ELECTRODIAGNOSTIC TECHNIQUES IN THE PRE-SURGICAL ASSESSMENT OF PATIENTS WITH CARPAL TUNNEL SYNDROME

A West Midlands Development and Evaluation Service Report

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About West Midlands Development and Evaluation Service

The West Midlands Development and Evaluation Service produce rapid systematic reviews about the effectiveness of healthcare interventions and technologies, in response to requests from West Midlands Health Authorities. Each review takes 3-6 months and aims to give a timely and accurate analysis of the cost-effectiveness of the intervention accompanied by a statement of the quality of the evidence.

About InterTASC

West Midlands DES is part of a wider collaboration with two units in other Regions (the Trent Working Group on Acute Purchasing (Trent DES) and the Wessex Institute for Health Research and Development (South & West DES)) to share the work on reviewing the effectiveness and cost-effectiveness of clinical interventions. This group, InterTASC, shares work, avoids duplication and improves the peer reviewing and quality control of these reports.

West Midlands Regional Evaluation Panel Recommendation:

Not Supported

There is no evidence of additional benefit from electrodiagnosis where there is a clear clinical diagnosis of carpal tunnel syndrome.

Anticipated expiry date

- **This report was completed in January 2000**
- **The searches were completed in December 1998**
- **It is not known whether any good quality studies of the value of electrodiagnosis in predicting surgical outcomes in patients with a clinical diagnosis of carpal tunnel syndrome are in progress. In default of such studies, there is no basis for a reliable estimate of the benefits associated with electrodiagnostic techniques in the pre-surgical assessment of patients with carpal tunnel syndrome.**

Contents

Summary

- **Aim**
  To address the value of electrodiagnostic studies as a prognostic tool for predicting outcome of surgery in patients with a clear clinical diagnosis of carpal tunnel syndrome (CTS).

- **Background**
  CTS comprises a complex of symptoms in the hand including pain and paresthesia and weakness of hand muscles. These are thought to result from compression of the median nerve where it runs through the carpal tunnel at the wrist.

- **Epidemiology**
  Up to 20% of the population may have symptoms of CTS but only about 0.5% present to medical services. Occupational exposure produces an increased risk.

- **Diagnosis and treatment**
  There is no 'gold' standard for diagnosing CTS but clinical diagnosis is generally accepted as valid and reliable. Many clinicians also refer patients for electrodiagnostic studies to aid diagnosis, but others find such studies unnecessary. However, electrodiagnostic studies may be useful as an aid to decisions on treatment. Patients are first treated conservatively or medically. If this fails, surgery is found to be 80-90% effective.

- **Methods**
  A comprehensive search for studies was undertaken which included patients with clinical diagnosis of CTS, undergoing electrodiagnostic tests and surgery, with outcomes of surgery reported.

- **Quantity and quality of research**
  Seven studies were found but one was retracted. Of the remaining six, all were retrospective case series (where prospective cohort studies would have been the preferred design) and of poor quality. Four studies reported outcomes of surgery in patients with both positive or negative electrodiagnostic results. Three of these measured symptom improvement as assessed by the patients.

- **Value of electrodiagnostic tests as a predictor of surgical outcome**
  Although surgery was found to be 74-98% effective, there was no statistical difference in surgical outcome between those who were electrodiagnostic test positive, and those who were negative.

- **Costs and consequences**
  No quantifiable benefits to patients could be identified from using electrodiagnostic tests as a prognostic tool. The cost at University Trust is £100,000 per year; using electrodiagnosis only to clarify diagnosis when the clinical symptoms are not clear would avert a large proportion of those costs.

