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# Guidelines of the First International Consensus Conference on Endovenous Thermal Ablation for Varicose Vein Disease – ETAV Consensus Meeting 2012

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## Abstract

**Aim:** Endovenous thermal ablation (ETA) procedures are catheter-directed, ultrasound (US)-guided thermal methods for treatment in varicose veins disease. Radiofrequency, laser or steam energy thermally denatures vein wall collagen, leading first to vein wall inflammation, then fibrosis and finally to occlusion. The aim of this guideline is to give evidence-based recommendations for ETA procedures.

**Methods:** These guidelines were drafted during a consensus meeting of a group of experts in the field of ETA in June 2012 (Hvar, Croatia) under the auspices of the International Union of Phlebology (IUP). These guidelines review the present state of knowledge as reflected in peer-reviewed published medical literature. The recommendations of these guidelines are graded according to the American College of Chest Physicians Task Force recommendations on Grading Strength of Recommendations and Quality of Evidence in Clinical Guidelines.

**Results:** Recommendations on the use of ETA procedures were made based on the quality of evidence for efficacy, safety, tolerability, cosmetic outcome, patient satisfaction/preference and, where appropriate, on the experts' opinion. Health economics were not considered, since differences in national health systems and pricing make it difficult to form general conclusions that are relevant at an international level.

## Keywords

Chronic venous disease, endovenous, thermal ablation, varicose veins

These guidelines were developed during a consensus meeting of a group of experts in the field of endovenous thermal ablation (ETA) in June 2012 (Hvar, Croatia) under the auspices of the International Union of Phlebology (IUP). A systematic literature review was conducted (using MEDLINE and EMBASE), and recommendations were made based on the quality of evidence for efficacy, safety, tolerability, cosmetic outcome, patient satisfaction/preference and, where appropriate, on the experts' opinion. Health economics were not considered, since differences in national health systems and pricing make it difficult to form general conclusions that are relevant at an international level. Quality of evidence and strength of recommendations,

where applicable, were scored according to the system developed by Guyatt in 2006 (Appendix 1).<sup>1</sup>

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## Definition

ETA procedures are catheter-directed, ultrasound (US)-guided thermal methods for treatment in varicose veins disease.<sup>2,3</sup> Most evidence has been so far accumulated for endovenous laser ablation (EVLA) and radiofrequency segmental ablation (RFSA). Separate guidelines for EVLA and radiofrequency ablation have been published earlier in the UK (NICE guidelines), and recently in the USA within general guidelines for care of patients with varicose veins and chronic venous disease.<sup>4-7</sup> For other methods, like endovenous steam ablation or bipolar radiofrequency ablation the evidence is still scarce.<sup>8-11</sup> Radiofrequency, laser or steam energy thermally denatures vein wall collagen, leading first to vein wall inflammation, then fibrosis and finally to occlusion.<sup>12-14</sup>

## Objectives of ETA

The objectives of ETA are:

- Ablation of varicose veins;
- Prevention and treatment of complications of chronic venous disorders (CVD);
- Improvement and/or relief of venous symptoms, improvement of quality of life;
- Improvement of venous function; and
- Improvement of the aesthetic appearance.

These objectives are in line with other methods of treatment for varicose veins.<sup>7</sup>

## Qualification of ETA providers

*Recommendation 1:* We recommend that the healthcare provider (as an individual or team) should possess competence required to diagnose the patient's venous disorder, establish his or her treatment needs, communicate, recognize and manage risks and deliver safe and appropriate ETA to treat superficial venous incompetence in accordance with current standards of care and patient's expectations (GRADE 1C).<sup>15</sup>

ETA is a part of a complex treatment plan of the disease which needs proper pre- and post-treatment diagnosis and treatment of all aspects of the disease. Therefore, phlebological training and skills in the different methods is mandatory.<sup>7</sup>

## Pre-treatment and post-treatment evaluation and documentation

*Recommendation 2:* We recommend a clinical and duplex pre-treatment and post-treatment evaluation

and documentation to be completed in conjunction with an ETA procedure (GRADE 1C).

### *Medical/surgical history including basic demographic data*

A complete medical/surgical history should be taken and recorded with a special attention paid to previous history of venous disease (in particular, the past and/or current venous thromboembolism) and treatment. Reasons for seeking phlebological attention should be carefully documented including patient's expectation from the treatment.<sup>16</sup>

### *Clinical examination*<sup>7</sup>

All changes relevant to the venous disorder are recorded by classifying the patient according to the CEAP classification. All visible changes which could be attributable to other causes (lymphedema, signs of peripheral arterial disease, etc.) should be documented. Height and weight (body mass index (BMI)) should be recorded.

### *Duplex ultrasound (DUS) investigation*<sup>7,17,18</sup>

DUS should be performed as put forward in a recently published UIP consensus document (Table 1).<sup>19</sup> Basically, DUS should be done in two steps. In step 1, the entire venous system should be examined. In step 2, veins selected for treatment should be carefully scanned. DUS should be performed by the operator or by another member of the team involved in the ETA.

### *Laboratory investigations*

*Recommendation 3:* We recommend against specific laboratory tests in routine cases. In special situations appropriate tests may be necessary (GRADE 2C).<sup>7</sup>

### *Disease-related measurements and reporting standards*<sup>7,21</sup>

*Recommendation 4:* We recommend the use of clinical outcome measurements to evaluate the primary outcome of ETA procedures (GRADE 1A).

