



**CLINICAL PRACTICE GUIDELINE
ON
THE DIAGNOSIS OF
CARPAL TUNNEL SYNDROME**

Adopted by the American Academy of Orthopaedic Surgeons

Board of Directors

May 2007

This clinical guideline was developed by an AAOS physician volunteer Work Group and is provided as an educational tool based on an assessment of the current scientific and clinical information and accepted approaches to treatment. It is not intended to be a fixed protocol as some patients may require more or less treatment. Patient care and treatment should always be based on a clinician's independent medical judgment given the individual clinical circumstances.

Endorsed By:



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Disclosure Requirement

In accordance with AAOS policy, all individuals whose names appear as authors or contributors to Clinical Practice Guideline filed a disclosure statement as part of the submission process. All panel members provided full disclosure of potential conflicts of interest prior to voting on the recommendations contained within this Clinical Practice Guidelines.

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***American Academy of Orthopaedic Surgeons Clinical Guideline
on
Diagnosis of Carpal Tunnel Syndrome
Summary of Recommendations***

Recommendation 1.1

The physician should obtain an accurate patient history (Level V, Grade C).

Recommendation 2.1

The physician should perform a physical examination of the patient that may include:

personal characteristics (Level V, Grade C)

performing a sensory examination (Level V, Grade C)

performing manual muscle testing of the upper extremity (Level V, Grade C)

performing provocative tests (Level V, Grade C), and/or

performing discriminatory tests for alternative diagnoses (Level V, Grade C).

Recommendation 3.1a

The physician may obtain electrodiagnostic tests to differentiate among diagnoses. (Level V, Grade C)

Recommendation 3.1b

The physician may obtain electrodiagnostic tests in the presence of thenar atrophy and/or persistent numbness (Level V, Grade C).

Recommendation 3.1c

The physician should obtain electrodiagnostic tests if clinical and/or provocative tests are positive and surgical management is being considered (Level II and III, Grade B)

Recommendation 3.2

If the physician orders electrodiagnostic tests, the testing protocol should follow the AAN/AANEM/AAPMR guidelines for diagnosis of CTS (Level IV and V, Grade C).

Recommendation 3.3

The physician should not routinely evaluate patients suspected of having carpal tunnel syndrome with new technology, such as magnetic resonance imaging (MRI), computerized axial tomography (CAT) and pressure specified sensorimotor devices (PSSD) in the wrist and hand. (Level V, Grade C).

Please note that Recommendation 3.3 is not based on a systematic literature review. An additional abbreviated review was completed following the face to face meeting of the Work Group on February 24, 2007.

American Academy of Orthopaedic Surgeons

Clinical Guideline

on

Diagnosis of Carpal Tunnel Syndrome

Overview

Evidence-based Practice (EBP) standards are in a state of continuous evolution. Current EBP standards now demand that physicians use the best available evidence to guide their clinical decision making processes. Increasingly rigorous EBP standards have also resulted in more rigorous clinical studies of ever stronger design, complexity and statistical analysis. This diagnostic clinical practice guideline consists of a systematic review of the available literature regarding the diagnosis of carpal tunnel syndrome. The purpose of this diagnostic clinical practice guideline is to help improve carpal tunnel syndrome diagnosis based on the current best evidence. The systematic review detailed herein was conducted between August of 2006 and March of 2007 and demonstrates where there is good evidence, where evidence is lacking, and what topics future research must target in order to improve carpal tunnel diagnosis. The AAOS Carpal Tunnel Syndrome (CTS) Guideline Work Group systematically reviewed the available literature, evaluated the level of evidence found in that literature, and subsequently wrote the following recommendations based on a rigorous, standardized consensus process.

Goals and Rationale

The AAOS has created this clinical practice guideline to improve patient care by outlining the appropriate information-gathering and decision-making processes involved in managing the diagnosis of carpal tunnel syndrome. This clinical practice guideline is also an educational tool that may guide qualified physicians (see Intended Users below) through a series of diagnostic decisions in an effort to improve the quality and efficiency of care.

For the purpose of this guideline, Carpal Tunnel Syndrome (CTS) is defined as follows:

Carpal Tunnel Syndrome is a symptomatic compression neuropathy of the median nerve at the level of the wrist, characterized physiologically by evidence of increased pressure within the carpal tunnel and decreased function of the nerve at that level. Carpal Tunnel Syndrome can be caused by many different diseases, conditions and events. It is characterized by patients as producing numbness, tingling, hand and arm pain and muscle dysfunction. The disorder is not restricted by age, gender, ethnicity, or occupation and is associated with or caused by systemic disease and local mechanical and disease factors.

This guideline should not be construed as including all proper methods of care or excluding methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment must be made in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

Scope and Organization

Intended Users

This guideline is intended to be used by Orthopaedic Surgeons and all qualified physicians considering a diagnosis of CTS. Typically, Orthopaedic Surgeons will have completed medical training, a qualified residency in Orthopaedic Surgery and some may have additional sub-specialty training. Insurance payors, governmental bodies, and health policymakers may also find this guideline useful as an evolving standard of evidence regarding Carpal Tunnel Syndrome. All will benefit from using the guideline to plan future work.

Patient Population

Persons of all genders, races, ages, occupations and health status may be afflicted by Carpal Tunnel Syndrome. The present guideline is aimed towards diagnosis of carpal tunnel syndrome in adults.

Incidence and Prevalence

Carpal tunnel syndrome incidence in the United States has been estimated at 1-3 cases per 1000 subjects per year¹. Prevalence is approximately 50 cases per 1000 subjects in the general population^{1,2}

Burden of Disease and Emotional and Physical Impact of CTS

While many Americans are experiencing symptoms of carpal tunnel syndrome, they also expect relief of the condition, which can only be accomplished with proper diagnosis. If the condition is diagnosed early, we expect better results of treatment. Untreated, carpal tunnel syndrome may worsen and progress to permanent sensory loss and thenar paralysis in some cases.

As carpal tunnel syndrome in the workplace demands attention, and as the number of cases filed increases, the expense for lost productivity and cost of treatment has and continues to increase. “During 1998, an estimated three of every 10,000 workers lost time from work because of carpal tunnel syndrome. Half of these workers missed more than 10 days of work. The average lifetime cost of carpal tunnel syndrome, including medical bills and lost time from work, is estimated to be about \$30,000 for each injured worker³.” As of 2005 the statistics indicate nearly half the workers who lost time from work because of carpal tunnel syndrome missed over 31 days of work⁴.

According to the US Bureau of Labor Statistics⁶, there were 16,440 cases of carpal tunnel syndrome involving lost work days in 2005⁶. Carpal Tunnel Syndrome has the highest median number of days away from work⁴ and the major industry division with highest number of events and exposures is manufacturing⁵.

This and other clinical guidelines benefit from reference to the World Health Organization (WHO) framework for International Classification of Function in defining the effects of disease on individuals. A broader recognition of disease as a social as well as personal feature of life puts its impact in better perspective. The contribution of external effects and personal factors such as

treatment adherence are important considerations in judging outcomes and compliance with regulations for performance. Very little has been written on the patient as a variable in health outcomes and will need to be addressed in the future.

Etiology

Carpal Tunnel Syndrome (CTS) is among the most common disorders of the upper extremity. It is related to many factors but is thought to be caused by increased pressure on the median nerve in the carpal tunnel at the wrist.

The clinician who diagnoses CTS is differentiating among verbalized, subjective symptoms and patient language, seeking clinical signs and a recognition between common and rare disorders to affirm the diagnosis. We use laboratory tests to confirm our clinical impression. These processes are imperfect and subject to variability in interpretation and performance. Experience with relieving the disorder through conservative management and surgical skills permits the clinician to recognize those patients who will benefit from specific treatment with the greatest probability.