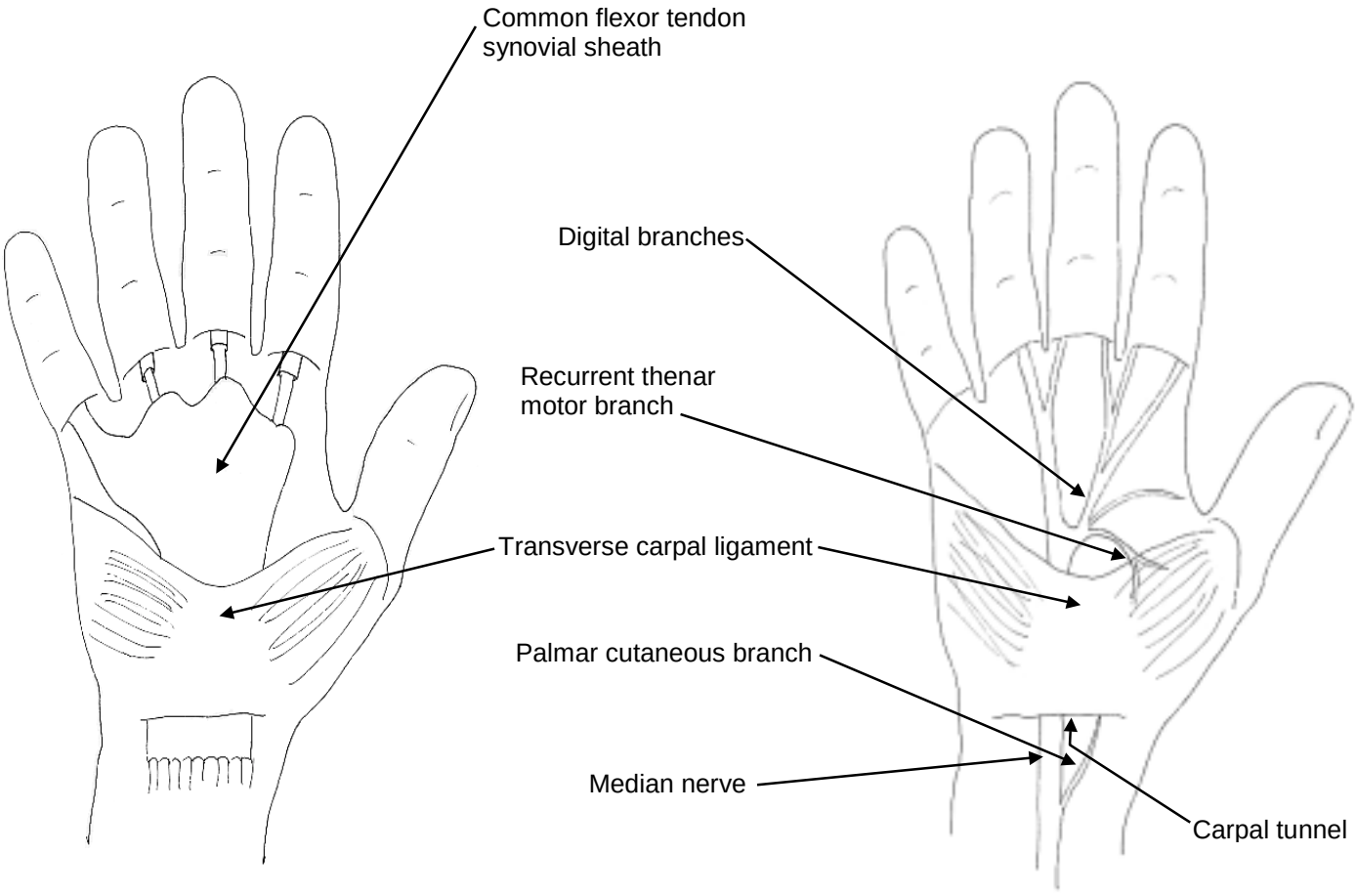
- **Conclusions**
  Despite the limited quality of the evidence, in cases of clear-cut clinical CTS, electrodiagnosis is not warranted either as a diagnostic test, where clinical symptoms are well defined, or as a predictive indicator. It may still be useful in cases where the clinical diagnosis is not clear.

Abbreviations & Definitions

CTS Carpal tunnel syndrome

NCS Nerve conduction studies

EMG Electromyography



1 Aim of the review

This review addresses the value of electrodiagnostic studies in patients with a clear clinical diagnosis of carpal tunnel, for predicting the outcome of surgery.

1.1 Rationale

In 1998 a West Midlands Health Authority noted that there was an increase in referrals of patients with suspected carpal tunnel syndrome for electrodiagnostic testing between Trusts and also a lengthening waiting list because there was a shortage of resources for this testing. They wished to assess:

- whether to expand the service to meet current and projected levels of demand.
- if so, whether it should be provided at the one existing centre or whether to make expertise more widely available.

Electrodiagnostic techniques are used in a wide variety of conditions but the investigation of carpal tunnel syndrome (CTS) and of suspected neuropathy in diabetics are the two commonest categories. Some hand surgeons rely on the results of electrodiagnosis in addition to clinical symptoms and signs; others proceed to treatment based mainly on clinical symptoms and signs but may perform electrodiagnostic studies as a form of risk management. The one published systematic review shows that electrodiagnostic studies are not as sensitive as clinical diagnosis in defining cases and therefore add little of value to the diagnosis when there are clear clinical signs. However, they may be of use as a prognostic tool when predicting the outcome of carpal tunnel surgery.

2 Background

2.1 Description of underlying health problem

2.1.1 Aetiology and pathology of carpal tunnel syndrome

Carpal tunnel syndrome (CTS) comprises a complex of symptoms in the hand and sometimes the forearm[1]:

Carpal tunnel syndrome common symptoms

- Pain and parasthesia over distribution of median nerve in hand, often worse at night
- Weakness of hand muscles innervated by median nerve

These are thought to arise from compression of the median nerve within the carpal tunnel at the wrist[1]. The carpal tunnel consists of a canal made up of the carpal bones and the flexor retinaculum (also known as the transverse carpal ligament), a tendinous band[1]. Swelling of any of the structures within the canal, especially in a canal of small dimensions, leads to compression. CTS is more common in diabetics and in those with rheumatoid arthritis. It may occur transiently during pregnancy and may also be associated with repetitive movements of the hands, especially in an occupational setting[1]. The precise pathological lesion in the nerve is not known but continuing compression may lead to permanent or only partially recoverable damage to the nerve and can also lead to wasting of the thenar muscles of the hand. Changes in nerve conduction and in muscle innervation are detectable by

electrophysiological techniques. Symptoms and nerve conduction changes may be unilateral but bilateral effects are relatively common[2; 3].

