Morphological and functional changes of the median nerve after neurolysis for carpal tunnel syndrome

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The objectives of this study are twofold:1. To describe morphological and functional changes of the median nerve after neurolysis using US and NCS. 2. To correlate the morphological and functional changes to the clinical symptoms and signs

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Observational non invasive

Summary

ID

NL-OMON37253

Source
ToetsingOnline

Brief title
ultrasonography of the median nerve after neurolysis for CTS

Condition

- Peripheral neuropathies

Synonym
carpal tunnel syndrome, median nerve neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: geen geldstroom

Intervention

Keyword: carpal tunnel syndrome, morphological changes, neurolysis, ultrasonography

Outcome measures

Primary outcome

Primary outcome measures

1. Change in intraneural vascularisation after neurolysis

2. Change in cross sectional area of the median nerve after neurolysis

3. Change in swelling and flattening ratio of the median nerve after neurolysis

Secondary outcome

Correlation of ultrasonographic changes and clinical/nerve conduction changes

after neurolysis.

Study description

Background summary

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy. The diagnosis can be made clinically but is usually confirmed by using nerve conduction studies (NCS) or ultrasound (US). NCS provides functional information by showing (a) slowing of the sensory or motor nerve conduction over the wrist and (b) signs of possible axonal loss. US may reveal nerve enlargement at the level of pisiform bone, as well as underlying causes for CTS. In addition Doppler studies may detect increased vascularity of the median nerve.

Surgery is the most effective treatment for CTS on the long term (1). Splinting and local corticosteroid injections may also provide temporarily relief of symptoms but a long term effect has not been proven (2). Repeated injections are usually not recommended (3). A previous studies suggested that a local steroid injection is less effective on the long term in patients with more pronounced nerve thickening on US (4). In general nerve thickening diminishes after surgery and injection for CTS and ulnar neuropathy at the elbow (5, 6).

There are also changes of vascularity of the median nerve after corticosteroid injection (5). It is not known how the US changes develop over time in surgery. Is there immediate decrease of nerve thickening? Does the shape of the nerve change (e.g., become less flattened)? Is there a decrease or even increase of vascularity? More knowledge of these changes may give insight in the pathophysiological changes after neurolysis and aid in decision making in patients in whom surgery was not successful. The Dutch guideline for CTS (www.cbo.nl) recommends renewed surgery when clinical and NCS improvement is insufficient three months after the initial operation. It is not clear what role US can play in these cases although experts report incomplete release of the transverse carpal ligament by means of US. Remaining abnormalities during US and NCS should be interpreted with caution: e.g., the median nerve may remain more or less thickened despite clinical improvement, the conduction velocity may remain slowed after surgery because the internodal myelin segments become shorter after remyelination.

Study objective

The objectives of this study are twofold:
1. To describe morphological and functional changes of the median nerve after neurolysis using US and NCS.
2. To correlate the morphological and functional changes to the clinical symptoms and signs

Study design

Clinical assessment at baseline

A. Clinical assessment

History:
- duration of symptoms
- previous episodes of CTS
- contralateral CTS
- paresthesias digits 1-4
- numbness digits 1-4
- clumsiness
- muscle weakness
- number of nights that the patient awoke, due to the symptoms, during the past week

Scales, questionnaires
- functional scales
- VAS pain
- VAS paresthesias

Examination
- thenar muscle wasting: no, mild, severe.
- muscle strenght using the MRC (0, 1, 2, 3, 4, 5), manually testing the abductor pollicis brevis and opponens pollicis brevis muscles.
- pin prick sensation in the area of the median nerve (volair aspect of digit 1-4).