In our consensus, the patient who has Carpal Tunnel Syndrome experiences numbness and tingling in the sensory distribution of the median nerve and may also have hand pain. As the syndrome progresses untreated over time, pain may be felt proximally in the forearm, and the duration and intensity of the paresthesias increases. Continued nerve pressure results in sensory loss and median motor paralysis with atrophy of the thenar muscles. The earlier the diagnosis is made, the less likely is the occurrence of irreversible damage to the nerve.

The accuracy of differential diagnosis from radiculopathy, metabolic, genetic and other forms of neuropathy is achieved through careful history taking, physical examination and laboratory tests, as well as clinical experience with all of these conditions.

Risk Factors

Several key co-morbidities and/or human factors increase the incidence of carpal tunnel syndrome. These include pregnancy, advancing age, female gender, specific occupations, hand-related repetitive motions, strong family history, specific medical disorders such as hypothyroidism, diabetes, autoimmune diseases, rheumatological diseases, arthritis, obesity, renal disease, trauma, anatomic predisposition in the wrist and hand due to shape and size, infectious diseases, and substance abuse. In many cases, there is no identifiable co-morbidity or causal relationship.

Persons involved in manual labor in some occupations have a greater incidence and severity of the symptoms. The relationships between work, co-morbidities and personal factors require good physician judgment, experience with medical evidence and a vast occupational literature in assigning and apportioning causation. The effect of work stress reduction will be assessed in the AAOS guideline on Carpal Tunnel Treatment, which is currently in development.

Methods

Process Overview

The CTS Guideline Work Group completed a systematic review of the relevant literature with the assistance of AAOS Guidelines Unit. Details of the systematic review are provided below. During the process of developing this document, the Work Group participated in a series of conference calls and one face to face meeting. Information from the literature was supplemented by the consensus opinion of the Work Group when necessary. Multiple iterations of written review were conducted by the participating Work Group, AAOS Guidelines Oversight Committee, AAOS Evidence-based Practice Committee, and the AAOS Council on Research, Quality Assessment, and Technology prior to final approval by the AAOS Board of Directors.

Consensus Development Process

Voting on guideline recommendations and performance measures was conducted using a modification of the nominal group technique (NGT), a method previously used in guideline development (Murphy MK, Black LA, Lamping, DL, McKee CM, Sanderson, CFB, Askham J, et al. Consensus development methods, and their use in clinical guideline development Health Technol. Assessment 1998; 2(3)). In this modification each Work Group member ranked a recommendation or performance measure on a scale ranging from 1 (“extremely appropriate”) to 9 (“extremely inappropriate”). One Work Group member could not participate in the face-to-face meeting, hence the AAOS Guideline Oversight Committee Chairperson, William C. Watters III MD, substituted as an alternate member via teleconference for voting purposes. For the purposes of this guideline, consensus was obtained when/if six (6) of seven (7) Work Group members ranked the recommendation or measure as a 7, 8, or 9. When two (2) or more Work Group members did not rank a measure in this range, three rounds of discussion and voting were held to resolve disagreements. If disagreements were not resolved after these rounds, no recommendation was adopted.

The final recommendations were refined via a teleconference call on March 17, 2007 with all members of the Work Group present.

References

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Key Questions

The clinical practice guideline recommendations are based on the answers to the following five Key Questions. These questions were specified *a priori* to conducting the literature searches and frame the scope of the guideline.

The Key Questions addressed by this guideline are:

1. a. *What is the diagnostic test(s) with the best performance for the diagnosis of CTS?*
b. *What is the diagnostic test(s) plus electrodiagnostic test(s) with the best performance for the diagnosis of CTS?*

Corresponding Finding:

The systematic literature review of primary studies indicated that published articles did not employ a consistent reference standard, few studies evaluated the same diagnostic test, and most studies enrolled only a few patients. In addition, the majority of primary studies used a case-control design, which is subject to spectrum bias, thus artificially inflating the sensitivity and specificity of the evaluated tests. Because of the diversity and suboptimal design of published studies no one test could be identified as a “gold standard” for carpal tunnel syndrome diagnosis.

2. *What is the hierarchy of electrodiagnostic tests that should be followed when confirming a CTS diagnosis?*

Corresponding Finding:

Based on the variability in reference standards and study results, the overall poor quality of study designs, and small studies there is insufficient evidence to recommend one test over another, or to suggest which test has the best performance for the diagnosis of carpal tunnel syndrome.

3. *What is the relationship between a patient’s symptoms (including duration) and the results of electrodiagnostic tests?*

Corresponding Finding:

Currently available evidence does not allow one to identify a relationship between patient symptoms and electrodiagnostic test results. Different studies reported varying results for the same electrodiagnostic tests. Spectrum bias, introduced by case-control study designs, may have confounded the results.

4. a. *Is there a correlation between clinical test(s) and patient post-surgical outcomes?*
b. *Is there a correlation between clinical test(s) plus electrodiagnostic tests and patient post-surgical outcomes?*

Corresponding Finding:

Neither clinical tests for carpal tunnel syndrome by themselves, nor electrodiagnostic tests by themselves reliably diagnose carpal tunnel syndrome. When clinical tests and electrodiagnostic tests are combined, our meta-analysis suggests a statistically significant correlation between these tests and positive post surgical outcomes among surgical patients.

Available evidence does not permit definitive conclusions about which combination of clinical and electrodiagnostic tests provide the best performance.

5. *Do targeted (at the wrist) steroid injections, splinting, or activity changes lead to more accurate diagnosis of CTS?*

Corresponding Finding:

The primary studies reviewed for this question employed varied interventions, varied reference standards, different durations of intervention, and varied outcome measures for patient evaluation. In addition, some studies did not employ validated questionnaires when inquiring about patients' health outcomes, and most studies were not blinded. Taken as a whole, these studies indicated that the greatest numbers of patients are improved at one month after steroid injections or a splint. If the physician uses these interventions as additional diagnostic confirmation tools and uses electrodiagnostic testing as the outcome measure, the electrodiagnostic test results illustrate the greatest percentage of patients are improved at three months (using change in distal motor latency score (ms) as an indicator of improvement).

Article Inclusion/Exclusion Criteria

Scope. The guideline Work Group did not search for, or include, all available evidence. Wherever appropriate, we searched for and included the best available evidence. Hence, if Level II evidence was available, the Work Group did not search for or include Level III evidence or lower unless there was very little Level II evidence and a great deal of Level III evidence.

Inclusion/exclusion criteria were developed for each Key Question. These criteria were specified before commencing the literature searches. The specific inclusion and exclusion criteria for each key question can be found in **Appendix II: Article Inclusions and Exclusions**. Studies were retrieved and included only if they met the specific inclusion/exclusion criteria.

Literature Searches

The Work Group searched Medline, to identify literature for this guideline between August of 2006 and March of 2007. Search strategies were reviewed by the Work Group prior to conducting the searches. These electronic searches were supplemented by hand searches of article bibliographies and by articles from Work Group members' files. These

latter citations were screened for eligibility for inclusion in the same manner as those identified by electronic searches.

Rating the Quality of Evidence

The quality of evidence was rated using an evidence hierarchy for each of four different study types: **therapeutic**, **prognostic**, **diagnostic**, and **economic** or **decision-modeling**. This hierarchy is shown in **Appendix I: Literature Searches** and on the American Academy of Orthopaedic Surgeons (AAOS) website at <http://www2.aaos.org/aaos/archives/bulletin/feb03/fline1.htm>.

Grading the Recommendations

Each guideline recommendation was graded using the following system:

- A: Good evidence (Level I Studies with consistent finding) for or against recommending intervention.
- B: Fair evidence (Level II or III Studies with consistent findings) for or against recommending intervention.
- C: Poor-quality evidence (Level IV or V) for or against recommending intervention.
- I: There is insufficient or conflicting evidence not allowing a recommendation for or against intervention.