2.1.2 The epidemiology of carpal tunnel syndrome

Estimates of prevalence and incidence are critically dependent on the diagnostic criteria used. Case definitions have recently been developed to aid standardisation (see below)[4].

The incidence of CTS in Rochester, Minnesota based on community surveys for five year periods between 1961 and 1980 was 33-68 per 100,000 person-years in males, and 130-170 per 100,000 person years in females. Peak incidence was at age 50 with the dominant hand most commonly affected[3]. A more recent US study found a rate 3.5 times this level[5]. A UK general practice survey found that 18.5 % reported classic CTS symptoms on questioning, while a further 14% had possible ones[6].

Nerve conduction defects may be present without symptoms and vice versa. The same UK survey of general practice populations estimated the prevalence of nerve conduction disorders at between 7 and 16%[7]. Excess risk of CTS may be associated with occupational exposure, with odds ratios of 5.5 in those performing repeated bending and twisting tasks and 1.9 in those using vibrating tools[3]. However, this is not universally accepted.

Only a small proportion of people with symptoms present to clinical services. 0.5% of a US population reported that they had CTS as identified by a medical person and there are some 200,000 CTS operations for it each year in USA[3]. In 1998 there were 8290 male and 21080 female admission with CTS to NHS hospitals in England, with a peak age of 45-55 (Personal communication – Wilson, R.) Most admissions will be for surgery.

2.1.3 The treatment of carpal tunnel syndrome

CTS may be treated conservatively by rest and splinting, with systemic analgesics, by injection of glucocorticoids into or near the canal[8] or by surgery. The non-surgical methods lead to resolution in some cases and are used, for instance in pregnancy or where CTS follows a period of excessive repetitive movement, where the cause is not continuing. They should be considered before proceeding to surgery[8]. The aim of surgical treatment is to decompress the canal by cutting the flexor retinaculum, either at open operation or by endoscopy. It is usually a day-case procedure. The success rate is high at 80-95% depending on the criteria used[9; 10]. In the USA nerve conduction defects may lead to surgery in contra-lateral asymptomatic hands with the aim of preventing future irreversible effects. This is not UK practice.

2.1.4 The diagnosis of carpal tunnel syndrome

There is no ‘gold standard’ for the diagnosis of CTS because the pathological changes are unspecified and diagnosis rests on a symptom complex of sensory and motor changes in the distribution of the median nerve. Patients are typically questioned about their symptoms and subjected to several physical tests, including:

1. Phalen’s test
2. Tinel’s test
3. point sensory discrimination
4. Grip and pinch strength.

Phalen's and Tinel's tests are clinical provocation tests to detect abnormal median nerve function. Phalen's test involves one minute of acute wrist flexion against resistance, and Tinel's sign involves percussion of the median nerve at the carpal tunnel. The tests are considered positive if the symptoms of CTS are reproduced[11].

A positive diagnosis of CTS based on symptoms and physical signs requires[4]:

1. Pain, or paresthesia, or sensory loss in the median nerve distribution
2. and one of:
   - Tinel's test positive,
   - Phalen's test positive,
   - nocturnal exacerbation of symptoms,
   - motor loss with wasting of abductor pollicis brevis,
   - abnormal nerve conduction time

Recently, many practitioners have introduced electrodiagnostic tests in order to aid diagnosis. There is great debate about the value of these tests[12]especially in USA, because in patients with a clear clinical diagnosis, electrodiagnostic tests do not appear to give any further information. A systematic review has assessed information on all studies in which patients were examined clinically and with electrodiagnostic studies[13]. Although the specificity of electrodiagnosis for confirming clinically characterised CTS was found to be high (95-100%), so that few people without clinical CTS would have abnormal electrodiagnostic results, the sensitivity was low and very variable (49-84%), so that a substantial proportion of patients with positive clinical symptoms would have normal electrodiagnostic results.

A second diagnostic procedure following clinical examination would only be useful if patients who would not benefit could be excluded from treatment (i.e. if the post-test probability was more accurate). In this case, if patients were required to fulfil both clinical and electrodiagnostic criteria before proceeding to treatment, many people could be prevented from receiving benefit.

Electrodiagnostic studies, however, form part of the practice guidelines of the relevant American Associations[14]. Further impetus to use electrodiagnosis arises as tests are used for the purpose of risk management and also required by some health insurance companies[9], especially in the US.

There is a divergence of views between clinicians who regard the desired outcome of treatment of CTS as an alleviation of the clinical symptoms and use electrodiagnosis for characterisation of the nature and severity of the symptoms, and clinicians who believe that the purpose of treatment is to correct a conduction defect caused by compression of the median nerve, and thus avoid damage and discomfort before they become irreversible[9; 15-18].

In the majority of cases of CTS the symptoms are well defined and electrodiagnostic tests would not seem worthwhile[19]. However, in some people, diffuse and poorly characterised symptoms are present and electrodiagnosis might be useful to identify abnormal nerve conduction in order to decide whether further treatment should be given[19; 20].

As electrodiagnosis does not assist in diagnosis of CTS in patients with clear symptoms, its use as solely as a diagnostic tool is not further considered in this review.

