Comparative randomized Clinical trial of Radiofrequency Ablation (VNUS)versus Steam Ablation for the treatment of Great Saphenous Veins

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To test whether the anatomical success rate of Steam Ablation is not inferior to that of VNUS in treatment of GSV insufficiency and compare the treatment safety, patient reported outcomes between and Steam Ablation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Venous varices
Study type	Interventional

Summary

ID

NL-OMON39248

Source
ToetsingOnline

Brief title
VAST trial

Condition

- Venous varices

Synonym
varices, varicose veins

Research involving
Human

Sponsors and support

Primary sponsor: Dermatologsich Centrum Wetering
Source(s) of monetary or material Support: geen. onkosten worden door Dermicis betaalt

Intervention

Keyword: Endovascular, insufficiency, Steam, VNUS

Outcome measures

Primary outcome

Primary outcomes

1. Obliteration of the GSV and/ or absence of reflux (>0.5 sec. of retrograde

flow over >10cm) along the treated segment of the GSV. This is measured using

US examination. The rates will be compared between RFA and Steam Ablation at 12

and 52 weeks.

2. Venous Clinical Severity Scoring (VCSS).

Secondary outcome

Secondary outcomes

1. Treatment safety:

a. Major complications: deep and superficial venous thrombosis (embolic

events), nerve injury, skin burns, and (sub)cutaneous infections.

b. Minor complications: ecchymosis, pain and hyperpigmentation.

Study description

Background summary

Lower extremity venous insufficiency is a common medical condition. A prevailing cause being an insufficiency of the GSV, approximately 30.000

patients are operated each year in Holland to exclude this insufficient GSV. Since varicose veins increase with age the prevalence of venous insufficiency will increase considerably. Classic symptoms of venous insufficiency are aching, discomfort, edema, and muscle cramps. Associated complications are eczema, lipodermatosclerosis, white atrophy, superficial thrombophlebitis, and venous ulcers.
About 1% to 2% of people older than 65 years of age have (a history of) venous ulcers. It has been estimated that half of the venous ulcers can be prevented when varicose veins are treated. Chronic venous insufficiency has a great impact on patients* health-related quality of life (HRQOL), which is comparable to other common diseases. The treatment of varicose veins reduces the symptoms and complications of chronic venous insufficiency and improves HRQOL of patients. Surgery has been the
standard of care in the treatment of saphenous varicose veins. The great saphenous vein (GSV) is traditionally treated by high ligation at the saphenofemoral junction (SFJ) followed by a short stripping to the knee. Most commonly, the small saphenous vein (SSV) is ligated at the saphenopopliteal junction (SPJ) only. Recurrence rates after surgery are about 25% and 50% at 5 years for the GSV and SSV, respectively. A study with a mean follow-up of 34 years showed recurrence in 60% of 125 limbs after SFJ ligation and GSV stripping. Failure after surgery may be due to neovascularization, double saphenous vein system, technical and tactical failure (up to 30%) , and/or incomplete procedure. Other disadvantages of surgical therapy are the use of general or epidural anesthesia, presence of at least two fairly long scars, postoperative down-time, more tissue damage wound healing problems , wound infection, neurologic injury (about 7% in short to 40% in long stripping of GSV) and lymphatic complications. To improve efficacy, patients* HRQOL, and treatment satisfaction and to reduce serious side effects, costs, and postoperative pain, new minimally invasive techniques, such as ultrasound-guided foam sclerotherapy (UGFS), endovenous laser ablation (EVLA), and radiofrequency ablation (RFA), have been introduced in the last decade. The mechanism of ablation of the latter two therapies is based on heating (of at least 85 degrees Celsius) of the venous structure including the creation of intravascular *steam bubbles* either using laser emission or radiofrequency . Advantageous of the endovascular procedures is that they can be performed under local anesthesia with absence of wound infections or lymphatic complications and lesser tissue damage as compared to the stripping procedure. The initially suggested theoretical disadvantage of the absence of a crossectomie in the endovascular procedures cannot be reproduced in clinical studies A comparison between RFA and EVLA in a recent study shows similar results, although the RFA scores significantly better regarding the postprocedural pain and early recovery, which is allotted to the relatively low working temperature.
A new minimally invasive endovenous therapy ha s been developed that generates and administers high pressure steam in the varicose vein (i.e., Steam Ablation. The theoretical advantages of this new procedure are the low working temperature combined with very local and extremely efficient transmission of

thermal energy and (probably) by consequence the low tissue damage, and possibly patient satisfaction. The steam generator is less expensive than existing laser and radiofrequency devices and requires little to no maintenance. In contrast to EVLA, RFA and UGFS, Steam Ablation uses sterile water, which is natural body*s substance and has not the possible disadvantage of inducing harm using or generating exogenous substances. (In comparison, the EVLA procedure produces foreign material, during the procedure blood is carbonized and also the laser tip seems to shrink or partially to evaporate).
Like in the VNUS catheter the temperature is fully regulated, the steam has a constant temperature of no more than maximally 140°C. Because the induced temperature rise is limited (in accordance with RFA), it is likely that the treatment related symptoms (i.e., pain and bruising) and complication rate is lower than EVLA, which may increase patient*s comfort and treatment safety. In comparison to the RFA there is a sublime and more efficient transmission of energy to the vessel wall: because of the pressure of the steam at 140 degrees a full contact with the vessel wall is guaranteed. As a result of this contact to the vessel wall the condensation of the steam takes place. It is during this condensation process that the largest part of the transmitted energy is released. (e.g. 1 gram steam produces 2260 J when it condensates into water and only 260 J is produced by cooling from 100 to 37 degrees celsius) Moreover in consequence of the pressure of the steam, blood is pushed out of the treated segment of the vessel and therefore the collateral absorption of energy is minimized.
In the RFA technique an outside compression of the vessel wall is needed to optimize the transmission of thermal energy and to evacuate the blood from the treated segment.