Pre-treatment evaluation should include appropriate disease-related measurement tools and assessment of patient's motivation, which will help assess the outcome of treatment and its impact on the patient.<sup>22-25</sup>

We recommend use of a standardized severity score (e.g. revised Venous Clinical Severity Score, VCSS) before and after treatment.<sup>26</sup> Other tools like photography and QoL scores should be used.

**Table 1.** Pre-operative duplex imaging.

1. Deep veins: assessment for patency, reflux and waveform analysis<sup>a</sup>
  - Common femoral vein (CFV)
  - Femoral vein
  - Popliteal vein
  - Calf veins
2. Junctions: assessment for reflux (terminal valve/pre-terminal valve)
  - Saphenofemoral junction (SFJ)
  - Saphenopopliteal junction (SPJ)
3. Main trunks: diameter measurement<sup>b</sup> and assessment of reflux (in the saphenous compartment):
  - Great saphenous vein (GSV)
  - Anterior accessory saphenous vein (AASV)
  - Posterior accessory saphenous vein (PASV)
  - Superficial accessory saphenous vein (SASV)
  - Small saphenous vein (SSV)
  - Thigh extension of SSV/Giacomini vein
4. Tributaries: if incompetent
5. Non-saphenous veins: if incompetent<sup>c</sup>
6. Perforating veins: diameter measurement and assessment of flux and/or reflux

<sup>a</sup>Waveform analysis should help detect any proximal venous obstruction.

<sup>b</sup>Diameter of saphenous veins should be measured 3 cm distal to the ostial valve, and at mid-thigh and mid-calf.

<sup>c</sup>Pelvic insufficiency should not be overlooked: clues such as unusual reflux patterns draining through pudendal or other pelvic/perineal veins, posterior thigh or buttocks drainage patterns may be helpful in this regard.<sup>20</sup>

*Recommendation 5:* We recommend the assessment of the technical/anatomical outcome of ETA as determined by DUS as a secondary outcome (GRADE 1A). The technical report should include:<sup>27</sup>

- Length of the patent saphenous junction, i.e. length of the patent saphenous vein distal to the junction, if applicable
- Diameters of treated saphenous veins at standard points, if applicable
- Patency of the treated vein
- If flow is detected along the vein, the length of the patent segment should be recorded
- If flow is detected, it should be specified is it ante-grade or retrograde (reflux) flow
- The reflux should be described as segmental or axial (all along the saphenous trunk)

These findings can be summarized in accordance with the IUP duplex classification.<sup>19</sup>

*Recommendation 6:* We recommend the following terminology for anatomical efficacy assessment (GRADE 1A):<sup>27</sup>

- Recanalization (with or without reflux): documentation of flow in a previously occluded vein.
- Neovascularization: presence of multiple small tortuous connections between the saphenous stump or the femoral (or popliteal) vein and the residual saphenous vein or its tributaries (new, or pre-existing dilated vessels outside the venous wall).
- Primary ablation: ablation after initial treatment.
- Primary assisted ablation: successful retreatment of anatomic recanalization before clinical failure has occurred.
- Secondary (retreatment) ablation: successful retreatment of patients with anatomic and clinical failure (retreatment method should be specified).

*Recommendation 7:* We recommend the careful documentation of all side effects occurring  $\leq 30$  days after the endovenous procedures which may be treatment-related (GRADE 1A).

## Indications and contraindications

Selection of patients should be made with respect to the patient's venous condition and his or her general health which may influence the choice of the treatment and the type of anesthesia, and office-based or hospital procedure.

### Veins amenable to ETA

*Recommendation 8:* We recommend the following veins applicable for ETA:

- Great saphenous vein (GSV) (GRADE 1A),<sup>23–25,28–42</sup>
- Small saphenous vein (SSV) (GRADE 1A),<sup>43–48</sup>
- Accessory saphenous veins (intrafascial part) (GRADE 1B),<sup>46,49</sup>
- Giacomini vein and cranial extension of the SSV (GRADE 1B),<sup>50</sup>
- Other superficial veins situated in the subcutaneous tissue (GRADE 1C),<sup>51,52</sup>
- Insufficient perforating veins (GRADE 1C),<sup>51,53–58</sup>
- Residual intrafascial veins after treatment (GRADE 1B),<sup>59–62</sup>
- Venous malformations (GRADE 1C).<sup>63,64</sup>

There may be specific requirements for some ETA methods (e.g. for RFSA the vein segment should be at least 10 cm long when standard catheter (7 cm heating element) is used or 5 cm when a shorter heating

element (3 cm) is used). EVLA has generally no such restrictions.

Incompetent perforating veins (IPVs) may be treated with EVLA or a special radiofrequency stylet device.<sup>51,53–58</sup> However, indications for ablation of IPVs are rather narrow or they can be equally successfully treated by other methods (e.g. phlebectomy or foam sclerotherapy).<sup>7</sup>

In general, veins to be treated by ETA should neither contain synechiae/membrane webs nor be tortuous to the extent which precludes advancement of the catheter even with the use of special guide-wires, manual maneuvers or multiple entry sites.<sup>65,66</sup>

### General health condition

*Recommendation 9:* Before treatment, in routine cases we recommend only a carefully taken medical history. In case of any known or suspected health disorder or documented disease it is necessary to review all of the pertinent medical documentation of the patient, and consult his or her physician (GRADE 2C).