Electrodiagnostic tests are, however, potentially useful as a predictive tool (prognostic indicator). It may be possible to use them to determine which patients will respond well to treatment, particularly to surgery. It is this question which will be addressed in the remainder of the review. It may also have unquantifiable benefits as an aid to surgical risk management by enabling pre and post intervention findings to be compared should the effectiveness of the procedure be questioned.

2.2 Current service provision

The provision of electrodiagnostic services in the West Midlands has not been studied in any detail. The original request for this review focused on the adequacy and appropriateness of existing services. These are provided by the Neurosciences Centre at the Queen Elizabeth Hospital. Referral to the Centre may be from GPs, who can request nerve conduction studies directly, or by hospital clinicians, mainly hand surgeons and rheumatologists, who are investigating outpatients referred to them. There are three consultant neurophysiologists. They and the technical staff at the Centre perform most of the median nerve conduction studies done in the Birmingham area. Median nerve studies are one of their most common procedures, although they have to compete with a wide range of requests for other tests, such as EEGs, for the resources in the Centre. There is also a technician-based clinic run by Centre staff once a week at the Royal Orthopaedic Hospital (ROH) which is almost exclusively for median nerve studies.

Some general practitioners send patients for nerve conduction studies, especially those with equivocal symptoms, to help them decide whether to refer them for surgery. Two of the three hand surgeons at ROH require electrodiagnostic studies on all patients to confirm the diagnosis of CTS and to avoid inappropriate surgical treatment. The third has operated without conduction studies where the clinical diagnosis is clear cut and sometimes uses a trial steriod injection for confirmation but is currently requesting nerve conduction studies on all patients as part of an investigation which he is undertaking into the effectiveness of surgery for CTS. One of the consultant neurophysiologists does all median nerve conduction studies referred to him personally, the others make use of technicians and report on their findings, selecting only the more complex cases for personal investigation. All those concerned with diagnosis of CTS in the Region regard nerve conduction studies as an important part of the process but there are differences in emphasis and varying views on the need for their routine use. In particular some see such studies as an important part of clinical risk management rather than as a key step in diagnosis in well-characterised cases.

1512 patients were seen for median nerve conduction studies in the year 1998-9. In addition, a small but unrecorded number had these studies done as part of wider investigations. 231 of these were GP referrals while 1281 came from hospital clinicians. No information summarising outcomes is available. A few examinations are undertaken by medical staff at a cost of £90 per test; most are done by technicians at a cost of £60 per test (Personal Communication –Al-Seffar, J.). The overall cost of providing this diagnostic service is therefore c. £100,000 per year.

2.3 Description of electrodiagnostic tests

Electrodiagnostic studies used in patients with CTS may include two distinct but complementary techniques: nerve conduction studies (NCS) and less commonly electromyography (EMG)[13].

Nerve conduction studies can be performed in the clinical laboratory setting with surface stimulating and recording electrodes on both motor and sensory nerves[13]. To perform a motor nerve conduction test, a peripheral nerve is stimulated with a pulsatile current and the time taken for the resulting muscle twitch (latency) is recorded[21]. A second stimulation at another site on the nerve is performed and the difference between the two latencies divided by the distance between the stimulation sites gives the conduction velocity[21]. Sensory nerve conduction tests are performed in a similar way, although only one stimulation site is used because there is no muscle or neuromuscular junction to worry about[21]. Sensory nerve conduction testing is very useful because most pathologies affecting peripheral nerves tend to affect the sensory components first, followed by motor nerves[21]. The amplitude of the muscle action potential created by the stimulation indicates the number of motor units being stimulated. A damaged nerve will produce slower conduction velocities and smaller amplitudes[21]. Technical factors which influence the results of NCSs include amplifier gain and filter settings, electrode size, distance between electrodes and limb temperature[13], therefore standardisation of conditions is necessary to compare results between and within studies. In CTS, the median nerve is usually examined across the carpal tunnel, although it may also be compared with the ulnar or radial nerves[13].

Electromyography involves the insertion of needle electrodes into a muscle and examining individual motor unit potentials. A typical examination involves the insertion of the needle at several different locations and measuring the amplitude, duration and complexity of the response under different conditions: insertion of the needle, rest, minimal contraction and maximal contraction[21]. Technical factors which influence the results of these studies include amplifier gain and filter settings, electrode size, shape and material[13].

The results of the tests are compared against tables of normative values to determine if there is a problem with the nerve. Unfortunately, different clinicians may use different normal values.

3 Question addressed by this review

In patients with a clear clinical diagnosis of carpal tunnel syndrome, how effective are electrodiagnostic studies as a prognostic tool for predicting the outcome of surgery?

4 Effectiveness

4.1 Methods for reviewing effectiveness

4.1.1 Search strategy for identifying studies

Primary studies in the English language were identified by:

- Search of MEDLINE(1966 - December 1998) using the following MeSH headings: 'Carpal tunnel syndrome' 'epidemiology/surgery/therapy' 'Electrodiagnosis'.
- Search of EMBASE (1988 - December 1998) using the same MeSH headings.
- Search of Cochrane database
- Search of OSHROM database
- Search of internet for carpal tunnel syndrome
- Personal contact with electrodiagnosticians and hand surgeons
- Citations from reference lists

4.1.2 Criteria for including studies

Study design

Primary studies of all types were sought. Ideally, well-designed prospective cohort studies would be obtained, but in practice, the information was likely to be retrospective.