Grading Recommendations Specific to the CTS Guideline:

1. When studies employ readers who were not blinded to each other and/or to the symptoms of the patient, we downgraded the quality of a study by one level of evidence (i.e., unblinded studies introduce the possibility of bias).

Statistical Methods

The purpose of the statistical analysis was to assess the diagnostic accuracy of various tests commonly used to diagnose carpal tunnel syndrome. Measures of diagnostic accuracy are based on the comparison of a test with a reference standard that determines the presence or absence of CTS. For this analysis, signs and symptoms of CTS and electrodiagnostic tests (Questions 1 & 2); symptoms of CTS (Question 3); surgical outcomes from open or endoscopic carpal tunnel release (Question 4); and disease status (Question 5) were used as the “gold” standards.

In order to be considered for the analysis, studies had to report outcomes in terms of the sensitivity and specificity or had to have sufficient information on the performance of the test regarding the true positive and true negative outcomes (or likelihood ratios) in order to calculate sensitivity and specificity. Studies also had to have tests, outcome measures or durations of follow up in common to perform meta-analysis of the data (Thompson &

Higgins 2002). Given the paucity and heterogeneity of the data for specific questions, we did not attempt the application of formal meta-analytic techniques in all circumstances. When possible, effect sizes were pooled across different studies, and heterogeneity was assessed with the I-squared statistic (Higgins & Thompson 2002).

We attempted to meta-analytically construct receiver operating characteristic (ROC) curves for each diagnostic group or individual test where sufficient data were available. These curves describe how the test's performance in those with CTS (sensitivity or true positive rate) varies with its performance in those without CTS (false positive rate or 1 - specificity). All ROC curves were calculated using Meta-DiSc version 1.4 (Zamora et al. 2006) and Comprehensive Meta Analysis version 2 (Borenstein et al. 2005). Due to unexplainable homogeneity results of these meta-analyses were not be reported.

Meta-analyses were also performed to pool the clinical outcomes of patients treated surgically with carpal tunnel release and to compare different individual and groups of diagnostic tests. Based on available data, meta-analyses were conducted for the diagnosis and surgery studies to determine whether clinical, electrodiagnostic, or clinical plus electrodiagnostic test results were associated with surgical outcomes. A meta-analysis of carpal tunnel surgery data examined pre-post surgery standardized mean differences in electrodiagnostic test results. Meta-regressions that consider diagnostic tests as predictors of surgical outcomes were examined as well. These meta-regressions employed the permutation method of Higgins & Thompson 2004. Several subgroup analyses were performed to identify factors that may be related to diagnostic variations. All meta-analyses and meta-regressions were performed using Stata 9.2 (StataCorp LP, College Station, Texas).

Data extraction

Four reviewers completed data extraction independently for all studies, except for studies where data were extracted by one reviewer and checked by another. Any disagreements were resolved by consensus. Evidence tables were constructed to summarize the best evidence pertaining to each key question and all evidence can be found in the accompanying technical report to this guideline.

Revision Plans

This guideline represents a cross-sectional view of the diagnostic methods of the day and will become outdated because more sophisticated tests, more objective assessments and more rigorous differential diagnosis are possible in the future. Linkage to other disorders, genetic diagnosis, and occupational and human factors literature will contribute to our understanding of the early stages of this condition and the means of differential treatment.

Because of the high profile of CTS in the workplace and the high level of interest in this topic by caregivers, payors and workplace insurers, the guideline will be revised in accordance with changing practice, rapidly emerging opinion, new technology and new evidence. It is anticipated that this guideline will be revised in 2010.

Relevant Issues

The Committee recognized the following language in constructing the recommendations; strong recommendation (Must), Recommendation (Should), Option (May) or no recommendation (Shiffman, 2007). These definitions help clarify the intent of the Work Group by reflecting the assessment of the importance of adherence to the recommendation based on the grade level of the recommendation.

Guideline Recommendations

Recommendation 1: History of present illness

1.1 *The physician should obtain an accurate patient history.*

There are several broad questions that may solicit complaints of hand numbness or hand/wrist pain and/or symptoms. These may include:

- a. **Duration:** How long have the symptoms been present?
- b. **Severity/Character:** How severe are the symptoms? When do symptoms occur (e.g., night-time)? Describe symptom quality (e.g., tingling, burning, aching, etc.). Is the numbness/tingling intermittent or persistent? What improves (e.g., shaking hand, holding hand down, warm water) or exacerbates symptoms (e.g., driving, holding a telephone, using vibratory tools, etc.)?
- c. **Location/Radiation:** What is the location of the pain and/or numbness? Are the symptoms in the median nerve distribution of the hand(s)? If the symptom is not focal, does it radiate to a specific area of the body? Are there any other associated symptoms (numbness in the feet; symptoms in the neck, shoulder, and more proximal in the arm; weakness, clumsiness, dropping things, etc.)?
- d. **Pace of illness:** Is the problem getting better, worse, or staying the same? If it is changing, what has been the rate of change?
- e. **Previous treatment:** What has been done and what makes it better (e.g., splint, injections, therapy, activity modification, medications, etc.)?
- f. **Lifestyle and activities:** What hand activities are common for the patient (e.g., hobbies, occupation, etc.)? Are there functional limitations due to these symptoms?

Level of Evidence: V

Grade of Recommendation: C

Rationale

Obtaining a history relating to carpal tunnel syndrome (CTS) serves to diagnose the disease and to plan appropriate treatment options. A high level of evidence is not available in the literature to assess the diagnostic utility of history data and the predictive value of the data in evaluating severity of disease and outcomes of treatment. Therefore, the Work Group employed expert opinion in creating recommendation 1 to guide physicians in the appropriate questions that should be asked during patient encounters to improve diagnosis.

It is unclear from the literature whether the duration of symptoms correlates with the amount of nerve injury or can be predictive of treatment outcomes. It is also unclear whether the severity and character of symptoms are related to the structural and physiological condition of the median nerve. The evidence from available studies does not illustrate a direct relationship between symptoms and electrodiagnostic test results either across all studies (regardless of design) or by looking at results for a single electrodiagnostic test (Please refer to the AAOS technical report figures 10-47). Symptoms such as numbness along the distribution of the median nerve, increasing symptoms at night when sleeping, improvement of symptoms by shaking the hand, and symptom exacerbation when driving or holding a telephone are classic symptoms that in combination may be highly suggestive of CTS (Please refer to the AAOS technical report table 10).

Identification of the location and radiation of symptoms may exclude or include other diagnoses such as proximal nerve compression syndrome that may mimic CTS. Having these associated symptoms may alert the physicians to look for diagnoses other than CTS.

The symptoms of CTS may vary on a day-to-day basis. Understanding the disease progression can be helpful in determining the appropriate diagnosis and treatment plan. For symptoms that are not increasingly severe but vary periodically, conservative management may be helpful in diagnosis (Please refer to the AAOS technical report figure 100-103).

Understanding patient response to previous treatment may verify the diagnosis of CTS and may support patient progression to carpal tunnel surgery. Response to conservative treatment varies. If the physician uses steroid injection, the greatest patient improvement is seen at one month. If the physician uses conservative management and measures improvement with electrodiagnostic tests, the greatest improvement is seen between three and six months using change in distal motor latency measurements (ms) (Please refer to the AAOS technical report figure 102).

In summary, the Work Group used expert opinion to formulate Recommendation 1 for obtaining appropriate history to make the diagnosis of CTS. Based on the level of evidence for the studies that reviewed conservative management, the Work Group rates this recommendation at a C level, which indicates poor quality of evidence consisting of level 2, 3 or 4 data for or against recommending intervention (Please refer to the AAOS technical report table 12 and figure 8).

