criteria, while the latter focuses on clinical features and functional impact. Despite their potential utility in CTS assessment, no previous studies have compared the diagnostic utility of these two tools. There were limited studies comparing the responsiveness of different evaluation scales; in one study, the Atroshi scale demonstrated significantly higher responsiveness as compared with Boston's 11-item symptom severity scale.[14] The primary objective of this study was to correlate the CTS-6 diagnostic tool scores and the 6-item Symptom Severity Index with the Timed Phalen's test in patients with suspected CTS. The findings are anticipated to provide valuable insights for clinicians in therapeutic decision-making to improve patient outcomes and better-informed clinical management strategies for CTS.

Material and Methods

The study was approved by the Institutional Review and Ethics Committees according to the terms of the Declaration of Helsinki. All subjects provided written informed consent before participation in the study after receiving complete verbal and written descriptions of the CTS protocol.

Study design and setting

It was a prospective cross-sectional study conducted in neuro-electrophysiology laboratory in a tertiary care hospital in Eastern part of India, involving new patients. Patients with a clinical suspicion of carpal tunnel syndrome or referred for the evaluation of compressive neuropathy of the median nerve at the wrist for the first time, based on history and physical examination with or without nerve conduction tests were included in the study. Each patient with a clinical diagnosis of CTS underwent detailed electrodiagnostic evaluation and grading to confirm median nerve compression at the wrist. This included segmental sensory conduction studies across the wrist, median-ulnar comparison studies (digit IV sensory and second lumbrical-second interossei), and median-radial comparison studies. The detailed analysis or values of electrodiagnostic tests were not included in this article. Patients with clinical features of severe polyneuropathy due to causes such as stroke, plexopathy, vitamin B12 deficiency, or taking medication that can cause neuropathy, diagnosed cervical radiculopathy, fracture-induced nerve injury, or who had undergone carpal tunnel release surgery, were excluded from the study. To exclude CTS mimics due to polyneuropathy (e.g. from diabetes, alcohol, or trauma), a detailed history of disease onset and progression was taken, along with thorough sensory and motor examinations. In cases of polyneuropathy, symptoms were not restricted to the median nerve distribution, and diabetic neuropathy showed length-dependent onset with sensory disturbances in other areas, often affecting small fibers more than large fibers. In addition, inching/short segmental nerve

conduction studies of the median nerve across the wrist were also performed to confirm compression in suspected CTS cases.

Patient assessment

After a detailed history and physical examination, patients fulfilling the inclusion criteria underwent assessment for carpal tunnel syndrome with the use of the 6-item symptom severity score and the CTS-6 tool; a combined score was calculated for both the scales, followed by Timed Phalen's test performed up to a maximum of 120 seconds, and subsequent further evaluation as needed. Patients completed both scales on the same occasion. The time in seconds when patients first reported symptoms was recorded as the TPT.

Statistical analysis

The data were entered and analyzed in Microsoft Excel 2013. Data were expressed as mean (SD) or median (IQR) depending upon the normality. Pearson's correlation coefficient and Spearman's rank correlation coefficient were used depending on data normality. A *P* value of less than 0.05 was taken as statistically significant.

Results

A total of 105 patients (84 females, 21 males) were included in the study that fulfilled the inclusion criteria with a mean ± SD age of 46.1 ± 8.5 years. 83 patients had presented with bilateral symptoms, 11 with only right hand and 11 with only left-hand symptoms, respectively. A total of 188 symptomatic hands were evaluated individually for 6-item symptom severity, CTS-6 and Timed Phalen's test. The demographics, evaluation tool scores and comorbidities are given in Table 1. All descriptive and analytical statistics were performed on the data of these 188 hands. The Mean ± SD of Symptom severity score, total CTS-6 score and Timed Phalen's test in seconds were 6.5 ± 4, 11.1 ± 6.7 and 32.4 ± 20.4 respectively.

According to the 6-item Symptom severity score by Atroshi *et al*.[5] [Table 2], the most common symptom reported was numbness and tingling at night (81.4%), followed by numbness and tingling during the day (77.1%). The least reported symptom was pain at night, causing the patient to wake up (32.4%).

Of the 188 hands, 71 (37.8%) hands reported a negative TPT. The TPT values showed a very significant strong negative correlation with the CTS 6 scores but no significant correlation with the symptom severity scores. This indicated that the higher the value of Timed Phalen's test, the lower the clinical CTS 6 score ($r = -0.59$, $P < 0.0001$) [Figure 1].