Study population

Studies were accepted if they included patients with suspected carpal tunnel syndrome as defined by clinical criteria.

Intervention

Studies were accepted if following clinical diagnosis, some of the patients had electrodiagnostic studies followed by carpal tunnel surgery.

Outcome

Studies were accepted only if the outcomes of surgery were reported, ideally by patient-assessed improvement.

4.1.3 Data extraction

Data was extracted by two independent abstracters using a pro-forma to record findings in a standard way. Any differences were resolved by discussion.

4.1.4 Quality assessment

The following criteria were used in the assessment of the quality of the studies:

Study design

1. Was the study design a prospective cohort study?

Population

2. Was the population well defined?
3. Was the number of hands stated?
4. Was the population representative of general CTS patients?
5. Were the clinical criteria given?
6. Were the criteria for physical signs clearly described?
7. Did the study include the surgical outcomes of those patients with both positive and negative electrodiagnostic results?
8. Were patients without electrodiagnostic testing included in the study?

Intervention

9. Was the electrodiagnostic procedure sufficiently well described?
10. Were procedures carried out in standardised conditions including temperature control?
11. Were clear criteria for abnormal results given?
12. Was the surgical procedure sufficiently well described?

Outcomes

13. Were the outcomes clearly stated?
14. Were the outcomes measured by a blinded assessor?
15. Were outcome measurements valid and unbiased?
16. Was follow-up complete?
17. Were any reasons for loss to follow-up given?

4.1.5 Data synthesis

The results are presented in tabular form, and were not of sufficient quality to be combined.

4.2 Results

4.2.1 Quantity and quality of research available

Seven studies in which electrodiagnostic results could be linked to surgical outcome were found. Six were from USA[9; 10; 15; 16; 19; 20] and one from Korea[22]. One was subsequently comprehensively retracted by its authors[19; 23], and will be excluded from further description. The remaining six are summarised in table 1.

The quality of all the studies were poor (see table 2). None were well-designed prospective cohort studies; all were retrospective. There is therefore potential bias in the selection and follow-up of cases, the patients may not have been treated in the same way, there is potential bias in recording patient data and potential for investigators views to influence outcome.

In most studies, the population was reasonably well-defined with mean age and sex mix frequently reported and general inclusion and exclusion criteria given. However, several of the studies did not report the number of hands being investigated, only the number of patients[15; 16]. The specific clinical and physical sign criteria were only defined in 3 of the 6 studies[9; 10; 22], with lists of symptoms and signs given in some of the others. In the Korean study[22], the criteria for surgery were given, but then appeared to be ignored as they persuaded some patients with positive electrodiagnostic results but negative clinical carpal tunnel syndrome to have surgery:

"We performed surgery on the patients who suffered physical symptoms and had a positive electrodiagnosis, except in cases where the patient had carpal tunnel syndrome in only one hand and had obscure physical symptoms, even though these patients tested positive with regard to electrodiagnostic criteria in the other hand. We persuaded these patients to have the operation on the hand with obscure symptoms because most of the patients were elderly housewives who used their hands often performing repetitive chores and, thus, were likely candidates to develop carpal tunnel surgery."

In one study, outcome information was only given on those patients with positive electrodiagnostic test results[22], in one other only in patients with negative results[20], but the remainder had outcome information in patients with both positive and negative results. In four of the studies, all patients underwent electrodiagnosis[10; 15; 20; 22]. However, in the remaining two[9; 16], some of the patients did not, for various reasons, including responding to the wish of the insurance companies. It is likely that this would produce a bias known a

Table 1 Study and patient characteristics

NCS = Nerve conduction studies EMG = Electromyelography NS = not stated.