The procedure itself is elective and thus patients should be healthy. A carefully taken medical history is usually all that is needed. However, in case of any health disorder or documented disease it is necessary to review all of the pertinent medical documentation of the patient, and consult his or her physician.

Being a bipolar radiofrequency system, well controlled cardiac arrhythmias including atrial fibrillation are not contraindication for RFSA as there should not be current propagation beyond the treated vein wall.<sup>67</sup> Patients on long-term oral anticoagulation can also be safely treated with RFSA/EVLA.<sup>68–70</sup>

Those unable to walk for at least 15–20 min several times daily are not good candidates for ETA. However, although not being ideal candidates, this method may be still better in these circumstances than other methods, like classical surgery.

### Contraindications

*Recommendation 10:* We recommend to consider the following absolute and relative contraindications (GRADE 1C).<sup>71,72</sup>

#### Absolute contraindications

- Acute deep vein thrombosis (DVT),
- Acute superficial phlebitis,
- Acute infections at puncture sites (infection should be treated first),

- Deep venous obstruction if the vein to be treated is a functional collateral.

#### Relative contraindications

Careful risk/benefits evaluated, and any modifications clinically indicated are considered, and discussed and agreed with the patient.

- Immobile or hardly ambulating patients (a relative contraindication – if low-molecular-weight heparin (LMWH) prophylaxis is given it is a safe procedure even in this setting (the experts' opinion)),
- Concomitant significant peripheral arterial disease with (ankle:brachial pressure index < 0.5 or an absolute ankle pressure < 60 mmHg) which prevents postprocedural compression (a relative contraindication – for ETA procedures it may not be necessary or a segmental eccentric compression may be used).<sup>73</sup> However, such patients are probably more likely to need conduits for peripheral arterial bypass, and destruction of even a mildly diseased truncal vein should only very carefully be considered.
- Patients unable to undergo local anesthesia (if allergic to lidocaine they may be treated in general or regional anesthesia with tumescence without lidocaine or another local agent may be used, like mepivacaine).<sup>74,75</sup>
- Elevated thromboembolic risk including documented thrombophilia and history of previous DVT. ETA may be safe even in patients with previous venous thromboembolic events.<sup>76</sup> In such cases thromboprophylaxis should be considered,
- Pregnancy,
- Patients with significant uncompensated (non-responsive to standard treatment) leg edema who cannot be adequately monitored by ultrasound; in these patients US scanning for DVT may be very difficult or impossible so that the edema should be treated first,
- Uncontrolled severe diseases.

### Technical issues which may be viewed as relative contraindications (GRADE 1C)<sup>65</sup>

- Tortuous vein difficult to catheterize
- Diameter of the vein at the accessing segment < 3 mm (may be difficult to puncture and pass the catheter)
- Partly occluded venous segment (intraluminal webs, thrombosed or hypoplastic)
- Vein segment to be treated shorter than necessary for catheter placement.

## Treatment plan

*Recommendation 11:* We recommend that the patient must be informed of the diagnostic results, treatment options including no treatment, the suggested treatment plan, any potential risks, and results expected to be achieved at the end of the treatment period (GRADE 1A).

In the majority of cases, EVLA/RFSa is not the only procedure to be performed during the operation. Additional interventions are foam sclerotherapy and/or phlebectomies.<sup>77-79</sup>

1. Findings are discussed with the patient, and treatment options recommended are clinically indicated and achievable within patient's expectations. Cost estimate is given or insurance coverage is discussed. If patient declines for whatever reason the proposed ETA treatment, the phlebologist should offer her or him other modalities of treatment or refer her/him to a colleague able to deliver the alternative treatment in case that it is not provided at the institution.
2. Risks of proposed treatment(s) and possible actions in the event of adverse outcomes are explained. Patient should be informed about major risks and complications. Risks associated with adjunct procedures are also presented and explained.
3. Written informed consent for the proposed treatment is obtained, and is signed by both the treating phlebologist and the patient.
4. If treatment is indicated, the interval between diagnosis by DUS and treatment is no more than 6 months. Otherwise DUS should be repeated.
5. Instructions are given for pre-operative requirements and for post-operative care. Depending on the stage of varicose vein disease and additional procedures, compression treatment and ambulation are recommended.<sup>80,81</sup>

## Patient preparation on the day of surgery

*Recommendation 12:* We recommend reviewing the pertinent health-related data on the day of surgery (GRADE 1C).

In the operating room a quick check of the vein to be treated is performed by DUS. If other clinical indications exist, DUS may be more detailed.

*Recommendation 13:* We recommend marking the veins to be treated with the patient in the standing position in routine cases before the treatment (GRADE 2C).

Marking is performed with the patient standing. If only ETA is planned then marking may be limited to this particular vein. However, most of the time, other

varicose veins are treated simultaneously with sclerotherapy and/or mini-phlebectomies, and marking should include all of these veins. The veins are visualized by observation, palpation and duplex scanning. The veins are marked with an indelible surgical pen with special attention paid to saccular dilatations, sinuosity, position with respect to the saphenous intrafascial compartment and distance from the skin surface. The access point into the vessel is marked on the skin.

