

[Endovenous Radiofrequency Ablation Protocol]

Purpose

The purpose of endovenous treatment is ablation of pathological reflux of blood by durable occlusion of the vein lumen. This goal can be achieved either by shrinkage of the vein until the vein lumen has vanished completely, or by substantial damage to the endothelium and inner vein wall leading to secondary occlusion of the lumen.

Prior to providing endovenous radiofrequency ablation, the facility considers indications, contraindications and pretreatment evaluation.

A. Indications

Prior to endovenous radiofrequency ablation the physician must ensure that the patient has reflux involving one of the main superficial veins or a perforator. This may be associated with one or several of the following presentations:

- Venous ulcerations
- Thrombophlebitis in the superficial venous system
- Edema in lower limb(s)
- Pain, cramps, heaviness, throbbing or burning in lower limb(s)
- Bleeding varicose blister

B. Contraindications

Prior to endovenous radiofrequency ablation, the doctor must ensure that the patient is not experiencing any of the following symptoms that would prohibit the procedure:

- Acute deep venous thrombosis
- Previous history of deep vein thrombosis (would possibly require more investigation)
- Severe systemic disease
- Peripheral arterial disease (refer to Arterial Protocol)
- Late stage cancer/ short life expectancy
- Bed rest
- Pregnancy
- Breastfeeding (patients should secrete & discard breast milk for two days after procedure; not absolute contraindication)
- Hypersensitivity to local anesthesia
- Fever
- Poor patient understanding

C. Pre-Treatment Evaluation

Prior to endovenous radiofrequency ablation, the facility performs and documents a complete history and physical examination that includes the following:

- Personal history of venous disorders
- Prior use of compression
- Medication history
- Allergies
- Family history of venous disorders
- Examination of peripheral pulses (see Arterial Protocol)
- Examination of the veins and of the skin of the lower extremities
- Previous venous insufficiency ultrasound studies
- Other previous diagnostic venous imaging studies
- Previous arterial perfusion studies, if any concern regarding the lack of normal pedal pulses

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The facility obtains the following:

- Pre-operation photographs
- Clinical class score (CEAP)
- Venous clinical severity score (VCSS)
- Duplex ultrasound for C2 disease or higher or as indicated with C0 or C1 disease

If endovenous radiofrequency ablation is deemed necessary, the facility performs the procedure adhering to the outlined protocol. Pre-procedural, procedural and post-procedural protocols are followed. Outcomes are then reported.

1. Pre-procedure protocol

Pre-operative treatment for the patient must include the following:

- a. Patient is instructed to initiate compression therapy and other conservative measures (leg elevation, analgesic) at initial consult with the doctor
- b. Patient is given prescription for compression stockings of appropriate length and compression, if this was not typically done at the time of the initial visit
- c. An available procedure date is scheduled
- d. Patient is usually provided with information regarding the endovenous radiofrequency ablation at the time of the ultrasound evaluation and second visit with the physician.

2. Procedure protocol

The steps for the endovenous radiofrequency ablation are executed in the following order:

- a. Equipment
 - High resolution Color Duplex Imaging System with appropriate frequency transducer in the range of 7.5 MHz-10 MHz
 - Ultrasound gel (sterile and non-sterile)
 - Radiofrequency Generator
 - Infusion pump for tumescent anesthesia
 - 21 gauge micropuncture catheterization set
 - .025 and .035 guidewires
 - 5 F and 7 F sheaths
 - Radiofrequency catheter
 - Tumescent local anesthesia (refer to mixing protocol)
 - Premixed pharmacologic and/or anesthetic agents is (must be) labeled with content, concentration and expiration date if not prepared immediately before use
 - Sterile Pak (Refer to sterile field policy)
 - Sterile gowns and drapes
- b. Set-up
 1. Staff members introduce themselves to the patient
 2. The risks, benefits, indications and alternatives of the procedure are reviewed with the patient. The patient must demonstrate an understanding of the discussion. The patient signs the endovenous radiofrequency ablation vein-specific consent form
 3. Baseline vital signs are obtained. Selected patients (based on prior cardiac or other significant past medical history) are placed on a cardiac monitor. The patient's original ultrasound is reviewed and the surgeon confirms the correct vein is being treated
 4. The patient's information is entered into the ultrasound machine