Authors	Study design	Patients (n) (M/F)	Mean age (yrs) (range)	Exclusion criteria	Inclusion criteria	Clinical criteria	Physical tests	Electrodiagnostic test details	Surgical details	Outcomes	Mean follow-up (range)
Grundberg, 1983[20]	Retrospective case series	292 but data only given on 26 (4/22) of 33 with normal electromyographic results. N=32 hands. General CTS patients	Median 41 (22-74)	NS	Patients with suspected carpal tunnel syndrome.	No criteria given but all had numbness & tingling, pain. Night pain, weakness, decreased sensibility present in most.	No criteria given but tests included Phalen's test, Tinel's sign, grip strength & pinch strength.	Sensory & motor latency, motor conduction velocity, motor-evoked potentials. Electromyelography of muscles. Method as Melvin et al. T = NS Normal values: As Melvin et al?	Carpal tunnel decompression. No other details.	Relief of symptoms. Questioned in person or by telephone.	16 mths (12-34).
Glowacki, 1996[9]	Retrospective case series	167 (35/132) 60% were workers compensation cases.	42 (17-84)	Underlying metabolic abnormality e.g. diabetes or hypothyroidism or a history of traumatic acute CTS or previous carpal tunnel release	Patients with one of two clinical criteria and one of two physical signs:	Numbness & tingling at night or during daily activities	Positive Phalen's test or Tinel's sign.	EMG and NCV performed in those whose insurance carrier required it or in those who had atypical additional complaints. Also if already requested in primary care. N = 94 patients. T = NS Abnormal values: Sensory Motor Amp(μV) <20 Cond. Vel.(m/sec) <50, with fibrill. Latency (msec) <3.7 <4	Open carpal tunnel release. Injection of steroid at first appointment pre-op. Wrist splint for 6 weeks post-op.	Categorised by patients and independent surgeon: 1. Symptoms resolved completely 2. Occasional symptoms 3. No change 4. Worse	Pos = 19mths (8-30) Neg = 24mths (8-47) No electrodiagnostic testing = 20 mths (9-43)
Choi, 1998[22]	Retrospective case series	154 (6/148) General CTS patients	52 (30-82)	NS	Patients with two clinical criteria and one of two physical signs: (Also, patients with positive electrodiagnosis in other hand even if symptoms were not present were included and	Numbness & tingling at night or during daily activities	Positive Phalen's test or Tinel's sign.	Electrodiagnostic studies on all patients. Electromyograph (Counterpoint MK2). T=34ºC. Abnormal values: Sensory Motor Amp(μV) <20 Latency (msec) >3.0 >4.0 Median/ulnar lat. > 1.2 >1.5 Median/ulnar amp. <0.6 3 of the 6 criteria indicated	Limited incision open carpal tunnel release. Injection of corticosteroid during surgery. Wrist splint for 1 week post-op.	Patient satisfaction: One interviewer – in person or by telephone. Interviewed twice. 1.Complete resolution of symptoms 2.Mild residual symptoms 3.Improvement but still	1 week 3 mths 1 year Overall variable – 3-24 mths

Authors	Study design	Patients (n) (M/F)	Mean age (yrs) (range)	Exclusion criteria	Inclusion criteria	Clinical criteria	Physical tests	Electrodiagnostic test details	Surgical details	Outcomes	Mean follow-up (range)
					operated on). i.e. criteria were ignored!			surgery.		symptoms 4.Unchanged 5.Worse	
Braun, 1994[16]	Retrospective case series	151 (NS) patients Workers compensation.	39?	Self employed physicians, attorneys, business persons. Excluded if involved in extremely strenuous work, had severe signs & symptoms of nerve injury & were not expected to improve significantly, or older or sedentary patients, or if not doing a job with repetitive hand use.	People who used their hands repetitively in their work.	NS	No criteria given but tests carried out: Grip strenth Range of motion Pinch strength Monofilament sensory evaluation Phalen's test Tinel's test	Electrodiagnostic tests carried out in 125/151 patients. Positive = abnormal on any test (usually sensory latency < 3.5ms).	All had surgery. All had received conservative treatment before surgery. No further details.	Blinded assessor. Outcomes included: Return to work; Physical tests as pre-op. Recovery measured as a percentage over preoperative scores.	NS
Higgs, 1997[15]	Retrospective case series Patients randomly selected from a large database of post-operative patients.	93 (30/63) All workers; 74% workers compensation cases.	43 (23-69)	Subjects without preop. NCS. Also subjects not employed outside of the home or with confounding medical problems.	Diagnosis of CTS from clinical examination and reported symptoms.	No criteria given but symptoms included numbness, tingling and nocturnal awakening.	NS	Motor and sensory terminal latencies and sensory conduction velocities. Normal values: Based on those reported by each centre. NCVs were "normalised" by subtracting critical values. Latency: 1msec prolongation was abnormal Cond. Vel.: 10msec slowing was abnormal	All had open surgical decompression.	Questionnaire interview by telephone by blinded research assistant. 1.Absent symptoms 2.Improved symptoms 3.Unchanged 4.Worse Job status: same or changed duties.	16-100 months

Authors	Study design	Patients (n) (M/F)	Mean age (yrs) (range)	Exclusion criteria	Inclusion criteria	Clinical criteria	Physical tests	Electrodiagnostic test details	Surgical details	Outcomes	Mean follow-up (range)
Concannon, 1997[10]	Retrospective case series Consecutive patients.	349 (107/242) who had carpal tunnel release General CTS patients		Patients successfully managed medically; patients with non-routine causes of CTS (e.g. reperfusion injury, trauma etc).	Diagnosis based on one or more of four symptoms or physical signs:	1.Night pain and paresthesias or 2. symptoms confined to the median nerve distribution.	3.Positive Phalen's test or 4.positive Tinel's sign.	Abnormal values: 1.Median motor latency $\geq$4.3ms and $\geq$0.5ms different from ulnar lat. 2.Median sensory latency $\geq$3.4ms and $\geq$0.5ms diff. From radial sensory lat.	All had surgery. No further details.	Resolution of symptoms.	NS