If endovenous fluence equivalent (EFE) is used for energy calculation in EVLA, the diameter of the vein should be measured and marked at three or more sites (e.g. at 3, 25 and 50 cm from the saphenous junction (in case of GSV) so that adequate EFE can be calculated and delivered). Because of the anatomic variability, the position of SPJ (in case of SSV treatment) is marked, which facilitates proper infiltration of tumescent solution in the uppermost portion of SSV.

The position of sciatic nerve and its major branches in relation to the SSV may be analyzed.<sup>82</sup> In obese patients, marking of GSV is best performed in the lying position as the vein may move in the recumbent position away from its skin marking if it was made while patient was standing.

## Anesthesia in ETA procedures

*Recommendation 14:* We recommend injecting tumescence fluid around the vein to be treated independently from the anesthetic method chosen (GRADE 1C). All ETA procedures can be performed in local tumescent, regional or general anesthesia.

ETA may be performed using local tumescent anesthesia or, alternatively, general or regional anesthesia.<sup>7,83</sup>

In case of general or regional anesthesia tumescent solution should be anyway infiltrated but should contain only normal saline.

## Vein cannulation and catheter introduction

*Recommendation 15:* ETA procedures must be performed under sterile conditions (GRADE 1A).<sup>84,85</sup>

Premises in which procedures are done should comply with local regulations but must always satisfy sterility requirements. Materials and equipment for ETA procedures are listed in Appendix 2.

*Recommendation 16:* We recommend ultrasound guidance when the vein is punctured to avoid catheter/fiber misplacement (GRADE 1C).<sup>84-86</sup>

It may be helpful to put patient into the reversed Trendelenburg position in order to enhance venous filling and make the puncture easier. When venous return

is noted, the guide-wire is gently inserted through the needle into the vein.

*Recommendation 17:* We recommend ultrasound guidance for the advancement of catheters and fibers within the vein (GRADE 2C).

*Recommendation 18:* The position of the fiber/catheter's tip at the junction must be controlled and documented by ultrasound (GRADE 1B).

The type of introducer sheath used is dictated by the method of ETA and technical requirements of a particular device. Catheters should always be introduced under US guidance along the vein. Catheter tip position, i.e. the distance from the deep vein depends on the safety criteria of the particular method and should be documented (e.g. for endovascular lasers with radial fibers, catheter tip is placed 1–2 cm distal to the saphenous junction, whereas for segmental radiofrequency, it is positioned just distal (0.5 cm) to superficial epigastric vein or 2.0 cm from the saphenous junction).<sup>87</sup> A recent paper suggested that it might be even safer to increase ablation distance peripheral to the saphenofemoral junction to greater than or equal to 2.5 cm for both EVLA and RFSA.<sup>88</sup> Further studies are needed to clarify this issue especially in relation to the frequency of thrombus extension into the deep system. Tip position should be checked in both longitudinal and transversal planes, and rechecked immediately prior to starting treatment.

### Infiltration of tumescent solution

*Recommendation 19:* We recommend ultrasound guidance for the placement of tumescent solution around the vein (GRADE 1B).

Ultrasound is crucial for proper placement of tumescent solution within the saphenous intrafascial compartment.<sup>36,89,90</sup> Infiltration may start at the distal end, close to the puncture site. In practice, the space should be filled enough so that the vein collapses around the catheter, and the distance from the skin surface should be at least 1 cm. For infiltration of the anesthesia an infiltration pump can be used on a low setting.

When the needle is within the saphenous compartment, the solution relatively easily flows proximally, and a few punctures along the vein's length may be enough to infiltrate the whole space. Always be sure that the needle is not within the vessel. Systemic symptoms such as tachycardia may indicate inadvertent intravascular injection of TA. Immediately cease injection of TA and monitor patient with pulse oximetry, blood pressure and monitor cardiac rhythm. Accurate ultrasound guidance of the tumescent anesthesia helps avoid intravenous injection since rapid dilation of the vein is easily seen on ultrasound.

*Recommendation 20:* We recommend ultrasound guidance for the careful placement of tumescent solution in the junctional area (saphenous veins) (GRADE 1B).

Special attention should be paid to the junctional area. After the infiltration of the area some 5 cm distal to the junction, and after final positioning of the patient, the catheter tip position is again visualized and checked for the proper placement, and the last portion is infiltrated (over and beyond the junction).

Within the popliteal fossa, proper amount of tumescent solution around SSV reduces the possibility of thermal damage to the sciatic nerve and its major branches (tibial, peroneal and sural nerves).<sup>91,92</sup>

In cases when patients prefer general or spinal anesthesia, the tumescence solution is often prepared without both lidocaine and adrenalin – only physiologic saline is used. This is particularly important in rare patients allergic to lidocaine.

### Thermal ablation

*Recommendation 21:* We recommend that the appropriate energy for the vein to be treated is calculated (e.g. LEED, EFE) and applied (GRADE 1A).

All methods of ETA involve delivery of thermal energy. Essential to their efficacy is calculation and delivery of appropriate amount of energy. It however differs with particular devices and operator should follow specific recommendations of manufacturers and/or data obtained from high-quality clinical trials.

