Tomy; Lasercrossectomy versus EVLA

Published: 16-12-2015
Last updated: 15-04-2024

Primary Objective: To prove that there is less development of recurrence and neoreflux seen from the AASV originating from the SFJ in the lasercrossectomy group than in the traditionally treated EVLA group. Secondary Objectives: The Lasercrossectomy…

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

Summary

ID

NL-OMON47125

Source
ToetsingOnline

Brief title
Tomy; Lasercrossectomy versus EVLA

Condition

- Venous varices

Synonym
recurrent veins, Varicosis

Research involving
Human

Sponsors and support

Primary sponsor: Biolitec Pharma
Source(s) of monetary or material Support: Centrum Oosterwal

Intervention

Keyword: Endovenous Laser Ablation, EVLA, Lasercrossectomy

Outcome measures

Primary outcome

Primary endpoints

1. DUS reflux status of AASV

2. Visible recurrent varicose veins connected to AASV.

3. DUS detected neovascularisation

Secondary outcome

Secondary endpoints

4. DUS detected SFJ reflux and proof of GSV ablation

5. Residual GSV stump length

6. Diameter intrafascial AASV before and after GSV ablation

7. Patency of the Superior Epigastric Vein

8. Thrombotic and other complications

9. Venous severity (VCSS) and quality of life (QoL)

Study description

Background summary

For ten years ago High (Flush)Ligation and Stripping (HL/S) of the Great Saphenous Vein (GSV) was the standard treatment for GSV incompetence. During the procedure all tributaries entering the saphenofemoral junction (SFJ) were ligated and/or resected , followed by stripping of the thigh portion of the GSV. Inadequate ligation of the Sapheno-Femoral Junction (SFJ) and these tributaries is suggested to be one of the causes of recurrent varicosities. However, current minimally invasive techniques that abolish axial vein reflux do not specifically interrupt these tributaries and critics of these techniques

believe that this may compromise their durability. Duplex Ultrasound (DUS)-findings after HL/S revealed that besides inadequate ligation the majority of recurrence was secondary to neovascularisation at the SFJ. One of the hypotheses is that hypoxia-induced activation of the vascular endothelial cells lining the residual saphenofemoral stump may stimulate angiogenesis by the release of growth factors .(1) After endovenous ablation contact of endothelial or perivascular progenitor cells with the surrounding wounded tissue, which serves as putative trigger for neovascularization, is avoided. (2) However on the other hand , endovenous procedures are associated with a risk for recanalization and neoreflux in persistent open junctional tributaries. Several RCT*s comparing endovenous ablation with HL/S showing apparently more neoreflux in groin tributaries , especially the anterior accessory saphenous vein (AASV) after endovenous ablation in comparison with HL/S (3-6) (7). One of the reasons can be the positioning of the tip of the fiber/catheter not close enough to the SFJ. This will increase the risk leaving a residual stump with open tributaries ,That arises the possibility that they become incompetent by pressure through a incompetent terminal valve which cause neoreflux.(8) To diminish the prevalence of SFJ recurrence caused by incompetent accessory veins after endovenous ablation it could be wise to avoid a residual GSV stump formation if possible analogous to open surgery. In most cases, if present, the AASV joins the GSV closest to the SFJ. .So it looks reasonable to close up the GSV including the SFJ (lasercrossectomy) to prevent neoreflux in the AASV Bare tip endovenous laser fibers and ClosureFAST RFA catheters both have a forward thrust of heat associated with the technique. That*s why many authors advise to stay about 1,5- 2 cm of the confluence to prevent intimal damage at the SFJ which can provoke a heat induced thrombus (EHIT) or deep venous thrombosis (DVT).(9) It is assumed that with the use of a radial laser fiber, without a forward laser beam, it is possible to occlude the saphenous vein including the SFJ in a safe way(10). To prove that this occlusion leads to less varicose vein recurrence caused by axial neoreflux in AASV, we want to study patients in which a visible AASV is present before treatment (50% of patients)(7, 11). It is also important to investigate what happens with the other tributaries in both groups and if occlusion will induce neovascularization

Study objective

Primary Objective:
To prove that there is less development of recurrence and neoreflux seen from the AASV originating from the SFJ in the lasercrossectomy group than in the traditionally treated EVLA group.

Secondary Objectives:
The Lasercrossectomy procedure is safe with similar risk of thrombotic complications after both treatments.
There will be a difference in severity of venous disease and quality of life

measurements in favour of lasercrossectomy

Study design

This is a randomised, half-blinded, single centre study. In this study we will compare group A (n=50) who will have a laser crossectomy and group B (n=50) who will have the traditional EVLA both with a radial laser fiber . In two years follow up the occlusion and recurrence rate, CEAP, quality of life, vein related symptoms and complications will be evaluated.