Recommendation 2: Physical examination

The physician should perform a physical examination of the patient that may include:

- a. Personal characteristics: age, gender, weight, height, body habitus, etc.
- b. Range of motion of hand/wrist
- c. Observation of deformity, swelling, atrophy, skin trophic changes
- d. Pinch/grip strength
- e. Hand diagram

- f. Sensory examination: e.g., two-point discrimination, Semmes-Weinstein monofilament, vibrometry, texture discrimination, etc.
- g. Manual muscle testing: of the upper extremity (e.g., examine for muscular atrophy, especially thenar muscle group)
- h. Provocative tests: (e.g., Phalen's test, Tinel's sign, median nerve compression test, reverse Phalen's, etc.)
- i. Discriminatory examination for alternative diagnoses: e.g., radiculopathy, neuropathy, pain syndromes, arthritis, tendonitis, vascular abnormalities, etc.

Level of Evidence: V

Grade of Recommendation: C

Rationale:

Personal characteristics such as age, gender, height, weight and body habitus are basic information which are important for fulfilling the Evaluation and Management documentation. Included in parts of this evaluation would be determination of vascular status, obvious deformity and testing for other related conditions (e.g., basilar thumb arthritis, deQuervain's, cubital tunnel syndrome and cervical radiculopathy.)

Sensory examination using two-point discrimination, Semmes-Weinstein monofilament, vibrometry, texture discrimination, etc. are important for defining the anatomical distribution of sensory changes. Sufficient evidence does not exist from the literature reviewed for this guideline to recommend one test over another or to suggest the overall utility of a test in diagnosing carpal tunnel syndrome. Future research will be required to confirm the diagnostic utility of these tests.

Manual muscle testing of the upper extremity including evaluation for obvious muscle atrophy is important especially for the thenar muscle area. Thenar atrophy has been reported to have a high predictive value in carpal tunnel syndrome, but its appearance can be rare (Gomes I, Becker J, Ehlers JA, Nora DB, 2006). This literature review only contained two primary studies (Gomes et al (2006) & deKrom MC, Knipschild PG, Kester AD, Spaans F (1990)) that specifically addressed thenar atrophy. No conclusion on the diagnostic value of thenar atrophy can be drawn conclusively from two studies.

There are several provocative tests that should be considered to aid in the evaluation and diagnosis of carpal tunnel syndrome. For multiple reasons (poor study design, variability in study results, inconsistent data, few studies examining the same tests and small data sets for each test), no one test has been identified as a "gold standard" for identifying carpal tunnel syndrome. Phalen's ranged in sensitivity from .46 to .80, and in specificity from .51 to .91 [Raudino F (2000), deKrom MC, Knipschild PG, Kester AD, Spaans F (1990); Katz JN et al. (1990); Fertl E, Wober C, Zeitlhofer J (1998)]. Tinel's sign ranged in sensitivity from .28 to .73, and in specificity from .44 to .95 [Raudino F (2000); Gomes I, Becker J, Ehlers JA, Nora DB (2006); deKrom MC, Knipschild PG, Kester AD,

Spaans F (1990); Katz JN et al. (1990)]. Median nerve compression test ranged in sensitivity from .04 to .79, and in specificity from .25 to .96 [Kaul MP, Pagel KJ, Wheatley MJ, Dryden JD (2001); deKrom MC, Knipschild PG, Kester AD, Spaans F (1990); Fertl E, Wober C, Zeitlhofer J (1998)]. Combining the results of more than one provocative test might increase the sensitivities and specificities. For example, combined results of Phalen's and median nerve compression tests yielded a sensitivity of .92, and a specificity of .92 [Fertl E, Wober C, Zeitlhofer J (1998)]; however further literature would be required to confirm if this result is diagnostically accurate.

Reverse Phalen's, tethered median nerve stress test and the tourniquet test have been evaluated only a few times, leaving insufficient evidence to draw any conclusions as to their accuracy in the diagnosis of carpal tunnel syndrome [Raudino F (2000); Gomes I, Becker J, Ehlers JA, Nora DB (2006); deKrom MC, Knipschild PG, Kester AD, Spaans F (1990)].

The clinical tests for carpal tunnel syndrome by themselves do not reliably diagnose carpal tunnel syndrome. Similarly, as will be discussed in Recommendation 3, electrodiagnostic studies by themselves also do not reliably diagnose carpal tunnel syndrome. However, when the symptoms, clinical tests and electrodiagnostic tests are combined, statistical significance ($p < 0.05$) is obtained when compared to post-surgical outcomes. Among surgical candidates, clinical tests and electrodiagnostic studies correlated with positive post surgical outcomes (Please refer to the AAOS technical report figure 96, 97, 98, 99).

Although CTS cannot be diagnosed primarily on clinical or electrodiagnostic grounds, the evidence shows that a combination of the two can better confirm the diagnosis and provide treatment orientation vis-à-vis carpal tunnel release. These combination tests vary considerably among the studies. For example:

Haupt et al. 1993 (Motor and sensory tests) + (distal motor latency of the median nerve, antidromic sensory nerve conduction velocity, EMG examination of abductor pollicis brevis)

Braun et al. 1994 (range of motion, grip strength, pinch strength, monofilament sensory evaluation, Phalen's, Tinel's) + (Sensory latency over 3.5 ms)

Glowacki et al. 1996 (Phalen's or Tinel's) + (Motor latencies > 4.0 ms, sensory latencies > 3.7 ms, amplitudes < 20uV, or a conduction velocity < 50m/s with evidence of fibrillation)

Boniface et al. 1994 (sensory tests) + (prolonged median sensory conduction velocity, distal motor latency to abductor pollicis brevis)

Given the small number of studies in the diagnostic groupings illustrated in these examples, definitive combinations of clinical and electrodiagnostic tests that provide the best performance could not be identified. Future research should compare the diagnostic accuracy of different combinations of tests in order to identify and recommend specific test combinations.

Other conditions may present with symptoms similar to those found in carpal tunnel syndrome (e.g., cervical radiculopathy, hypothyroidism, peripheral neuropathy, wrist/trapeziometacarpal arthrosis, wrist tendonitis/tenosynovitis, Raynaud's, arterial injury or thrombosis, nerve laceration, neuroma, brachial plexus injury, other nerve entrapment syndromes, pain syndromes, etc.). Physical examination should include other areas of the upper extremity and neck that may relate to these alternative diagnoses. This may include the following:

1. Muscular atrophy or weakness of the shoulder, elbow, wrist, thumb and/or fingers.
2. Active range of motion, particularly for the wrist and digits.
3. Swelling, masses and/or tenderness around the wrist or digits.
4. Capillary refill, radial and ulnar pulses, Allen's test.
5. Wounds or scars on the upper extremity.
6. Cervical spine range of motion, Spurling's sign.
7. Thyroid enlargement.
8. Radiographs of the wrist.

These recommendations were formed by expert opinion of the Work Group; no literature searches were performed to support these recommendations.

Recommendation 3: Nerve conduction studies

3.1a The physician may obtain electrodiagnostic tests to differentiate among diagnoses.

3.1b The physician may obtain electrodiagnostic tests in the presence of thenar atrophy and/or persistent numbness.