B. Nerve conduction studies

For sensory studies ring electrodes will be used and for motor studies surface electrodes placed over the abductor pollicis brevis muscle in a belly-tendon montage. Skin temperature must be held > 32 ºC. When necessary arms and hands must be warmed by using hot tubs or packings. The following tests will be performed:

1. Stimulating at the wrist, recording from digit 4: comparison of the sensory conduction of the median and ulnar nerve over the wrist * digit 4 segment over equal distances. A latency difference of > 0,4 ms is considered abnormal. Digit 5 will be recorded simultaneously to detect costimulation.
2. Stimulating at the wrist and palm, recording from digit 3: comparison of the sensory conduction of the median nerve over the wrist * palm segment and the palm * digit 3 segment over equal distances. A latency difference of > 0,4 ms is considered abnormal.
3. Stimulating at the wrist, recording from digit 1: comparison of the sensory conduction of the median and radial superficial nerve over the wrist * digit 1 segment over equal distances. A latency difference of > 0,4 ms is considered abnormal.
4. Recording from the APB muscle at 6 cm from the wrist: a distal motor latency of > 4 ms is considered abnormal.

When necessay the following test can be performed:

1. Stimulating at the wrist, recording from the lumbrical II and interosseous II muscles over equal distances. A latency difference of > 0,5 ms is abnormal.

NCS is considered supportive for the diagnosis of CTS when:

1. Two or more of the above mentioned tests are abnormal. After two abnormal tests the NCS exam will be stopped. The DML to the APB muscle should always be measured.

or:

2. The combined sensory index (CSI) is >1,1 ms, CSI = sum of the latency

differences of tests 1, 2 and 3 (sensitivity 82%, specificity 100%).

The following classification will be used:

- mild sensory conduction abnormal, normal APB DML
- moderate sensory conduction abnormal, prolonged APB DML
- severe no median SNAP, prolonged APB DML
- very severe no median SNAP and no APB CMAP

C. Ultrasonography

Sonography of the median nerve will be performed using a 4-16 MHz probe.The pisiform bone is easily identified during US and will be used as a reference level. Measurements will be performed whithin the hyperechoic rim surrounding the nerve. The scanning protocol will be as follows:

1. Transverse plane: from 10 cm proximal of the pisiform bone to the level of the pisiform bone

Measurement of the CSA, AP diameter and transverse diameter:
- at the level of 10 cm proximal of the pisiform bone
- at the level of the pisiform bone
- at the level om maximal thickness at the wrist, noting the distance from the pisiform bone

Images of these measurements should be stored and printed.

2. Longitudinal plane: including level of the pisiform bone and level of maximum thickness

Measurement of the AP diameter:
- at the level of the pisiform bone
- at the level om maximal thickness at the wrist, noting the distance from the pisiform bone

Images of these measurements should be stored and printed.

In case of a bifid median nerve the two parts of the nerve will be measured separately as described above. Furthermore, the same measurements will be done by assessing the entire circumference around the two parts.

In addition a swelling ratio will be calculated by dividing the CSA at the level of maximum thickness at the wirst to the CSA at the level of proximal forearm. A flattening ratio will be calculated by dividing the anteroposterior and transverse diameter at the level of maximum thickness at the wrist and at the level of the pisiform bone. Abnormal structures (e.g., persistant median

artery) will be noted.

A CSA at the level of the pisiform bone of > 10 mm2 is considered diagnostic for CTS but this criterium will not be used for inclusion in this study.

3. Power flow signals

Screening for blood flow was done at the level of the pisiform bone.
Color doppler settings are chosen to optimize identification of weak signals from vessels with slow velocity. The pulse repetition frequency (PRF) used is 0.5- 1 kHz and the band filter is set at 50 Hz. The presence of blood flow signals in the epineurial plexus or endoneurial vessels indicates intraneural vascularisation of the nerve during CD imaging. When bloodflow was seen, the color gain and PRF were adjusted to optimize the imaging of bloodflow. We used both CD and power doppler ultrasonography, and when in doubt about arterial versus venous flow, spectral analysis was used.

Outcome measures

The following clinical, ultrasonograhic and neurophysiological data will we obtained 7-10 days, 1, 3 and 6 months after surgery.