Study objective

To test whether the anatomical success rate of Steam Ablation is not inferior to that of VNUS in treatment of GSV insufficiency and compare the treatment safety, patient reported outcomes between and Steam Ablation.

Study design

A non-inferiority randomized single blinded unicenter clinical trial with one year follow up.

Study questions
I. Is Steam Ablation not inferior to RFA in occluding the insufficient GSV after a follow-up period of one year?
II. Does Steam Ablation induce fewer (major and minor) complications than RFA?
III. Has Steam Ablation less impact on patients* lives the month following therapy.
IV. Do patients experience a higher treatment satisfaction after Steam Ablation than after RFA?

V. Is Steam Ablation cheaper than RFA?

Intervention

1. Radiofrequency Ablation

RFA will be performed with the patient under local tumescent anesthesia in an outpatient setting. Venous access is obtained by a puncture with a 19 G needle under US guidance. Most commonly, the insufficient GSV is entered at knee level because of ease of access and the smaller risk of nerve injury. A precut is made under local anesthesia, introduction of an Medex easy glide, 7 french introducer in the next sequence: puncture with 19 G needle, insertion of a guide wire, insertion of the canula, removal of the guide wire. Insertion and positioning of the RFA catheter and positioning of its tip. Position: tip of the catheter is located 2cm distal of the saphenofemoral junction (SFJ). Administration of the tumescent into the perivenous space under US guidance using a mechanical infusion pump. Composition of tumescent fluid is 500 cc NaCl 0,9, bicarbonate and lidocaine 400 mg. Tumescent anesthesia is warranted because it reduces pain, cools perivenous tissue, and decreases the venous diameter.
Radiofrequency waves are applied to the heating element in 20-second intervals to sequentially heat and ablate the vein in seven centimeter increments. The first segment, near the SFJ, is heated twice the 20 second interal. After each segment is treated, the RFA catheter is manually withdrawn down the vein and the process is repeated until the entire length of the vein has been ablated. The ablated vein becomes scar tissue and is eventually absorbed by the body. After the procedure patients are advised to wear medical elastic compression stockings for 48 hours and to mobilize immediately.

2. Steam Ablation

The procedure of Steam Ablation is very similar to the radiofrequency procedure. Steam Ablation will be performed with the patient under local tumescent anesthesia in an outpatient setting. Venous access is obtained by a puncture with a 19 G needle under US guidance. Most commonly, the insufficient GSV is entered at knee level because of ease of access and the smaller risk of nerve injury. After entrance to the varicose vein is established, the Steam Ablation catheter (1.2 mm) is passed through
the hollow needle into the vein until it is positioned a few centimeters below the junction. The most pivotal step in the Steam Ablation procedure is positioning the echo-dense tip of the sheath approximately 2 cm distally from the junction (under longitudinal US visualization). Tumescent is administered for the same reason and with the same composition as in the RFA procedure. After activation, the catheter will release small *puffs* of steam and the catheter is pulled back stepwise. Every centimeter one puff of steam is administered in veins <7 mm diameter, 2 puffs of steam in veins 7-10 mm and 3 puffs in veins >10 mm in diameter. So, the steam will be administered in a

pulsed manner. Approximately 2258 J is released when 1 g of steam is condensated. In
order to occlude 30 cm of vein, theoretically 1 to 1.5 cc of water is needed. In practice, 2 to 5 cc water will be needed, because not all steam will be condensated at the vein wall. After the procedure patients are advised to wear medical elastic compression stockings for 48 hours and to mobilize immediately.

Study burden and risks

not applicable

Contacts

Public
Dermatologsich Centrum Wetering

Nieuwe Weteringstraat 11
Amsterdam 1017 ZX
NL
Scientific
Dermatologsich Centrum Wetering

Nieuwe Weteringstraat 11
Amsterdam 1017 ZX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Patients over 18 years old
• No prior treatment of the insufficient GSV
• Insufficieny of the GSV measured with ultrasound imaging, reflux > 0.5 s, and diameter of vein >5 mm.
• Informed consent

Exclusion criteria

• Acute deep or superficial vein thrombosis
• Agenesis of deep vein system
• Vascular malformation or syndrome
• Post-thrombotic syndrome, occlusive type
• Pregnancy
• Immobility
• Allergy to lidocaine
• Arterial insufficiency
• Use of coumarine anticoagulants
• Mentally unable to give informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2011
Enrollment:	260

Type:	Actual

Ethics review

Approved WMO Date:	14-02-2011
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	12-09-2013
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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	NL32352.094.10