### Radiofrequency

In order to obtain a near-bloodless field, external compression is applied over the treated segment of the vein along with the Trendelenburg position.<sup>86,90</sup> This may be performed by manual compression with the ultrasound transducer or with a fabric roll by an assistant. However some operators do not use additional compression relying on the compressive effect of tumescent solution.

RF energy delivery depends on the system used.

For segmental RF ablation (Closure FAST<sup>TM</sup>) power is automatically adjusted by the generator in order to maintain the temperature of the heating element at 120°C. It will typically begin at 40 W and drop to below 15 W at the end of the cycle.<sup>86</sup> The temperature should rise to 120°C within 5 s. The heating cycle lasts 20 s. After the treatment time interval, RF energy delivery will terminate automatically. If indicated, a second cycle may be initiated immediately after the first one – for instance, in the first (junctional) segment. In case of any unusually wide segment (e.g. sacular dilatations), two or even three cycles may be applied. It may be that

double heat cycles applied along the whole length of the vein result in even better final outcomes.<sup>93,94</sup> The catheter is pulled back stepwise until the next shaft mark is aligned with the catheter hub and the procedure is repeated.

For the Celon™ system the output setting is usually set on 20 W so that the energy delivery approaches 40–45 J/cm of the vein (linear endovenous energy density; LEED).<sup>11,95</sup> The catheter is pulled back at a rate 0.5–0.7 cm/s. It is basically guided by the acoustic signaling of tissue impedance (automatic impedance feedback-power output control) during the thermal ablation process – the pullback velocity is monitored and can be adjusted.

### Endovenous laser ablation

Appropriate power and energy settings are selected on the laser. Energy density is the most important factor influencing success.<sup>96</sup> Calculation of energy to be delivered depends on the dimensions of the vein, the wavelength of the laser, the laser power (Watt) and the fiber type used. It can be calculated as LEED in J/cm of the vein treated or in EFE in J/cm<sup>2</sup>. LEED is independent from the vein diameter, whereas EFE takes the diameter into account. Using 810–980 nm lasers and bare fibers the recommended LEED for the GSV should be above 60–80 J/cm and the EFE should be above 20 J/cm<sup>2</sup>.<sup>97–99</sup> With higher wavelength lasers and other fiber dimensions the effective energy density may be lower but no good evidence-based data are available so far.<sup>3,85,100</sup> Power (Watt) and pullback speed are influencing both parameters. Higher power for a shorter time causes more vaporization, whereas lower power for a longer time causes more coagulation.<sup>101</sup> Most studies use a power of 10–15 W. Fiber pullback can be performed step by step or continuously. In most of the studies continuous pullback is used.

The aiming beam confirms the localization of the fiber tip but it does not replace duplex guided localization. Probe pressure over the saphenous junction may protect the femoral vein from the laser energy. Pullback of the laser fiber as the laser is activated may be manual or via a mechanical device. Energy delivery is not started with mechanical pullback devices until there is ultrasound evidence that withdrawal has commenced.

### Management after energy application

After energy delivery has been completed the catheter is withdrawn from the vein. The laser is placed on standby just before withdrawal of the fiber from the vein. It is not useful to evaluate the treatment outcome by ultrasound immediately after the procedure since the diameter of the vein is already quite small because of

the perivenous tumescent anesthesia. The puncture site is compressed for several seconds and may be closed by steri-strips. Absorbent pads are put over the puncture site and along the vein path, fixed with underwrap, and a 30–40 mmHg graduated compression stocking is applied. The additional thigh compression (when thigh veins are treated) applied as eccentric compression may reduce post-operative pain after EVLA.<sup>102,103</sup>

### Treatment records

*Recommendation 22:* We recommend that treatment records include (experts' opinion):

- ETA catheter (fiber) type and its lot number
- treatment time,
- For RF ablation (Celon™):
  - power settings
  - energy delivered
- For RF segmental ablation (Closure FAST™):
  - number of RF cycles per vein's segment
  - total number of cycles per vein
- For laser procedures:
  - laser type
  - laser's settings (power, continuous or pulse mode)
  - energy delivered
  - type of laser fiber
- Accurate description of veins treated and location, i.e. saphenous trunks, tributaries and/or perforators
- Diameter of the vein(s) treated (standing position)
- Length of vein(s) treated
- Puncture site(s)
- Type of anesthesia
- Total volume and composition of tumescent solution infiltrated
- Operation time
- Description of additional procedures (phlebectomies, foam sclerotherapy, etc.) with all data relevant to these procedures
- Any adverse/unexpected events and/or interventions
- Patient written instructions given
- Compression hosiery fitted and class, and time of application
- Bandaging system fitted if applicable
- Any medication given
- Timing of follow-up visits

### Troubleshooting

From the practical standpoint, there are several steps which may be technically and tactically very demanding. Every operator should have them in mind.



### *Vein puncture*

High-quality, very sharp needles should be used. Some operators find using thinner needles (21G or 22G) within micropuncture sets easier to puncture the vein.

Never forget to rinse the needle with saline before attempting vein puncture. It does happen that it is not either patent or the luer-lock cap might not have been removed.