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5. The patient is asked to lay on surgical bed and is secured to the bed and raised into the reverse Trendelenburg position
 6. A time out is performed. The surgeon and nursing staff ensure and document the correct patient, the correct procedure and the correct site immediately before initiation of the procedure. The procedure start time is documented.
- c. Access and Tumescence Anesthesia delivery
1. A staff member preps the skin and creates a sterile field (refer to Sterile Field Policy)
 2. Physician numbs the access site and the tumescent access points along the treated vein
 3. Physician locates access site in transverse or longitudinal view
 4. Physician uses a 21 gauge micropuncture kit needle to cannulate the vein to be treated
 5. Physician uses a 5 F sheath to insert a .035 guidewire, followed by a 7 French sheath (2 step approach); alternatively physician uses a 7 F sheath directly over the micropuncture guidewire (1 step approach)
 6. Physician verifies that the radiofrequency catheter tip is 2-3 cm distal to the appropriate junction (saphenofemoral or saphenopopliteal)
 7. Physician locates access site and vein to be treated in transverse or longitudinal view (accurate perivenous tissue plane is perpendicular to target vein) for adequate tumescent anesthesia
 8. Physician delivers 1-2 cm halo of fluid surrounding the target vein and separates the vein from the overlying skin
- d. Radiofrequency Energy Delivery
1. Assistant activates the Radiofrequency generator.
*Energy delivery during endovenous treatment of saphenous vein is maintained at 120 degrees Celsius for twenty seconds (considered one cycle).
 2. Assistant changes status from standby to ready at physician's request.
 3. Physician delivers radiofrequency energy at 120 degrees Celsius for twenty seconds and performs two to three cycles in the first segment, depending on the resistance (a third cycle is usually given if >14Watts after 10 seconds). Two cycles are usually provided for all other segments (refer to Operation Report).
 4. The physician proceeds to deliver cycles in a continuous fashion, in combination with step wise catheter pullback.
 5. Vital signs are monitored accordingly.

3. Post-procedure protocol

Post-operative treatment of the patient must be executed in the following order:

- Physician or sonographer assesses with ultrasound the CFV, SFJ, and proximal FV (or the popliteal vein, proximal tibioperoneal veins and SPJ) with and without ultrasound compression
- Physician or sonographer assesses the CFV, SFJ, epigastric vein, and proximal FV with color flow imaging (or the popliteal vein, proximal tibioperoneal veins and SPJ)
- Physician or sonographer documents closure of the treated vein
- Assistant applies ace wrap and grade II (two) 30-40 mmHg compression stockings on the treated limb
- Patient is instructed to walk for five to ten minutes to promote blood flow into the deep venous system
- Patient is instructed to sit down with the treated limb elevated
- Nurse visually checks for oozing 30 to 40 minutes after completion of the procedure.
- If visual check is satisfactory, post-operative instructions are again reviewed with the patient

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- The patient is instructed to take stockings off after 48 hours. Patient is instructed to call if he/she develops pain or numbness.
- One week and one month follow-ups are scheduled for the patient

4. Outcome reporting

After the procedure, the physician documents outcomes in the operative note. The operative note includes all or part of the following (depending on the procedure performed):

- Summary of the procedure
- Pharmacologic and/or anesthetic agents used, including the volume and concentration of tumescent anesthesia
- Use of ultrasound guidance
- Location of varicosities
- Number of incisions
- Veins treated (e.g. varicose tributaries, great saphenous, small saphenous, perforator)
- Treatment site(s)
- Length of vein treated
- Catheter insertion site(s)
- Radiofrequency cycles used and time
- Immediate complications or adverse events
- Patient status post-procedure
- Type and duration of compression are documented in chart (technical worksheet and procedure note)
- Date and time of follow-up appointment is documented on the technical worksheet and patient's instruction sheet

Following the post-op visit, a staff member documents the patient's information in the facility's procedure complication log. This is a separate log kept to document the outcomes, including complications, of the procedures that are performed. This log will be reviewed bi-annually per the facility's quality improvement measures.

References:

The Vein Book

Effects of Different Laser Wavelengths on Treatment of Varices; Lowell Kabnick, pg. 275

VNUS Closure of the Saphenous Vein, Nick Morrison, pg. 283

IAC Vein Center Accreditation: Superficial Venous Evaluation and Management

Tumescent Anesthesia Protocol

Purpose

A technique for the delivery of local anesthesia that maximizes safety by using pharmacokinetic principles to achieve complete anesthesia of skin and subcutaneous tissue.

Equipment

- 30 cc disposable syringes
- 250 cc or 500 cc bag of sterile normal saline, depending on the length of the treated vein
- 18 gauge and 22 gauge needles
- Alcohol wipes
- 1% Lidocaine with Epinephrine 1:100,000 (each ml= 10 mgs Lidocaine/ 10 mcg Epin)
- 8.4% Sodium Bicarbonate

Preparation

- Take 58 cc out of the 500 cc bag of normal saline
- Put 50cc of 1% Lidocaine with Epinephrine 1:100,000 in the 500 cc bag of normal saline
- Put 8cc of 8.4% Sodium Bicarbonate in the 500 cc bag of normal saline
- Mark bag
- If using a 250 cc bag of normal saline, the amount of Lidocaine with Epinephrine and of Sodium Bicarbonate is cut by 50%

Keep the tumescent solution at room temperature.

Delivery

- Dermal wheel of anesthetic solution with 30-gauge needle
- Subcutaneous infiltration with 21 gauge 1 ½ inch needle
- Use either Autofill syringe (if only small area treated) or automated infusion pump (Klein or other type)