The CTS-6 scores also showed a significant moderate positive correlation with the Symptom severity score ($r = 0.34$, $P = <0.0001$) [Figure 2]. This implies that patients experiencing more severe symptoms are more likely to meet the clinical criteria for CTS diagnosis, highlighting the importance of symptom assessment during clinical diagnosis.

Table 1: Demographic details, evaluation tool scores and comorbidities

Parameters	Mean (SD) or *n* (%)
Number (*n*)	105
Females	84 (80%)
Males	21 (20%)
Age	46.1 (8.5)
Total Symptomatic hands (*n*)	188
Only Right	11 (5.9%)
Only Left	11 (5.9%)
Both	83 (88.3%)
Diabetes	8 (7.6%)
Hypertension	21 (20%)
Hypothyroid	22 (21%)
Smoking	16 (15.2%)
Trauma on hand	26 (24.8%)
6-item symptom severity score	6.5 (4)
CTS-6 score	11.1 (6.7)
CTS-6 >12	98 (52.1%)
CTS-6 >5 & <12	37 (19.7%)
Timed Phalen's test	32.4 (20.4)
Positive	117 (62.2%)
Negative	71 (37.8%)

Of 188 hands, 98 (52.1%) hands reported CTS 6 scores >12, indicating an 80% probability of diagnosing CTS; 37 (19.7%) hands reported CTS 6 >5, indicating a 25% probability of diagnosing CTS. Among the 188 hands, considering CTS-6 score >12 as gold standard, the positive predictive value for TPT was found to be 70.1% with a sensitivity of 83.7% and specificity of 61.1% and the positive predictive value for Symptom Severity Indexing was found to be 53% with a sensitivity of 100% but low specificity of 3.3%.

Discussion

This study is the first of its kind, aimed to correlate the 6-item Symptom Severity Index and the CTS-6 diagnostic tool with the Timed Phalen's Test (TPT) in patients suspected of having Carpal Tunnel Syndrome (CTS). The primary outcome measures included the correlation between TPT values and CTS-6 scores, whereas secondary outcome measures included the diagnostic performance of the CTS-6 tool and the 6-item Symptom Severity Index in predicting CTS.

Clinicians reliably use the CTS-6 as a screening and diagnostic tool for carpal tunnel syndrome.[11,15] The study found a significant negative correlation between TPT values and CTS-6 scores, indicating that higher TPT values corresponded to lower clinical CTS-6 scores. In addition, considering the CTS-6 score >12 as the gold standard, the diagnostic performance of TPT was evaluated, with a positive predictive value of 70.1%, suggesting its utility in diagnosing CTS, especially when combined with other clinical criteria. However, the 6-item Symptom Severity Index demonstrated higher sensitivity but lower specificity, highlighting its limitations as a standalone diagnostic tool but extremely valuable when used in combination with the CTS-6 diagnostic tool.

Table 2: 6-item symptom severity score

How severe are the following symptoms in your hand?	Total responses *n* (%)	Mild (Score 1)	Moderate (score 2)	Severe (score 3)	Very severe (score 4)
Pain at night	106 (56.4%)	31	38	29	8
Pain during daytime	100 (53.2%)	54	34	10	2
Numbness or tingling at night	153 (81.4%)	35	57	47	14
Numbness or tingling during daytime	145 (77.1%)	62	57	23	3
How often did the following symptoms in your hand wake you up at night?	**Total responses *n* (%)**	**Once (score 1)**	**2 or 3 times (score 2)**	**4 or 5 times (score 3)**	**>5 times (score 4)**
Pain	61 (32.4%)	23	35	2	1
Numbness or tingling	79 (42%)	31	41	5	2

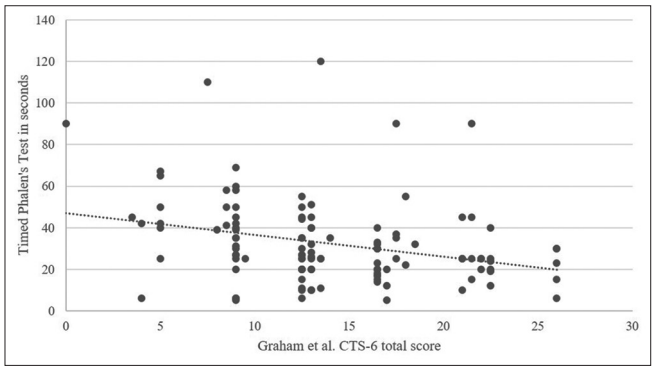

Figure 1: Correlation between Graham *et al.* CTS-6 total score on x-axis and Timed Phalen's test in seconds on y-axis for all the hands (n = 188). r = -0.59, $P < 0.0001$*