If the needle is inserted into the vessel but blood dripping suddenly stops, do not remove the needle but first try to identify the position of the needle by ultrasound using longitudinal and transverse imaging, and then unclog the needle (e.g. aspirating with a syringe) or carefully reposition it. If the vein is completely penetrated, it is useful to carefully withdraw the needle under US control getting into the lumen on the way back. Removing the needle after having punctured or even scratched the vein wall may induce the vessel spasm making it impossible to reinsert the needle into the vein segment (sometimes the spasm affects a longer segment of the vein).

Waiting, massaging, increasing the reverse Trendelenburg's position, warming up the leg with a warm compress and applying nitroglycerine ointment – all of that may be helpful to reduce venous spasm but in some patients the spasm may last for several hours.

### *Catheter advancement*

While introducing and advancing introducer sheath and catheter one might come across a resistance. If the vein was checked for patency prior to the procedure, the most frequent cause may be a tortuous segment which should be carefully passed through. First check with ultrasound and locate it, then try to manually straighten the leg.<sup>66</sup> If not successful, correct it by stretching, lifting or pushing down the skin (depending on the spatial orientation of the kinking). This situation most commonly appears in the thigh segment of the GSV. Never introduce the catheter with force – it may perforate the vein. Use of a hydrophilic guide-wire (widely used in all current endovascular procedures) resolves almost all the catheterization difficulties, but sometimes, especially in case of a recurrence, the veins are so tortuous that it is best not to attempt catheter insertion. Pre-operative DUS will give reliable information on the sinuosity of the vein. In cases of a tortuous segment of a short length, as previously described, it might be possible to access the vein at two puncture sites, above and below the problematic segment.

### *Positioning catheter tip*

The third important step is adequate positioning of catheter tip, depending on the type of ETA procedure.

While searching for the optimal position it is helpful to obtain both longitudinal and transversal view and moving the catheter back and forth may help to properly visualize and place the catheter tip. It is again checked immediately before the tumescent solution is infiltrated over the saphenous junction and in general before starting the treatment application. Misplacement of the heating element or fiber tip into a deep vein may produce a severe damage with DVT and/or PE.

Determination of the catheter tip position by measuring the distance from the insertion point to the groin is far less reliable than identification by ultrasound.

### *Thermal ablation*

During the RFSA (Closure FAST™) the operator must always monitor the display for temperature, power and time. If the set temperature (120°C) is not reached within 5 s after RF energy delivery initiation, or if the power level is maintained above 20 W, there may be flow within the vein that is cooling the treatment segment (in other words, venous wall is not in a close contact with the heating element). Terminate RF energy delivery, verify effectiveness of compression and proper tip position, correct as necessary, and re-initiate treatment of the segment. In case of the Celon™ Lab RFIIT system, the acoustic signaling of tissue impedance during the entire coagulation process also makes it possible to determine the optimum withdrawal velocity for the radiofrequency induced thermotherapy (RFITT) applicator.

Sometimes, during RFA tumescent solution is too cold and prevents the rise in temperature up to the desired point. Waiting for a couple of minutes would be necessary to allow the tissue warming or, alternatively, use tumescent solution pre-warmed to 37°C.

Continuous temperature readings below the set temperature may result in incomplete treatment. If this occurs, stop the treatment and reconfirm vessel opposition to the catheter heating element and absence of blood flow in the vessel segment to be treated. Apply more firm external compression if needed or inject more tumescent anesthesia and retreat the segment. High energy delivery persisting at the end of the cycle indicates that one additional heating cycles is needed.

During the EVLA the operator must monitor the display for energy and take care about the pull-back time – the latter may be followed on a special clock.

After a vein segment has been treated and catheter withdrawn, never try to re-advance the catheter again into the acutely treated vein. It may result in the perforation of the vessel with hematoma formation.

## Post-treatment advice

*Recommendation 23:* We recommend giving written details of the post-operative requirements to the patient (experts' opinion).

Possible adverse events, which may be of concern post-treatment, are explained to the patient and she or he is instructed to contact office urgently if they arise.

Elderly or anxious patients are advised to come with an accompanying person. Driving immediately after surgery should not be allowed if any sedation was administered.

Analgesic medications are not routinely prescribed as a great majority of patients do not feel the need to take it.

*Recommendation 24:* We recommend against routine prescription of prophylactic anticoagulation (GRADE 1C).

*Recommendation 25:* We recommend at least two follow-up visits (GRADE 1C):

- A clinical follow-up and a DVT scan within 10 days
- A clinical and duplex review of treatment results within 3–6 months

Ensure the patient understands all of the following symptoms of concern, and knows when to contact the practitioner:

- Painful or swollen limbs – may indicate DVT and requires immediate assessment by ultrasound,
- Chest pain, cough or shortness of breath may indicate a pulmonary embolus in which case patients are directed to go to an emergency department immediately,
- Redness, heat or localized swelling over the treated vessel may indicate a thrombophlebitis, panniculitis or cellulitis,
- Any other serious health-related problems, especially when arising within the first 30 days after surgery.