Intervention

Lasercrossectomy

After the patient is positioned on the operating table. DUS-guided percutaneous access to the GSV at the most distal insufficient part is obtained with 18 G needle. A 5 F 11 cm sheet is introduced and followed by introduction and exact positioning of the laser fiber tip just caudal of the terminal valve (TV) under DUS guidance . If the AASV is joining the GSV cranial from the terminal valve the AASV will be ablated by the same fiber . Perivenous tumescent anesthesia with lidocaine 0.05 %; cold saline (5-10 °C) is administered under DUS guidance with a roller pump (Nouvag Dispenser DP20). After complete installment of the tumescent fluid the location of the tip of the fiber is controlled and eventually repositioned if needed. Laser treatment is performed with continuous mode with a power of 10 Watt.
At the junction a dose 80 joules is given in 8 seconds without moving the tip, , followed by slowly withdrawing the fiber delivering a targeted energy dose that is determined by the diameter of the GSV (0.3-0.4 cm=50 J/cm, 0.4-0.5 cm=60 J/cm, 0.5-0.6 cm=70 J/cm, >0.6 cm=80 J/cm.
One week after the EVLA treatments, sclerotherapy (Aethoxysclerol 0.5-3.0%, Kreussler) of residual superficial varicose veins is performed by a phlebologist. Whole leg compression stockings (Struva) are applied for one day and night week and only during daytime for the rest of the week.

Traditional EVLA
After the patient is positioned on the operating table. DUS-guided percutaneous access to the GSV at the most distal insufficient part is obtained with 18 G needle. A 5 F 11 cm sheet is introduced and followed by introduction and positioning of the laser fiber tip 1,5- 2 cm distal of the SFJ (cranial of the superior epigastric vein) under ultrasonographic(DUS) guidance . Perivenous tumescent anaesthesia with lidocaine 0.05 %; cold saline (5-10 °C) is administered under DUS with a roller pump (Nouvag Dispenser DP20). After complete installment of the tumescent fluid the location of the tip of the fiber is controlled and eventually repositioned if needed. Laser treatment is performed with continuous mode with a power of 10 Watt
By slowly withdrawing the fiber a targeted energy dose is delivered that is

determined by the diameter of the GSV (0.3-0.4 cm=50 J/cm, 0.4-0.5 cm=60 J/cm, 0.5-0.6 cm=70 J/cm, >0.6 cm=80 J/cm
One week after the EVLA treatments, sclerotherapy (Aethoxysclerol 0.5-3.0%, Kreussler) of residual superficial varicose veins is performed by a phlebologist. Whole leg compression stockings (Struva) are applied for one day and night week and only during daytime for the rest of the week.

Study burden and risks

Patients referred to our centre with varicose vein disease and a SFJ and GSV trunk insufficiency and eligible for endovenous laser treatment are screened for the study. The observations are conducted after one week, as usual, and extra duplex scans are carried out after 6 months and 1 and 2 years. During these control visits, a DUS is performed with special emphasis on the groin area VCSS are generated by the physician. Participants fill in validated questionnaires (pain VAS, QoL). The contribution of the participants will consist of completing the questionnaires and additional controls in our centre. The technique of endovenous laser treatment is not different than from non-participants in our center. The preoperative assessment and inclusion, the postoperative monitoring are done by experienced phlebologists and the endovenous ablation by very experienced surgeons in venous disease With the radial fiber EVLA is > 5 years experience in > 1000 cases

Contacts

Public
Biolitec Pharma

Otto Schotstrasse 15
Jena 07745
DE
Scientific
Biolitec Pharma

Otto Schotstrasse 15
Jena 07745
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patients age > 18 < 80 years.
2. Patients who have an incompetent GSV with venous symptoms.
3. GSV suitable for EVLA
4. Mean diameter of the GSV > 3 mm.
5. DUS visible AASV joining the GSV
6. Incompetent SFJ after provocation manoeuvres
7. CEAP C2-C6

Exclusion criteria

1. Patients age < 18 > 80 years.
2. Mean diameter of GSV < 0,3 cm
3. GSV not suitable for endovenous ablation
4. AASV not joining the GSV
5. The use of Warfarin or other oral coagulans
6. Riskfactors for DVT
7. Competent SFJ .
8. CEAP < 2

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-04-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	16-12-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
Other	22301
CCMO	NL52367.094.15