Level of Evidence: V

Grade of Recommendation: C

Rationale:

There were no prospective studies that evaluated a broad spectrum of patients. In addition, there was no consistent independent reference standard (including atrophy and persistent numbness) used across studies, and none attempted to differentiate CTS from other diagnoses. There were multiple studies differentiating CTS patients from normal subjects, mainly as case-control or cohort studies (Please refer to the AAOS technical report figure 5 and 9). There were considerable problems with spectrum bias, and lack of a "gold standard" for diagnosis. Thus the quality of studies fell to level V or expert opinion. Despite this, there was expert opinion that in some cases nerve conduction studies and needle EMG can differentiate carpal tunnel syndrome from other peripheral nerve problems (e.g., polyneuropathy, brachial plexopathy, or cervical radiculopathy). Additionally, thenar atrophy and/or persistent numbness may suggest severe nerve injury, which may warrant more aggressive management or diagnostic evaluation. NCS and EMG can assist in documenting this severe nerve injury.

3.1c The physician should obtain electrodiagnostic tests if clinical and/or provocative tests are positive and surgical management is being considered.

Level of Evidence: II & III

Grade of Recommendation: B

Rationale:

Improvement in symptoms after surgical release is a clinically relevant reference standard that is important to patient care and patient management. Four studies [Boniface (1994); Braun (1994); Glowacki (1996); Prick (2003)] found a correlation between a combination of clinical presentation (symptoms and Phalens' or Tinels') and NCS with good surgical outcome (Please refer to the AAOS technical report figure 98). See the meta-regression of surgical outcome and clinical and electrodiagnostic tests (Please refer to the AAOS technical report figure 99). The association with clinical tests alone or electrodiagnostic tests alone did not have a statistically significant association with surgical outcome (Please refer to the AAOS technical report 96 & 97). There were no other high-quality studies that attempted to correlate outcomes of other treatments (e.g., splinting, steroid injections) with pretreatment diagnostic results. Good response to surgery does not prove the diagnosis of CTS, because other factors may provide symptom relief (e.g. placebo, surgery activity modification, or postoperative splinting). However, post surgical improvement is a clinically relevant outcome. Clinicians who are considering surgical management should know that good surgical outcome is correlated with a combination of positive clinical and positive electrodiagnostic tests [Boniface (1994); Braun (1994); Haupt (1993); Glowacki (1996); and Prick (2003)]. Again, it is important to note that the evidence shows a statistically significant association between the combination of clinical tests, electrodiagnostic testing and positive surgical outcomes (Please refer to the AAOS technical report 96-99).

The literature does not permit calculation of sensitivities and specificities of all tests. Additionally, sensitivity and specificity of nerve conduction studies cannot be determined with absolute certainty primarily because a diagnosis of CTS cannot be made with absolute certainty without a "gold standard". The lack of a reliable "gold standard" and the use of reference standards that are variable from study to study give disparate results. Further, no universally agreed-upon diagnostic criteria exist for the diagnosis of carpal tunnel syndrome. The case control studies for electrodiagnostic testing consistently showed receiver operating curves of a very high specificity and variable sensitivity (Please refer to the AAOS technical report figure 11), illustrating inflated results due to spectrum bias. The case-control studies are, therefore, not considered useful.

Few well-designed cross-sectional and cohort studies were found. Based on the low availability of quality studies as well as the small size of the study populations, statistically significant receiver operating curves (Please refer to the AAOS technical report for this guideline) could not be constructed.

3.2 If the physician orders electrodiagnostic tests, the testing protocol should follow the AAN/AANEM/AAPMR guidelines for diagnosis of CTS.

- a. Sensory nerve conduction studies to the median nerve with distal latency compared to the ulnar and radial nerve.
- b. Median motor nerve conduction in most patients.
- c. Needle EMG at the discretion of the physician.

Level of Evidence: IV & V

Grade of Recommendation: C

Rationale:

Thirteen published studies were evaluated and met criteria for review when compared to a reference standard of signs, symptoms and one electrodiagnostic test. Twelve of these studies were Level IV (Sheu et al.; Lew et al., Sharma et al.; Cherniack et al.; Foresti et al.; Kothari et al.; Kuntzer et al.; Uncini et al.; Jackson et al.; Seror et al.; Lesser et al.; Sander et al.) and one was Level II (Schuhfried et al.). The reference standard used included signs, symptoms and a different electrodiagnostic test than the electrodiagnostic test being evaluated in the study. The index test could not be part of the referenced standard and vice versa. These inclusion criteria were comparable but slightly different than the criteria used in the AANEM Practice Parameter, which the Work Group agreed to use as a protocol for electrodiagnostic testing. The AANEM reference standard included clinical symptoms and did not include another NCS (Jablecki 2002).

The vast majority of studies were a case-control design, suggesting spectrum bias. A result of spectrum bias is that the sensitivities and specificities are likely inflated. There were multiple Nerve Conduction Studies (NCS) reported in the primary articles. These articles employed 11 different NCS techniques (Please refer to the AAOS technical report figure 6), including median sensory to ulnar sensory comparison, median sensory to radial sensory comparison, mixed nerve comparison and median motor testing. A review of these studies again could not determine conclusively that any of the electrodiagnostic tests were clearly superior (Please refer to the AAOS technical report table 3). Comparisons cannot be made and a test hierarchy cannot be constructed (Please refer to the AAOS technical report for this guideline) when case control studies are used because of the probability of spectrum bias. The Diagnosis and Treatment of Worker-Related Musculoskeletal Disorders of the Upper Extremity (2002), another evidence-based systematic review that examined 31 databases and 1600 journals, found similar conclusions.

The 2002 publication of the AANEM, AAN, and AAPMR, whose protocol is preferred by the Work Group for electrodiagnostic testing, was an evidence-based review of 278 articles of which 22 met literature inclusion criteria. This review also illustrated that there is no conclusive evidence that one single study has the highest sensitivity or specificity. It did however conclude that median sensory latencies across the wrist compared to ulnar or

radial latencies or proximal median conduction, improved sensitivity as opposed to absolute median sensory or motor distal latencies (Jablecki, 2002).

3.3 *The physician should NOT routinely evaluate patients suspected of having carpal tunnel syndrome with new technology such as magnetic resonance imaging (MRI), computerized axial tomography (CAT) and pressure specified sensorimotor device (PSSD).*

Level of Evidence: V

Grade of Recommendation: C

Rationale:

Changes in the appearance of the median nerve have been reported with MRI and CT scanning. Following the face to face Work Group meeting on February 24, 2007 an additional nonsystematic literature review was completed. This review included 6 of 25 articles on MRI and no studies on CT scanning. Five of the six articles on MRI were case control study designs and therefore introduced spectrum bias. There is no good evidence to date that these imaging modalities improve sensitivity or specificity in making the diagnosis of carpal tunnel syndrome (Chapell R et al. 2002). In the opinion of this committee, there is no role for the routine use of MRI or CT scans in the diagnosis or management of carpal tunnel syndrome. These imaging modalities should be reserved for the evaluation of related conditions in the appropriate clinical setting (e.g., Kienbock's disease, ruling out occult fracture, hook of the hamate nonunion, etc.).

PSSD (pressure-specified sensory device) has also been described for evaluation of patients with symptoms of carpal tunnel syndrome. Two of three studies investigating this technology were included in this additional literature review process. Two studies do not provide sufficient evidence to provide a recommendation. There is however, significant experience and literature supporting the use of NCV/EMG in the evaluation of CTS. In the opinion of this committee, there is insufficient evidence to support the routine use of PSSD in the evaluation of CTS at this time.

Future Research

Although every effort has been made to include studies of the highest evidence, high-quality evidence is not readily available for carpal tunnel syndrome diagnosis at this time. This guideline has been hindered by a relative lack of studies of the best design (e.g., Level I and II evidence), and specifically hindered by an abundance of case control studies (which are subject to spectrum bias). To achieve a high-quality literature base, academic authors and scientists should invest their time and effort in studies designed to avoid bias (e.g., blinded controlled trials that are not case control studies). Future studies should, from the onset, be based on improved study design. The recommendations of this guideline have therefore depended to some degree on lesser evidence, including consensus and expert opinion.