The incidence of DVT and/or pulmonary embolism after ETA procedures is generally low (0–2%) and there is no need for a routine antithrombotic prevention after the procedures.<sup>7</sup> Where there are other intrinsic or extrinsic risk factors for vein thrombosis such as age >60, obesity, immobility, oral contraceptive or hormone replacement therapy use, cancer, history of superficial or deep venous thrombosis, or a known severe thrombophilia, consider covering the procedure with prophylactic doses of low molecular weight heparin daily according to international guidelines, starting at the time of the surgery.<sup>104</sup> One may use the Caprini's assessment method or NIH guidelines to calculate the

thrombotic risk and decide upon the type of prophylaxis.<sup>105–107</sup>

## Complications

ETA is a very safe procedure (Table 2).<sup>91,92</sup> However side effects and complications can occur. The untoward effects are listed below:

*Recommendation 26:* We recommend considering the following adverse events (GRADE 1C):

Side effects and minor complications

- Pain
- Bruising (ecchymosis)
- Erythema
- Hematoma
- Hyperpigmentation
- Paresthesias (hypo, hyper)
- Tender (phlebitis) or non-tender palpable treated vessel (most commonly thigh GSV)
- Infection
- Telangiectatic matting

Major complications

- DVT and/or pulmonary embolism
- Arterial damage including arteriovenous fistulas (very rarely reported)
- Severe nerve damage (very rarely reported)
- Skin burns (seen almost exclusively in patients treated without tumescence)
- Infection
- Fiber breakage during EVLA
- Stroke (a single case reported after EVLA)<sup>108</sup>

Post-operative pain is mild or absent, and a majority of treated patients do not require analgesics or may be prescribed NSAID for a few days.<sup>30,109,110</sup> Pain and bruising seem to be less common with water-absorbing in comparison to hemoglobin-absorbing lasers and with radial fibers compared to bare fibers.<sup>111–113</sup> However, after the first week, some patients report a specific sensation along the treated vein, especially GSV, and describe it as “dragging” or “pulling” – probably as a result of continuous vein contraction after thermal ablation. In patients where additional procedures were done (e.g. phlebectomies) it might be difficult to relate some side effects to the ETA procedure itself (e.g. pain or localized paresthesias may be a consequence of nerve injury during stab phlebectomy).

Ecchymosis (bruising) is mostly confined to the treated limb segment. It seems to be less common with water-absorbing in comparison to hemoglobin-absorbing lasers and with radial fibers compared to bare fibers.<sup>111–113</sup>

**Table 2.** Adverse events after endovenous laser and radiofrequency ablation, modified and updated from Anwar et al.<sup>91</sup> and Dexter et al.<sup>92</sup>

Designation	Incidence
****Very common	≥ 10%
***Common	≥ 1–<10%
**Uncommon	≥ 0.1–<1%
*Rare	≥ 0.01–<0.1%
*Very rare and isolated cases	<0.01%
Type of adverse event	Frequency
<b>Severe complications</b>	
Deep vein thrombosis	*Very rare to **Rare
Pulmonary embolism	* Very rare ** Rare
PASTE (EHIT) <sup>a</sup>	* Very rare to ****Common
Nerve injuries	**Rare to ****Common
Arteriovenous fistulas	*Isolated cases
Stroke	*A single case <sup>108</sup>
<b>Benign complications</b>	
Phlebitis	** Rare to ****Common
Skin pigmentation	****Common
Skin burns	*Very rare to **Uncommon
Ecchymosis <sup>b</sup>	****Common to ****Very Common
Pain <sup>c</sup>	**Rare to ****Common

<sup>a</sup>Very dependent on the timing of ultrasound follow-up examination; generally, in most studies it is common, detected in around 3% of patients.

<sup>b</sup>Less frequent in radiofrequency procedures though treatment with newer higher wavelength lasers result in less ecchymoses.

<sup>c</sup>Pain which required analgesics is less common in radiofrequency ablation than in laser ablation with the bare fiber and comparable with radially emitting fibers.

Hematoma formation is a very rare side-effect and usually completely resolves under adequate compression.

Neurologic side effects result from thermal damage of adjacent nerves and their branches (saphenous, sural, peroneal or tibial nerves). Severe injuries with longer lasting neurologic deficits are extremely rarely reported, and are usually prevented by careful scanning and adequate tumescent anesthesia which should separate the nerve structures and the vein to be treated.<sup>91,92</sup> It seems that at least for SSV the puncture site does not always help reduce the incidence of nerve injuries.<sup>114,115</sup>

Hyperpigmentation is seen in less than 2% of RFA treated patients but may persist beyond 2 years in 1%.<sup>30</sup> It is found mainly when treated vein is close to the skin surface or might suggest partial patency of the treated vein segment.

Superficial burns are very rarely reported.

Phlebitis responds to compression, non-steroidal anti-inflammatory drugs and continued ambulation.