Table 2 Quality assessment

	Grundberg, 1983[20]	Glowacki, 1996[9]	Choi, 1998[22]	Braun, 1994[16]	Higgs, 1997[15]	Concannon, 1997[10]
Study design						
Was the study design a prospective cohort study?	No	No	No	No	No	No
Population						
Was the population well defined?	Yes	Yes	Yes	Yes	Yes	Yes
Was the number of hands stated?	Yes	Yes	Yes	No	No	Yes
Was the population representative of general CTS patients?	?	Yes	No	No	No	Yes
Were the clinical criteria given?	No	Yes	Yes	No	No	Yes
Were the criteria for physical signs clearly described?	No	Yes	Yes	No	No	Yes
Did the study include the surgical outcomes of those patients with both positive and negative electrodiagnostic results?	No	Yes	No	Yes	Yes	Yes
Were patients included who did not have electrodiagnosis?	No	Yes	No	Yes	No	No
Intervention						
Was the electrodiagnostic procedure sufficiently well described?	Yes	Yes	Yes	No	No	Yes
Were procedures carried out in standardised conditions including temperature control?	NS	NS	Yes	NS	NS	NS
Were clear criteria for abnormal results given?	?	Yes	Yes	No	No	Yes
Was the surgical procedure sufficiently well described?	No	Yes	Yes	No	Yes	No
Outcomes						
Were the outcomes clearly stated?	Yes	Yes	Yes	Yes	Yes	Yes
Were the outcomes measured by a blinded assessor?	NS	Yes	NS	Yes	Yes	NS
Were outcome measurements valid and unbiased?	No	No	No	Some	No	No
Was follow-up complete?	No	NS	Yes	NS	No	NS
Were any reasons for loss to follow-up given?	No	No	No	No	No	No

NS = not stated ? = can't tell

diagnostic access bias, where the patients who did not undergo testing would have a different prognosis from those who did. It is therefore unlikely that these studies would have included patients representative of the general CTS population. Further, each of the studies had different general inclusion and exclusion criteria. Three studies stated that they excluded patients with other predisposing causes[9; 10; 15], while one study included these patients[22]. Most were from secondary or tertiary referral centres, but three studies either included patients only if they were workers or had a high percentage of worker's compensation cases[9; 15; 16]. It is difficult to compare these studies as they had differing populations, and also difficult to relate them to the general CTS population.

In most studies, the electrodiagnostic procedure was well described, although different in each study. Only one study mentioned standardised temperature control[22]. Each study had criteria for abnormal results, although this varied and in one study was based on inadequate/incorrect methodology for normalising means and standard deviations between six centres,[15] some of which had inadequately described their abnormal thresholds. In general, the surgical procedure was not described in much detail.

The outcomes were clearly described in each study, although few would be valid and unbiased. Most were based on questions asked of the patients about the improvement (or not) of their symptoms. Some of the assessors were blind to the pre-operative data. One study measured outcome in terms of physical assessments such as grip strength[16], which, although objective, might not be a true indication of patient satisfaction. There was no generic or disease-specific measure of quality of life either before or after the operation. Side effects or complications were only mentioned in two studies[10; 22]. Mean follow-up time was usually given, but only one study clearly stated that seven patients were lost to follow-up[20] (no reasons given) and in the others it was not clear whether the patients had been included in the study because they had complete follow-up.

4.2.2 Assessment of the value of electrodiagnosis as a predictive tool

In four studies it was possible to compare the outcomes of surgery in patients with both positive and negative electrodiagnostic test results[9; 10; 15; 16]. These are displayed in table 3, which shows the flow of patients through each study. Overall, in all patients with electrodiagnostic test results (positive or negative), surgery was found to be between 73% and 98% effective in alleviating symptoms. However, in no study was there a statistically significant difference in surgical outcome (as measured by improvement in symptoms) between those who had positive electrodiagnostic findings and those who had negative diagnostic findings.

In view of the poor quality of studies and the disparity between populations, interventions and outcomes, it is not appropriate to combine the data.

Five authors acknowledged the limited utility of electrodiagnostic testing as a predictor of surgical outcome. The sixth[15] concluded that those with more abnormal electrodiagnostic results would benefit more from surgery. However, the methods the researchers used for categorising patients as normal or abnormal were totally incorrect and therefore invalidate their results.

In conclusion, the evidence for the use of electrodiagnostic tests as predictive indicators of surgical outcome in people with clinically well-defined CTS is weak. However, even despite the limited quality of the evidence, the dramatic lack of support from the studies indicates that electrodiagnosis for this purpose does not appear to be warranted.

No studies are available on the contribution of electrodiagnosis as a predictor of surgical outcomes in situations where the full pattern of clinical symptoms is not present.