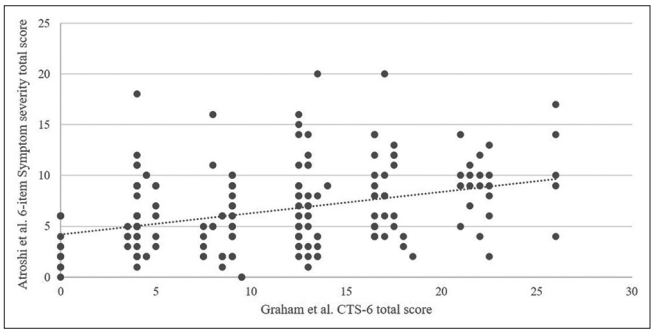

Figure 2: Correlation between Graham *et al.* CTS-6 total score on x-axis and Atroshi *et al.* 6-item Symptom severity total score on y-axis for all the hands (n = 188). r = 0.34, $P < 0.0001$*

The strengths of this study include its prospective cross-sectional design, which allowed for the direct assessment of correlations between different assessment tools in real-time. However, several limitations should be acknowledged. Firstly, the study's sample size was relatively small, which may limit the generalizability of the results. In addition, the study's cross-sectional design precludes the establishment of causality or the assessment of long-term outcomes. Furthermore, the reliance on self-reported Symptom Severity Index may introduce bias and variability in the data. To avoid bias, interviews and examinations were conducted by an experienced nursing officer who was blinded to the clinical and neurophysiological diagnoses. Finally, the study was conducted at a single centre, which may limit the external validity of the findings.

In the context of the totality of evidence, this study adds valuable insights into the correlation between different assessment tools in CTS evaluation. By elucidating the relationship between symptom severity scores, clinical diagnostic criteria and objective diagnostic tests, this research contributes to the refinement of diagnostic algorithms and the development of evidence-based clinical guidelines for CTS management.

These findings have significant implications for patient care and health policy. Clinicians should consider using a comprehensive approach, incorporating both subjective and objective measures, for CTS diagnosis and treatment outcomes. Moreover, the integration of novel diagnostic tools such as the TPT may enhance diagnostic accuracy and facilitate timely intervention, ultimately improving patient outcomes and reducing healthcare burden.

One potential controversy raised by this study is the discrepancy between the diagnostic performance of the subjective Symptom Severity Index and objective diagnostic tests. Although the 6-item Symptom Severity Index demonstrated higher sensitivity, its lower specificity may lead to overdiagnosis and unnecessary interventions. Clinicians must carefully weigh the benefits and risks of relying solely on subjective symptom assessments in clinical practice.

Future research directions for this particular research collaboration may include validating the findings in larger patient cohorts and exploring the comparative effectiveness of different diagnostic strategies in diverse clinical settings. In addition, longitudinal studies are needed to assess the prognostic value of these assessment tools and their impact on treatment outcomes in CTS patients.

Furthermore, investigations into the underlying mechanisms driving the correlation between subjective Symptom Severity Indices, clinical diagnostic criteria and objective diagnostic tests are warranted. This may involve exploring the pathophysiological processes underlying CTS and identifying biomarkers, imaging modalities and electrodiagnostic studies that can reliably predict disease progression and treatment response.

On the clinical research front, efforts should focus on developing novel diagnostic tools and therapeutic interventions that address the limitations of existing assessment methods. Collaborative efforts between researchers, clinicians and policymakers are essential to translate research findings into actionable strategies that optimize patient care and improve health outcomes in CTS and other peripheral nerve disorders.

In conclusion, this study provides valuable insights into the correlation between different assessment tools in CTS evaluation and underscores the importance of integrating multiple modalities in clinical practice. By addressing key research questions and identifying areas for future investigation, this research lays the foundation for advancing our understanding of CTS pathophysiology, diagnosis and treatment.

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Conflicts of interest

There are no conflicts of interest.

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