

The carotid sinus syndrome: long term results of carotid denervation

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Evaluation of the long term results of surgical carotid denervation in patients suffering from CSS. Primary question: Is surgical denervation an effective treatment option for symptoms caused by CSS, eg dizziness and syncope, on the long term....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON31452

Source

ToetsingOnline

Brief title

geen

Condition

- Other condition
- Cardiac arrhythmias

Synonym

carotis sinus syndrome, hypersensitive carotid sinus

Health condition

pathologische reflexbaan

Research involving

Human

Sponsors and support

Primary sponsor: Máxima Medisch Centrum

Source(s) of monetary or material Support: Wetenschapsfonds MMC

Intervention

Keyword: carotid denervation, carotid sinus syndrome, periadventitial stripping

Outcome measures

Primary outcome

Changes in VRS pre- and postoperative: dizziness, syncope, falls.

Symptoms of dizziness and syncope caused by carotid sinus massage

Secondary outcome

- chronic hypertension:

antihypertensive drugs

BP_{syst}>160 mmHg and/or BP_{diast}>95 mmHg or

BP_{mean}>160/95 during 24 hour measurement

- Disrhythm

Anti-aritmic drugs, ECG, Holtermonitoring

- chronic postoperative complications:

Cranial nerve injury: tongue deviation (n. hypoglossus)

Sensibility changes skin

- Dilatation internal carotid artery: carotid Duplex

Study description

Background summary

Carotid sinus syndrome (CSS) is a relatively unknown cause of syncope in the elderly leading to high comorbidity. An abnormal carotid baroreflex can lead to asystole (cardioinhibition) or extreme hypotension (vasodepression) leading to syncope, dizziness and unaccidental falls. Symptoms are reproducible by carotid sinus massage. Last decades pacemaker implantation is considered to be treatment of choice in CSS. However pacemaker implantation is not effective in all types of CSS. Surgical carotid denervation seems to be an effective treatment option in all types of CSS on the short term.

In our hospital 27 patients suffering from CSS underwent a surgical carotid denervation in the period 1980-2007.

Study objective

Evaluation of the long term results of surgical carotid denervation in patients suffering from CSS.

Primary question:

Is surgical denervation an effective treatment option for symptoms caused by CSS, eg dizziness and syncope, on the long term.

Secondary question:

- Does surgical denervation lead to chronic hypertension, dysrhythms or baroreflex failure on the long term ?
- Occurrence of postoperative complications: cranial nerve injury (nervus hypoglossus, nervus facialis) en sensibility loss of the skin
- Dilatation/ aneurysm of the internal carotid artery after peri-adventitial stripping?

Study design

Patient selection:

Patients with CSS who underwent a surgical carotid denervation in our institute

Inclusion criteria:

Patients who underwent a surgical carotid denervation

Exclusion criteria:

Exclusion from carotid sinus massage if:

- carotid stenosis on duplex
- myocardial infarction < 3 months
- TIA or CVA < 3 months

A carotid duplex is performed to:

1. exclude carotid stenosis
2. measure the diameter of the internal carotid artery. Dilatation?

History taking is performed by drs. M. van der Leest

Clinical examination is performed by R.J. Toorop.

Cardiac care unit:

An intra-arterial line is placed by R.J. Toorop. A Finapres blood pressure device is placed around a finger.

Carotid sinus massage is performed during 10 s on the left and right side in lying position. If there is no response, the test is repeated in 60 degrees tilt. If a cardioinhibitory response is observed the test is repeated after IV injection of 1 mg atropine to unmask a vasodepressor response. Then a table tilt test is performed by dr. Huige, cardiologist.

Study burden and risks

Risks

-intra-arterial catheter:

The incidence of complications is low. The small catheter (22 gauge), is immediately removed carotid sinus massage, so there is a very low risk of thrombosis. No Seldinger technique is performed, so there is little chance of dissection of the radial artery. There is always a chance of a small hematoma.

-Carotid sinus massage:

The incidence of neurological complications is low, eg 0.4%.

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

Patients treated by surgical carotid denervation for carotid sinus syndrome

Exclusion criteria

Exclusion from carotid sinus massage if:

-carotid stenosis on duplex

-acute myocardial infarction < 3 months

-TIA or stroke < 3 months

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated):	16-09-2009
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO	
Date:	23-09-2008
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL20350.015.07