Few studies describe the impact of health policy on process optimization. Skillful and timely delivery of carpal tunnel syndrome care, the access that patients have to definitive management and the choices patients make in the management of disease all affect outcomes. Studies of cost burden to the community from a common disabling source of productivity loss need restatement, and future studies must address all of these issues.

Conclusion:

Although thousands of publications have been written regarding the diagnosis and treatment of carpal tunnel syndrome, greater precision and transparent methodology are needed to bring the next generation of academic papers to the forefront of review so they directly contribute to quality medical care. The process of periodically assessing our medical and surgical progress in diagnosing and treating common conditions becomes more precise each year. A common protocol for evaluation of the literature should spur more consistently sound design and greater health for the cost of care expended. This clinical practice guideline is based on stronger evidence-based analysis methodology than ever previously conducted by the AAOS and is therefore state-of-the-art. The details of the statistical methods used in this guideline are further explained in the Appendix, as well as the criteria to replicate the guideline and for its future revision/improvement. The CTS Guideline Work Group hopes that future AAOS guideline committees have the same strong academic support.

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Appendices

Appendix I: Literature Searches

In general, the Work Group did not search for or include all available evidence. Rather, the Work Group searched for and included only the best available evidence. In general, there was not a sufficient amount of Level I or II evidence available to answer any of the five key questions. The total amount of literature available on carpal tunnel syndrome and various diagnostic tests is large; however, the literature base available for individual diagnostic tests is small. A wide variety of tests are reported as well as a plethora of methods. Generally, Level III evidence and lower was found and hence, the quality of available research studies contributed to the inherent weaknesses in the recommendations.

Search strategies were reviewed by the Work Group prior to conducting the searches. Work Group members supplemented the searches of electronic databases with articles not identified by those searches. The search strategies used are provided below.

Databases Searched

The compressed timeframe for this guideline required that steps be taken to expedite work. Specifically:

1. The Work Group had to rely on published, evidence-based guidelines, published systematic reviews, and published meta-analyses before searching for clinical studies. However, at the discretion of the Work Group, we also conducted supplemental searches for some studies. These supplemental searches were restricted to searches for articles published after the end date of the searches described in the guideline/systematic review/meta-analysis.
2. The Work Group was unable to search some commonly used databases (e.g., Embase) due to time constraints. Therefore, the Work Group almost exclusively relied on PubMed/Medline for locating clinical studies.

Search Strategies

The published literature was searched using the Medline electronic database to identify potentially relevant studies that shed light on the questions. A manual search was performed of the bibliographies of all publications accepted for inclusion into the evidence base. In addition, the bibliographies of recent review articles were searched for potentially relevant citations.

The Medline search included the following search strategies, with limits of publication dates 1966 to present, English language, and humans:

Questions 1 & 2: (((*"Diagnosis"*[MeSH] OR *"diagnosis"*[Subheading] OR *diagnosis*[Text Word]) AND (*"Carpal Tunnel Syndrome"*[MeSH] OR (*"carpal tunnel syndrome"*[TIAB] NOT *Medline*[SB]) OR *"carpal tunnel syndrome"*[MeSH Terms] OR *carpal tunnel*[Text Word]))) OR *"Carpal Tunnel Syndrome/diagnosis"*[MeSH]) AND (*"Sensitivity and Specificity"*[MeSH] OR *"Predictive Value of Tests"*[MeSH] OR *"Comparative Study"*[MeSH])

Questions 3, 4 & 5: ((*"Diagnosis"*[MeSH] OR *"diagnosis"*[Subheading] OR (*"diagnosis"*[Subheading] OR *"diagnosis"*[MeSH Terms] OR *diagnosis*[Text Word])) AND (*"Carpal Tunnel Syndrome"*[MeSH] OR *"Carpal Tunnel Syndrome"*[All Fields] OR *"Median Neuropathy"*[All Fields] OR (*"carpal tunnel syndrome"*[TIAB] NOT *Medline*[SB]) OR *"carpal tunnel syndrome"*[MeSH Terms] OR *carpal tunnel*[Text Word])) OR *"Carpal Tunnel Syndrome/diagnosis"*[MeSH]

Additionally, a list of potentially relevant studies was provided by the Work Group members. These citations were screened in the same manner as those identified by electronic searches.

Appendix II: Article Inclusions and Exclusions

Inclusion/exclusion criteria

During Phase I screening (see [Figures 1-4](#)), all abstracts were downloaded, reviewed and evaluated for the following exclusion criteria:

- Reviews, practice guidelines, meta-analyses (except those regarding diagnosis).
- Letters, case reports, historical articles, editorials, and commentaries.
- Abstracts and unpublished study reports.
- Non prospective studies.
- Animal or *in vitro* studies.
- Cadaveric studies.
- Studies written in languages other than English.
- Studies with < 10 patients.
- Studies with patients under 21 years of age.
- Studies where gender is restricted.
- Studies where limb temperature was not monitored during electrodiagnostic tests.
- Studies where results for CTS population cannot be separated from results from other populations.
- Industrial and familial diagnoses of Carpal Tunnel Syndrome;
- Studies not pertaining to diagnosis of CTS.

a. Inclusion criteria

Full articles were retrieved for all abstracts passing Phase I screening. The articles then underwent Phase II screening, which consisted of evaluating the articles for the following inclusion criteria:

- Studies that meet this review's reference standard (defined as signs and symptoms and nerve conduction study outcomes consistent with CTS) to confirm the diagnosis of CTS. (Questions 1 & 2)
- Studies addressing any diagnostic test to establish or support a diagnosis of CTS.
- The following study designs: observational [cohort, case-control, and cross sectional (XS)], or interventional [RCTs, non-randomized controlled trials (nRCTs), XS].
- Studies that compare a minimum of two diagnostic tests. (Questions 1 & 2)
- Studies where the limb temperature of the CTS patient is continuously monitored during electrodiagnostic testing according to the American Association of Electrodiagnostic Medicine Practice Parameter (Jablecki et al. 2002)
- Studies where data can be abstracted for statistical analysis.
- Studies reporting at least one of the following specific interventions:
 - Open or Endoscopic Carpal Tunnel Release. (Question 4)
 - Splinting, steroid injection or change in lifestyle. (Question 5)
- Studies reporting at least one of the following specific outcomes:
 - Post surgical improvement or resolution of CTS signs and symptoms, test results, or patient satisfaction. (Question 4)
 - Post treatment improvement or resolution of CTS signs and symptoms, test results, or patient satisfaction following splinting, steroid injection or change in lifestyle. (Question 5)

The most recent version of multiple publications was always used.

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Included and Excluded Articles Flowchart

Figure 1. Flowchart of literature review process (Questions 1 & 2)