DVT and thromboembolism are potential serious complications of the ETA. After EVLA the incidence of venous thromboembolism was found in up to 2.2% patients.<sup>116–118</sup> After RFA it was detected in up to 0.7% treated patients.<sup>118,119</sup> In a prospective study, Chi and Woods<sup>120</sup> followed by ultrasound 360 consecutive patients undergoing EVLA. At an examination after one week, DVT was detected in 5.3% of the patients. Except for one popliteal vein DVT all other were actually extensions of thrombi at the saphenous junctions (post ablation superficial thrombus extension (PASTE) class II and III). The latter is a special type of DVT in ETA, an extension of thrombus to the saphenous junctions and further into the deep vein (femoral or popliteal) –PASTE. Synonymously the term endovenous heat induced thrombosis (EHIT) is used for this condition.<sup>118,121</sup> It is classified into four stages: PASTE (EHIT) type I involves thrombosis to the level of the superficial-deep junction, type II involves thrombus extension into the deep venous system with cross-sectional area ≤50%, type III involves thrombus extension into the deep venous system with cross-sectional area ≥50%, and type IV is total occlusion of the deep vein.<sup>92</sup> In a large series of 1000 RFA procedures with 35% patients undergoing concomitant phlebectomies (examined by ultrasound 24–72 h after the procedure) PASTE class II and III was found in 4.1% of the patients.<sup>122</sup> One patient developed pulmonary embolism despite a normal post-operative ultrasound. The only risk factor linked to PASTE was the diameter of the GSV >10 mm.<sup>122</sup> In patients with EVLA, the age >66 years, female gender and prior history of superficial thrombophlebitis were associated with increased risk of DVT postprocedure.<sup>120</sup> In a largest so far prospective study, the authors found the EHIT (PASTE) incidence of 3% in 6707 treated limbs, nonfatal pulmonary embolism in 2 patients (0.03%) and 9 limbs had acute tibial or gastrocnemial vein thrombosis with no continuity to ablated saphenous vein.<sup>123</sup> Large vein diameter, male sex and multiple phlebectomies were risk factors for development of EHIT in these patients. Others found that larger GSV diameter and previous superficial venous thrombosis were significantly related to the DVT after RFA.<sup>76</sup> It seems that this sort of DVT has a more benign course and spontaneous resolution in most of the cases. Sufian et al.<sup>123</sup> suggested that patients with PASTE (EHIT) class 1 and 2 may be managed with observation or antiplatelets or both, with class 3 and 4 should be fully anticoagulated with low-molecular weight heparin. In all cases, the resolution may be expected within 4 weeks. Early follow-up, within 10 days from the ETA procedure, should be used to detect PASTE and distinguish it from DVT in

the femoral and/or popliteal vein. Catheter tip position at the saphenous junction during RFSA does not seem to influence the incidence of PASTE.<sup>124</sup> A retrospective analysis of 482 EVLA and 396 RFA procedures showed that PASTE occurred in 6.4% of EVLA and 2.1% of RFA patients. The only predictive factors for PASTE after ETA procedures were male gender and increased Caprini score.<sup>125</sup> More data on the incidence of DVT, and the need for post-operative thromboprophylaxis are necessary to formulate evidence-based clinical guidelines.<sup>126</sup>

## Combination procedures

In many cases, ETA is performed along with adjunct phlebologic procedures, commonly phlebectomies and/or foam sclerotherapy.<sup>77–79,124</sup>

- ETA may be performed on two or more incompetent veins during a single session. When procedure is done solely in local tumescent anesthesia, the major limiting factor may be a total amount of tumescent solution infiltrated, taking into account the upper safety limits of lidocaine.<sup>127</sup> Concomitant phlebectomies have been shown to reduce the need for secondary procedures after EVLA and to significantly improve quality of life and severity of venous disease.<sup>78</sup>
- When performing phlebectomies and/or foam sclerotherapy, healthcare provider should comply with available guidelines or accepted practices for these procedures.<sup>128,129</sup>

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## Appendix 1

### American College of Chest Physicians Task Force recommendations on Grading Strength of Recommendations and Quality of Evidence in Clinical Guidelines.<sup>1</sup>

Grade of recommendation/ description	Benefits vs. risk and burdens	Methodological quality of supporting evidence	Implications
1A/Strong recommendation; high quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs without important lim- itations or overwhelming evidence from observa- tional studies	Strong recommendation, can apply to most patients in most circumstances with- out reservation
1B/strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limita- tions (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evi- dence from observational studies	Strong recommendation, can apply to most patients in most circumstances with- out reservation
1C/strong recommendation, low quality or very low quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A/weak recommendation, high quality evidence	Benefits closely balanced with risks and burden	RCTs without important lim- itations or overwhelming evidence from observa- tional studies	Weak recommendation, best action may differ depend- ing on circumstances or patients' or societal values
2B/weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burden	RCTs with important limita- tions (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evi- dence from observational studies	Weak recommendation, best action may differ depend- ing on circumstances or patients' or societal values
2C/weak recommendation, low quality or very low quality evidence	Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

## Appendix 2

### Materials and equipment recommended for ETA procedures

- Infiltration pump with accompanying sterile tubing
- 20 or 22G (spinal) needles for tumescent anesthesia infiltration
- 19G or 21G ultra thin-walled Seldinger needle OR a micropuncture set for venous access
- A sterile 0.018" or 0.025", 0.035" guide-wire (optionally, for sinuous veins may be used a hydrophilic guide-wire)
- Laser, RF or steam generator
- Disposable RF catheters
- Disposable steam catheters
- Disposable laser fibers

- Scalpel blade No11 or microblade
- Appropriate introducer sheaths (4F, 5F or 7F)
- Sterile ultrasound gel
- Sterile ultrasound transducer cover
- Tilt operating table
- Duplex ultrasound scanner with peripheral vascular probe (7.5–12 MHz)
- Materials for tumescent anesthesia
- Monitoring equipment (depending on the type of anesthesia)
- Emergency equipment