A. Clinical

History:
- paresthesias digits 1-4
- numbness digits 1-4
- clumsiness
- muscle weakness
- number of nights that the patient awoke, due to the symptoms, during the past week

Scales, questionnaires
- functional scales
- VAS pain
- VAS paresthesias
- Level of satisfaction on a 11 point scale
- patient based improvement score + date of improvement on a 6 point scale: (1) completely
recovered, (2) much improved, (3) slightly improved, (4) no change, (5) slightly worse, (6) much worse.

Examination
- thenar muscle wasting: no, mild, severe.
- muscle strenght using the MRC (0, 1, 2, 3, 4, 5), manually testing the abductor pollicis brevis and opponens pollicis brevis muscles.

- pin prick sensation in the area of the median nerve (volair aspect of digit 1-4).

B. Ultrasound

The measurements mentioned at baseline will be repeated. The follow-up measurements must be done at the same levels as at baseline. New findings should be noted.

C. Nerve conduction studies

The following tests will be repeated at follow up, only if performed at baseline:
- Stimulating at the wrist, recording from digit 4: comparison of the sensory conduction of the median and ulnar nerve over the wrist * digit 4 segment over equal distances. Digit 5 will be recorded simultaneously to detect costimulation.
- Stimulating at the wrist and palm, recording from digit 3: comparison of the sensory conduction of the median nerve over the wrist * palm segment and the palm * digit 3 segment over equal distances.
- Stimulating at the wrist, recording from digit 1: comparison of the sensory conduction of the median and radial superficial nerve over the wrist * digit 4 segment over equal distances.
- Recording from the APB muscle at 6 cm from the wrist. Stimulating at the wrist, recording from the lumbrical II and interosseous II muscles over equal distances.

Follow-up

The following clinical, ultrasonograhic and neurophysiological data will we obtained 7-10 days, 1, 3 and 6 months after surgery.

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- Stimulating at the wrist, recording from digit 1: comparison of the sensory conduction of the median and radial superficial nerve over the wrist * digit 4 segment over equal distances.
- Recording from the APB muscle at 6 cm from the wrist. Stimulating at the wrist, recording from the lumbrical II and interosseous II muscles over equal distances.

Study burden and risks

Clinical examination, NCS and US can be considered standard practice and are safe. Surgery for CTS is a commonly and well accepted treatment modality, and is not part of the study as such. Surgeons will inform the patients about the operation (procedure, risks, advices) as usual. The four visits for clinical exam, US and NCS after surgery are extra but without any important risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age > 18 years
2. Clinical signs of carpal tunnel syndrome, as described by the AAN criteria for CTS: paresthesias, pain, swelling, weakness, or clumsiness of the hand (digit 1-4) provoked or worsened by sleep, sustained hand or arm position, or repetitive action of the hand or wrist that is mitigated by changing posture or by shaking of the hand; sensory deficits in the median innervated region of the hand; and motor deficit or hypotrophy of the median innervated thenar muscles
3. Electrophysiological evidence of CTS (see below)
4. Surgery is the preferred treatment modality
5. Patients having bilateral CTS can only participate with the most affected side.
6. Criterium for the time interval between initial exam and surgery: within 5 weeks
7. Able to read and understand written questionnaires (in Dutch)

8. Informed written consent

Exclusion criteria

1. Unable to follow up
2. Prior surgery or trauma on the wrist / median nerve
3. Previous surgery for carpal tunnel syndrome; previous surgery for CTS on the contralaterale side is not an exclusion criterium.
4. Treatment with splints or corticosteroids the past 6 months.
5. Clinical or electrophysiological evidence of conditions that could mimic CTS or interfere with its
validation (cervical radiculopathy, brachial plexopathy, thoracic outlet syndrome, pronator teres syndrome, ulnar neuropathy, polyneuropathy, Raynaud*s disease, sympathic dystrophy)
6. Underlying causes of CTS: diabetes, thyroid disease, rheumatoid arthritis, chronic renal failure
treated by hemodialysis, space-occupying lesions a the volar wrist. A bifid median nerve of persistant median artery are no exclusion criteria.
7. Pregnancy

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-11-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	25-06-2012
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL40637.096.12