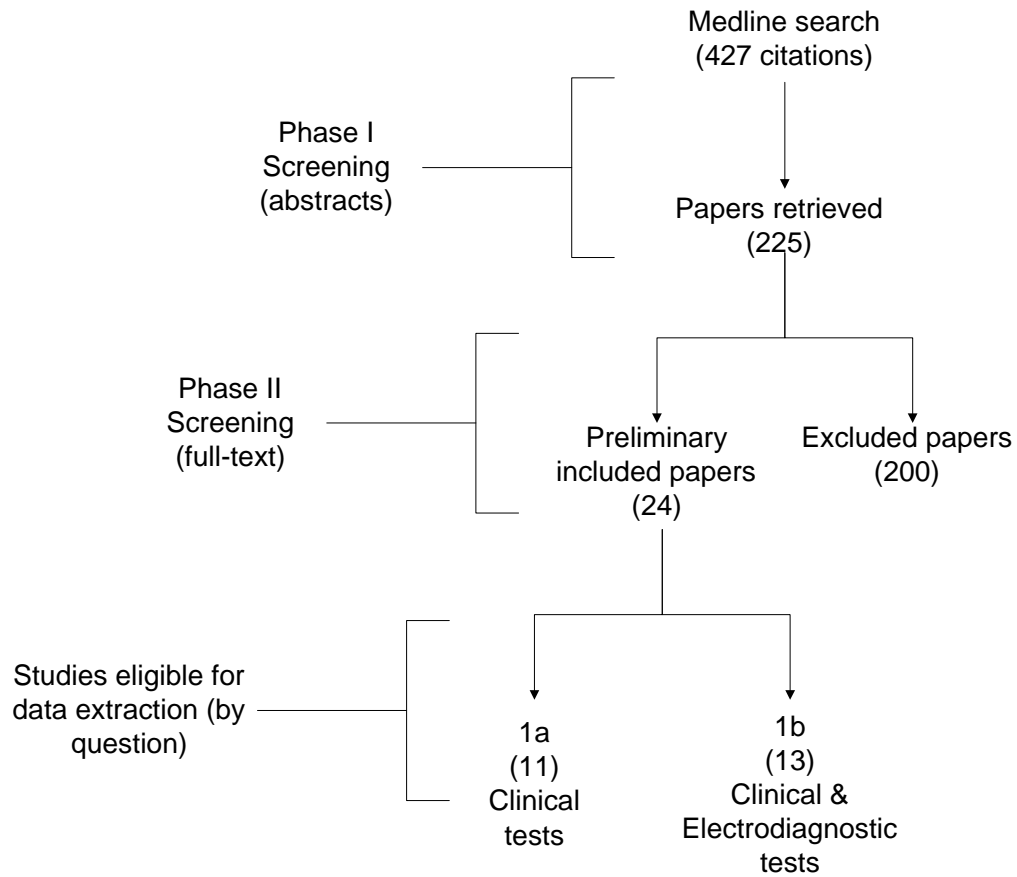


Figure 2. Flowchart of literature review process (Question 3)

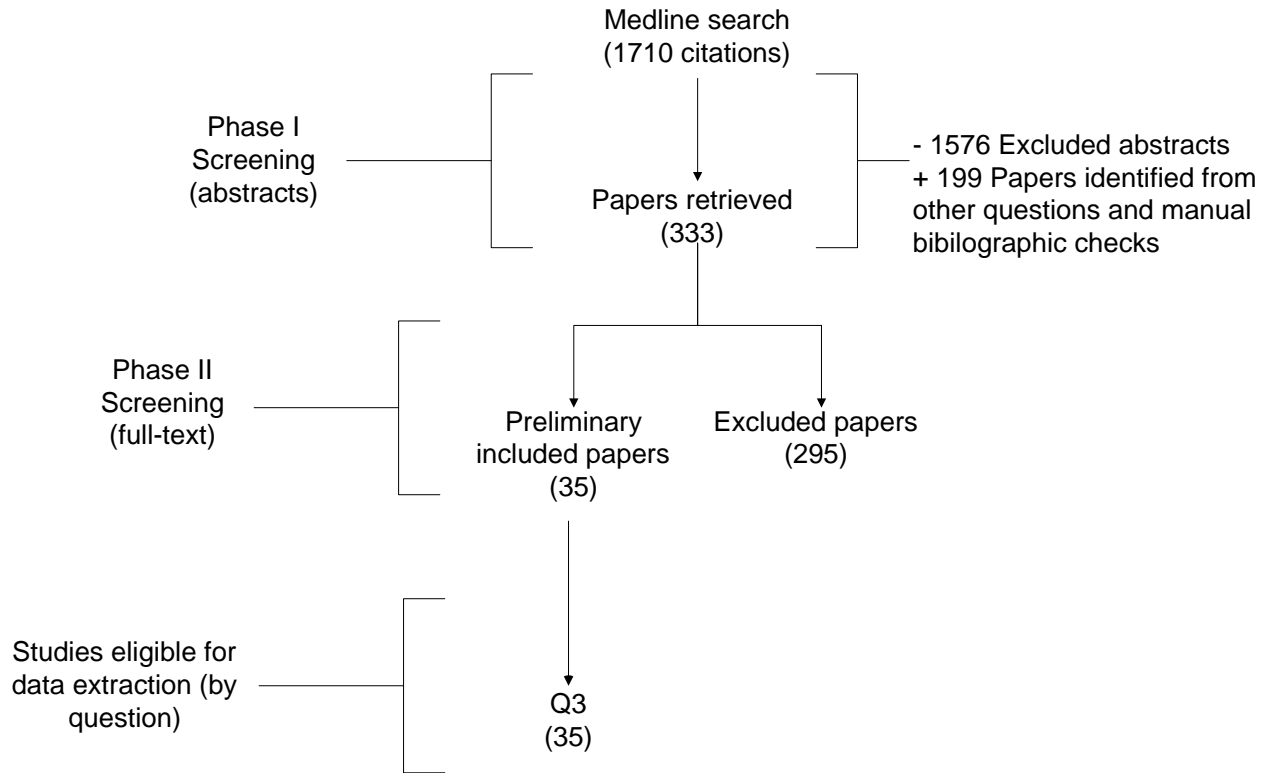


Figure 3. Flowchart of literature review process (Question 4)

