Lymph vessel mapping in femoropopliteal bypass surgery, a feasability study

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To prove that lymph vessels in the legs can be visualized with methylene blue, so they can be spared during surgery, what possibly may lead to decreased postoperative lymph edema.Hypothesis: Methylene blue visualizes lymph vessels in the legs, so...

Ethical review	Approved WMO	
Status	Recruiting Vascular therapeutic procedures	
Health condition type		
Study type	Observational non invasive	

Summary

ID

NL-OMON35920

Source ToetsingOnline

Brief title Lymphvesselmapping in femoropopliteal bypass surgery

Condition

- Vascular therapeutic procedures
- Lymphatic vessel disorders

Synonym Lymph edema

Research involving Human

Sponsors and support

Primary sponsor: Alysis Zorggroep Source(s) of monetary or material Support: St. Elizabeth Stichting;Arnhem

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Intervention

Keyword: Femoropopliteal, lymphedema, Lymphvesselmapping, Methylene blue

Outcome measures

Primary outcome

Primary study parameters:

- Visibility of lymph vessels or lymph nodes
- Quantity of visible lymph vessels or lymph nodes per wound area
- Location of visible lymph vessels or lymph nodes: proximal and distal

incision and little additional incisions for removing of the vein

- Per- and postoperative complications

Secondary outcome

n.a.

Study description

Background summary

Lymph edema is a common complication after vascular surgery. An incidence of 50-100% is described after surgical infrainguinal arterial reconstruction, usually during the mobilization period. The vulnerable lymph vessels are situated next to the arteries and veins, whereby there is a substantial possibility of injuring these lymph vessels during an operation. Peroperative injury of lymph vessels during vascular surgery is an important cause of wound leakage, seroma and lymph edema.

The pathofysiologic mechanism in lymph edema is not totally cleared yet, but injury to the lymph vessels seems to play an important role. Lymph edema arises when the balance is disturbed between rate of production and capacity of the lymphatic system to remove the increased volume of lymph. An abnormal accumulation of proteins and fluid exists. Increased production of interstitial fluid after successful revascularization leads to an increased lymphatic load. Also, the transport capacity in the surgical area is disturbed, because of obstruction and injury to the lymphatic system. A number of studies have been performed in patients with lymph edema after bypass surgery, at which the lymph vessels were visualized postoperatively with lymphangiography. This showed injury and abnormal anatomy of the lymph vessels in patients with edema. Ideally intact lymph vessels would cause less postoperative edema. Injury to the lymphatic system should be limited during surgery, but the big concern is that they are very thin and difficult to visualize.

In practice one attempts to prevent or decrease edema by elevating the leg, using support hosiery and slow mobilization. Until now this has not led to satisfactory results. The symptoms patients experience are progressive swelling, a heavy or tight sensation, fatigue or pain in their limbs and limitations of movement. Postoperative edema has a negative effect on mobilization of already vulnerable, older patients and their daily lives. Limited and altered movements may lead to possible invalidity of the patient. Also, wearing support hosiery is inconvenient and help is often needed. Long-term issues can be an increased risk of developing skin lesions and infections, like cellulitis and erysipelas. Lymph edema is often an unexpected and disabling condition that has a negative influence on the quality of life. Thus preventing or reducing postoperative lymph edema is necessary.

Up until now methylene blue has been used for researching lymph node metastasis, it visualizes the lymph vessels and nodes. This method could also be used to visualize the lymph vessels in the legs, so these can be saved during surgery, what possibly may lead to decreased postoperative edema.

Study objective

To prove that lymph vessels in the legs can be visualized with methylene blue, so they can be spared during surgery, what possibly may lead to decreased postoperative lymph edema.

Hypothesis: Methylene blue visualizes lymph vessels in the legs, so they can be spared preoperatively.

Study design

The study *Lymph vessel mapping in femoropoliteal bypass surgery* is a feasibility study. When this study proves that is possible to visualize lymph vessels, it will be followed by a randomized study in which bypass surgery with lymph vessel mapping will be compared with bypass surgery without lymph vessel mapping, with as outcome postoperative edema and other related complications. This study will be carried out in the Alysis Zorggroep, location Rijnstate in Arnhem.

Ten patients with an indication for femoropopliteal bypass surgery, without previous surgical intervention of the legs, will be included. They all ought to

sign the informed consent form.

Preoperatively the results will be scored in a standardized manner, so no further follow-up is indicated for this study.

Injection with methylene blue:

1% novocaïne will be added to the injection with methylene blue in a 1:3 ratio. Between dig 1 and dig 2 0,5ml will be injected, 0,25ml between dig 2 and dig 3 and 0,25ml between dig 4 and dig 5. The injections will be given 45 minutes before surgery.

Study burden and risks

The injections can be uncomfortable, therefore 1% novocaïne will be added to the methylene blue in a 1:3 ratio. The risks for the patients don*t differ from the usual risks in femoropopliteal bypass surgery: wound infection, bleeding, thrombosis, lung embolus, pneumonia, cystitis or myocardial infarction. The addition of methylene blue does not increase the risks on these complications. It is also possible that patients show an allergic reaction on methylene blue.

Contacts

Public Alysis Zorggroep

Wagnerlaan 55 6800 TA Arnhem NL **Scientific** Alysis Zorggroep

Wagnerlaan 55 6800 TA Arnhem NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Inclusioncriteria

- Indication primary femoro-popliteal bypass
- Signed informed consent
- Age >18

Exclusion criteria

Exclusioncriteria

- No informed consent
- Previous surgical interventions of the leg
- Allergy for methylene blue

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Prevention	

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	26-03-2012
Enrollment:	10
Туре:	Actual

Ethics review

Approved WMODate:08-06-2011Application type:First submissionReview commission:CMO regio Arnhem-Nijmegen (Nijmegen)

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 CCMO ID NL35704.091.11