Table 3 Results of electrodiagnostic studies and outcomes of surgery

Study	Patients entered (no. of hands)	Positive clinical diagnosis (no. of hands)	Underwent electrodiagnostic studies (no. of hands)	Electrodiagnostic results (no. of hands) (%)	Having surgery (no. of hands)	Patient-based outcomes of surgery			Statistical test†	Loss to follow-up	Side effects
						Outcome measures	Pos ED	Neg ED	p value		
Grundberg, 1983[20]	292*	292*	292*	Pos= 259* (89%) Neg= 33* (11%)	292*	Cured or mild remaining symptoms No relief	NS	30 2	-	7*	1? Reactive fibrosis
Glowacki, ‡1996[9]	227	227	126	Pos= 99 (79%) Neg= 27 (21%)	227	Complete resolution or occasional symptoms No change or worse	92 7	25 2	Fisher's exact p=1.0	NS	NS
Choi, 1998[22]	294	NS	294	Pos = 294	294	Complete resolution or Mild residual symptoms Improvement but still symptomatic Unchanged or worse	242 39 13	NS	-	NS	Incisional pain & tenderness at 1 yr = 6/294
Braun, 1994[16]	151*	151*	125*	Pos= 75* (60%) Neg= 50* (40%)	151*	No significant residual discomfort Persistent significant Discomfort	60* 15*	40* 10*	χ^2 (Yates correction) p=0.82	NS	NS
Higgs, 1997[15]	93*	93*	93*	Sensory latency: Pos= 21* (60%) Neg= 72* (40%)	93*	 Good Poor Good Poor Good Poor	Numbness 19* 2* Pain 19* 2* Nocturnal symptoms 20* 1*	Numbness 49* 23* Pain 54* 18* Nocturnal symptoms 57* 13*	χ^2 (Yates correction) or Fisher's exact p= 0.08 p= 0.23 p= 0.18	NS	NS
Concannon, 1997[10]	460	460	460	Pos= 398* (87%) Neg= 62* (13%)	460	Symptoms resolved Symptoms not resolved	390 8	61* 1*	Fisher's exact p=1.0	NS	Complications: Pos ED = 20 Neg ED = 3

n = number of patients; ED = electrodiagnosis; Pos ED = abnormal; Neg ED = normal. ‡ Only positive results followed up.

† It has been assumed that outcomes for two hands in the same patient are independent. Insufficient data were available to take any other approach

5 Economic analysis

5.1 Methods for economic analysis

There were no quantifiable benefits found for the use of electrodiagnostic studies pre-operatively as a prognostic tool. A cost-effectiveness analysis was therefore not appropriate, but the costs of both diagnosis and surgery have been examined and are presented.

5.1.1 Estimation of costs

The minimum costs of electrodiagnosis per case are £60 (see para.2.2). The total costs for those seen by QEH staff are therefore c.£100,000p.a.; of this, 15% are primary care referrals.
The average cost of surgery for a case of CTS at the Royal Orthopaedic Hospital (ROH) is £382. 338 cases were operated on in 1998-9 at an estimated total cost of c.£130,000. Extrapolating this to the whole of the NHS in England gives an overall cost for CTS surgery of c.£11 million. The QEH and ROH populations are not identical. However the cost of electrodiagnosis represents 15% of the total in each operated case and the overall cost of the diagnostic service for all cases seen is nearly comparable with the total surgical costs. Its role in reducing the number of operations cannot be assessed.

5.1.2 Cost-effectiveness

Given that no quantifiable benefits from pre-surgical electrodiagnosis have been identified no rational utility can be ascribed to the procedure. In principle, therefore, all the costs of doing the procedure could be saved without any disbenefits. Some investigations would probably still need to be carried out when the clinical symptoms are unusual or unclear. It is not possible to quantify the benefits which have been claimed from holding electodiagnostic test results as an aid to surgical risk management in those cases where the quality of diagnosis or treatment are subsequently called into question.

6 Implications for other parties

Waiting for electrodiagnostic studies before proceeding to surgery involves not only expense for the NHS, but expense for patients and employers in terms of time off work and financial penalties and a longer duration of pain and discomfort. However, during the waiting period, it is possible that some CTS patients will improve of their own accord, and therefore avoid the need for surgery.

7 Discussion and conclusions

Firstly, a published systematic review shows that electrodiagnosis as a *standard diagnostic test* for CTS is slightly less specific but substantially less sensitive than a diagnosis based on clinical signs and symptoms[13]. It may however be a useful supplementary test to help increase the probability of making the correct diagnosis where the clinical findings are equivocal.

Secondly, the data available on the value of electrodiagnostic tests as a *predictive indicator* of surgical outcome for patients with CTS could lead to two different conclusions. There is no doubt that the quality of the available studies is not ideal. This might lead to the view that the evidence is too poor to lead to any firm conclusions about the value of electrodiagnosis as a predictive indicator, and that further research with properly designed and executed studies is required. One of the main limitations of the studies published (and probably also clinical

practice) is the lack of standardisation for electrodiagnostic testing and the thresholds for abnormal. If there was information regarding the outcome of surgery in a large series of patients who had electrodiagnosis test results recorded but not acted upon, sensible thresholds to produce a high sensitivity and specificity might be calculated.

The alternative and most plausible way of viewing the evidence is that despite the limitations of the studies reviewed, the results show no association between electrodiagnosis and outcome, such that there does not appear to be any indication to justify routine electrodiagnosis in those with the characteristic clinical signs and symptoms of CTS.

A large proportion of the costs (£100,000 p.a. at QEH) of electrodiagnostic tests for CTS could be reduced if the test were used only when the clinical signs and symptoms of CTS are not clear. How far the savings would be realised is difficult to say given the complexities of staffing at different combinations of technician and consultant led services.

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Conflicts of interest

None

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