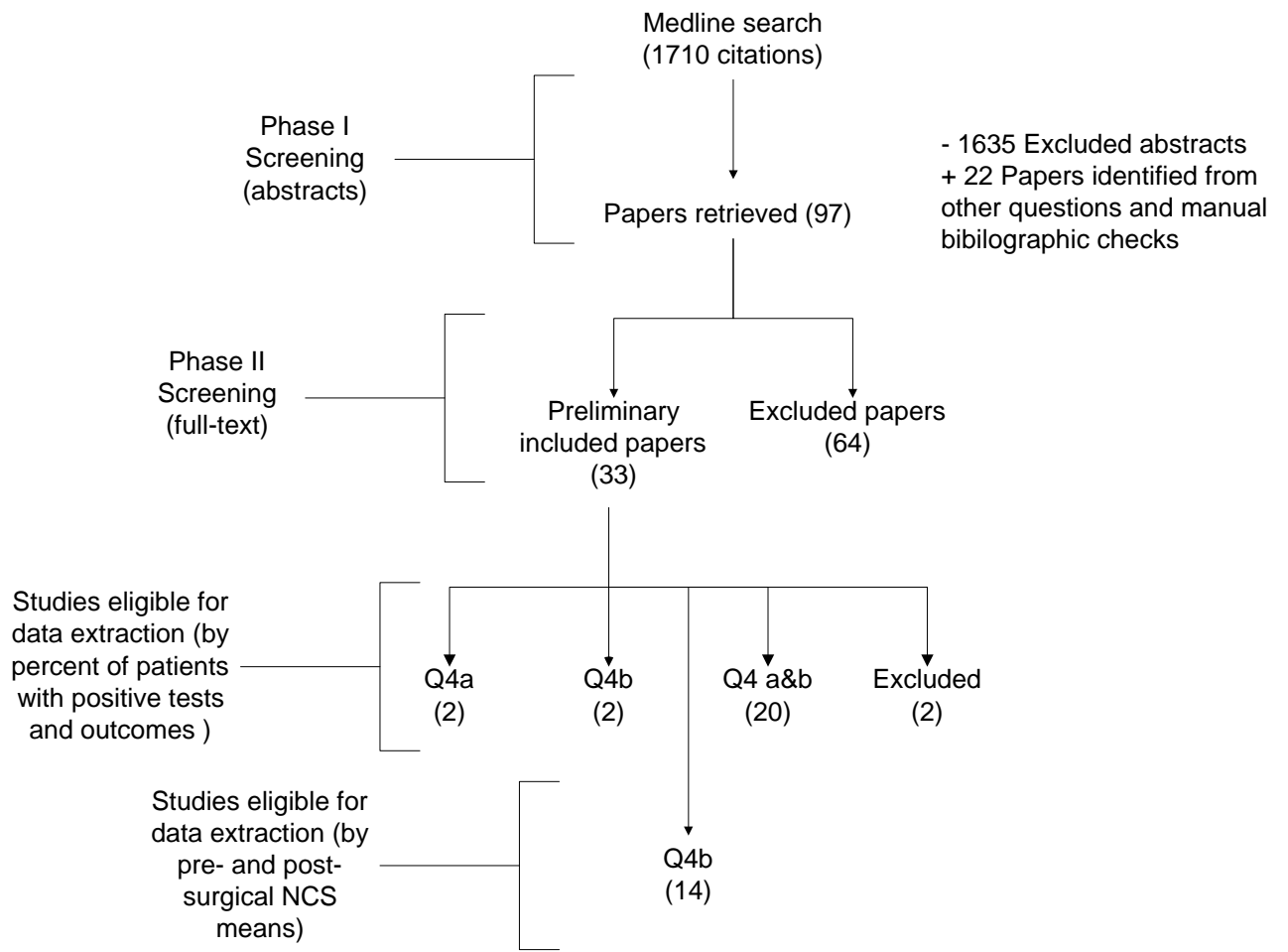
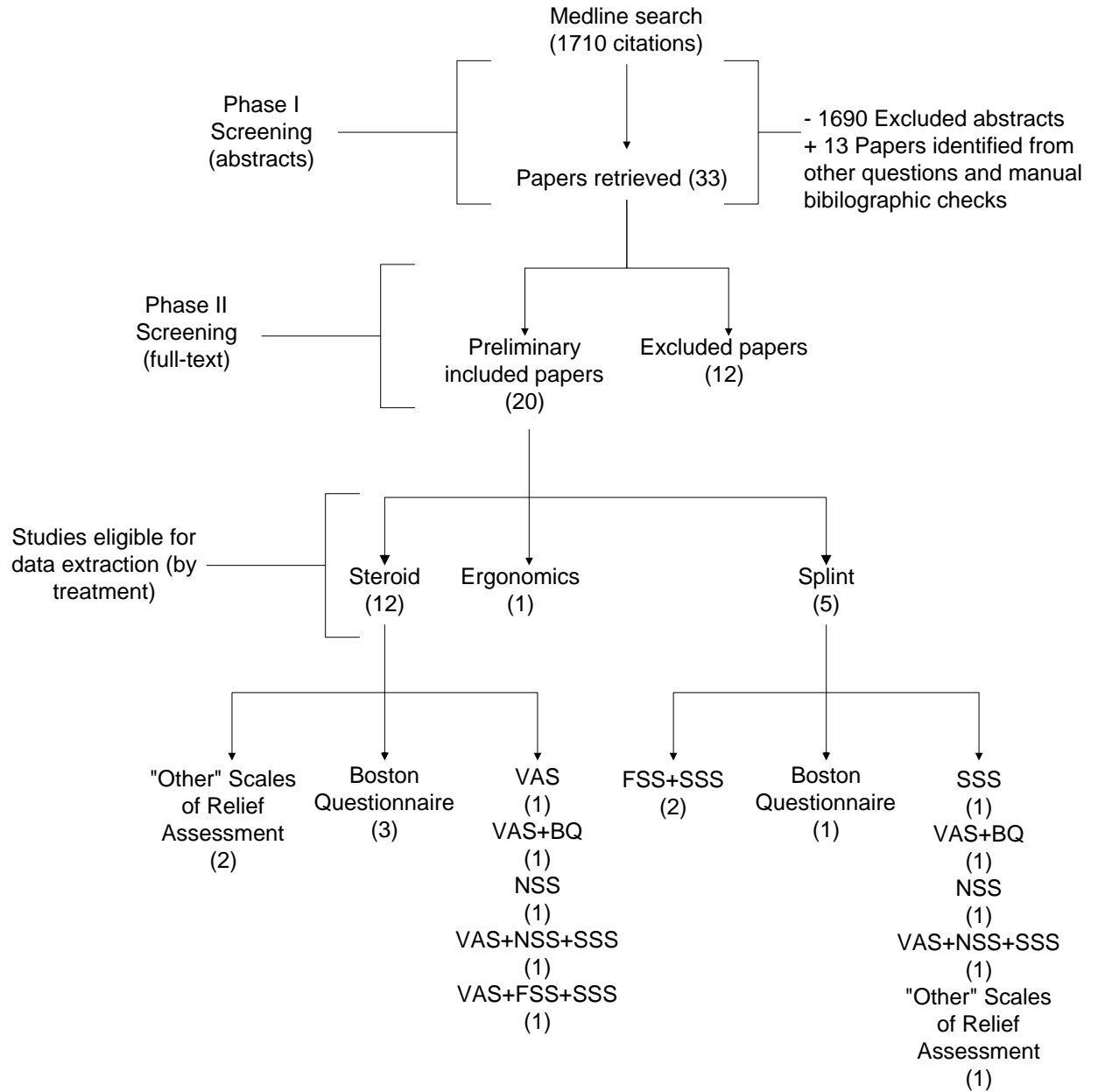


Figure 4. Flowchart of literature review process (Question 5)



Appendix III: Rating Evidence Quality

We considered the quality of the available evidence when grading the strength of guideline recommendations. Quality was determined using a “Levels of Evidence” approach in which five levels of evidence were designed for each of four study designs; **therapeutic, prognostic, diagnostic and economic or decision modeling**. The higher the level of evidence, the greater the ability to draw causal inferences from the results of a study and hence, the greater the quality of that study.

Levels of Evidence for Primary Research Question ¹

Types of Studies				
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	<ul style="list-style-type: none"> • High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic Review² of Level I RCTs (and study results were homogenous³) 	<ul style="list-style-type: none"> • High quality prospective study⁴ (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) • Systematic review² of Level I studies 	<ul style="list-style-type: none"> • Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) • Systematic review² of Level I studies 	<ul style="list-style-type: none"> • Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses • Systematic review² of Level I studies

Types of Studies

	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level II	<ul style="list-style-type: none"> • Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization) • Prospective⁴ comparative study⁵ • Systematic review² of Level II studies or Level 1 studies with inconsistent results 	<ul style="list-style-type: none"> • Retrospective⁶ study • Untreated controls from an RCT • Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.) • Systematic review² of Level II studies 	<ul style="list-style-type: none"> • Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) • Systematic review² of Level II studies 	<ul style="list-style-type: none"> • Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses • Systematic review² of Level II studies
Level III	<ul style="list-style-type: none"> • Case control study⁷ • Retrospective⁶ comparative study⁵ • Systematic review² of Level III studies 	<ul style="list-style-type: none"> • Case control study⁷ 	<ul style="list-style-type: none"> • Study of non-consecutive patients; without consistently applied reference “gold” standard • Systematic review² of Level III studies 	<ul style="list-style-type: none"> • Analyses based on limited alternatives and costs; and poor estimates • Systematic review² of Level III studies
Level IV	Case Series ⁸	Case series	<ul style="list-style-type: none"> • Case-control study • Poor reference standard 	<ul style="list-style-type: none"> • Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.

4. Study was started before the first patient enrolled.
5. Patients treated one way (e.g. cemented hip arthroplasty) compared with a group of patients treated in another way (e.g. uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called “cases”; e.g., failed total hip arthroplasty, are compared to those who did not have outcome, called “controls”; e.g. successful total hip arthroplasty.
8. Patients treated one way with no comparison group of patients treated in another way.

Appendix IV: Conflicts of Interest

No member on the Carpal Tunnel Guideline Work Group disclosed a conflict of interest.