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Review

Consensus for the Treatment of Varicose Vein with Radiofrequency Ablation

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The objective of this paper is to introduce the schematic protocol of radiofrequency (RF) ablation for the treatment of varicose veins. Indication: anatomic or pathophysiologic indication includes venous diameter within 2-20 mm, reflux time ≥0.5 seconds and distance from the skin ≥5 mm or subfascial location. Access: it is recommended to access at or above the knee joint for great saphenous vein and above the mid-calf for small saphenous vein. Catheter placement: the catheter tip should be placed 2.0 cm inferior to the saphenofemoral or saphenopopliteal junction. Endovenous heat-induced thrombosis ≥class III should be treated with low-molecular weight heparin. Tumescent solution: the composition of solution can be variable (e.g., 2% lidocaine 20 mL+500 mL normal saline+bicarbonate 2.5 mL with/without epinephrine). Infiltration can be done from each direction. Ablation: two cycles' ablation for the first proximal segment of saphenous vein and the segment with the incompetent perforators is recommended. The other segments should be ablated one time. During RF energy delivery, it is recommended to apply external compression. Concomitant procedure: It is recommended to do simultaneously ambulatory phlebectomy. For sclerotherapy, it is recommended to defer at least 2 weeks. Post-procedural management: post-procedural ambulation is encouraged to reduce the thrombotic complications. Compression stocking should be applied for at least 7 days. Minor daily activity is not limited, but strenuous activities should be avoided for 2 weeks. It is suggested to take showers after 24 hours and tub baths, swimming, or soaking in water after 2 weeks.

Key Words: Varicose veins, Radiofrequency, Ablation, Consensus

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INTRODUCTION

Varicose veins are highly prevalent. In western countries, an estimated 23% of adults have varicose veins, and 6% have more advanced chronic venous disease, including skin changes and healed or active venous ulcers [1]. There are several modalities to treat varicose veins. Open surgical treatment with ligation and stripping of the saphenous vein, combined with excision of large varicosities, has been the standard of care for many years. In 1999, radiofrequency

ablation (RFA) of the saphenous vein was firstly introduced as a new and minimally invasive modality for the treatment of superficial venous insufficiency. This causes thermal damage while in direct contact with the vein wall. Initial studies in the 1990s mainly used the ClosurePlus (Covidien, Mansfield, MA, USA) continuous pullback catheter. This device has evolved and the newer version of the ClosureFast (Covidien) catheter has a longer heating element. This enables operators to heat the target vein segments at a reduced procedural time. Endovenous laser ablation (EVLA) was also approved by the Food and Drug Administration (FDA), three years later, in 2002. Now, these endothermal ablation procedures have caused a dramatic shift from the open, invasive procedure to a minimally invasive, simple procedure [2].

A prospective randomized trial by Lurie et al. [3,4] in 2003 randomized patients to either open stripping or RFA. The authors concluded that the RFA demonstrated statistically significant differences with regard to decreased pain and better global and physical scores in quality-of-life (QOL) measurements. Although some studies comparing RFA with EVLA showed similar results in terms of occlusion rate, clinical outcome, and quality of life improvement [5-8], several randomized controlled trials have shown that RFA resulted in better clinical outcomes. A prospective, single-blind study was conducted at five American sites and one European site and studied 87 veins in 69 patients who were randomized to RFA using ClosureFAST or EVLA using a 980-nm laser catheter [9]. It was concluded that RFA was significantly superior to EVLA with respect to recovery and QOL. Almeida et al. [9] reported results comparing RFA using ClosureFast and EVLA using 980-nm laser. The authors concluded that RFA was significantly superior to EVLA in terms of post-procedural recovery and QOL. According to a prospective double-blind randomized control trial of RFA using ClosureFast versus laser using 810-nm laser by Nordon et al. [7], RFA is associated with less periprocedural pain, analgesic requirement, and bruising. Randomized clinical trials comparing EVLA using 980-nm and 1,470-nm laser, RFA using ClosureFast, foam sclerotherapy, and surgical stripping for great saphenous varicose veins by Rasmussen et al. [8] showed the technical failure rate was highest after foam sclerotherapy, but both RFA and foam sclerotherapy were associated with a faster recovery and less postoperative pain than EVLA and stripping.

There is no well-established standardized protocol for the RFA procedure in spite of initial favorable results. Therefore, a consensus working group for RFA was established in 2014. Our working group had a meeting in Covidien Center of Innovation Korea (Osong) on September 21th, 2014. Their objective was to formulate a consensus statement for standard practice of RFA procedure in Korea. The working group had thorough, step-by-step discussions about the procedure details. At the end of the meeting, a consensus statement for standard protocol of RFA procedure in Korea was written.

INDICATION

The indication for RFA can be classified with respect to two aspects. The first aspect is the general indication related to the patients' symptoms and signs. This aspect might be the same with other treatment modalities such as the conventional open surgery and EVLA. The second aspect includes the anatomic or pathophysiologic indications concerning the RFA procedure using the ClosureFast catheter.

1) General

Many patients who seek treatment for varicose veins have cosmetic concerns. The symptomatic patients with varicose veins require treatment for relief of symptoms including aching, throbbing, a feeling of a heavy leg, fatigue, cramps, pruritus, restless leg, ankle swelling, and tenderness or pain along bulging varicose veins. It requires treatment in patients with various complications such as thrombophlebitis, bleeding from superficial varicose veins, or signs of more advanced forms of chronic venous insufficiency (CVI) such as edema and skin changes including lipodermatosclerosis, eczema, pigmentation, atrophie blanche, and healed or active ulceration [10].

2) Vein diameter

The ClosureFast catheter eliminates the need for continuous pull-back of the energy source, allowing for more controlled and repeatable RFA and consistent, reproducible delivery of energy. This catheter treats a 7-cm vein segment in 20-second energy cycle. The vein wall is heated conductively by a 7-cm coil at the distal end of the catheter. The outer diameter of the catheter is compatible with a 7 Fr introducer sheath. With the unique configuration, the venous diameter should be considered in terms of indication.

RFA of veins >12 mm in diameter has been a controversial subject since the ClosurePlus catheter was submitted for FDA approval. Veins >12 mm were excluded in the initial study. However, the 12-mm size limit was not used in the studies for the ClosureFast catheter approval. In the study from ClosureFast Europe Group, exclusion criteria did

not consider the venous diameter [11]. Calcagno et al. [12] evaluated the effect of saphenous vein diameter on closure rate with the ClosureFast catheter. Veins were divided into ≤12 mm diameter and >12 mm diameter. Six-month duplex scans showed 98% occlusion in veins ≤12 mm diameter and 100% occlusion in veins >12 mm diameter. The authors concluded a vein diameter >12 mm had no effect on closure rate with the ClosureFast catheter. According to the study by García-Madrid et al. [13], the maximal venous diameter for RFA was 19 mm. With the accurate infiltration of tumescent solution, the vein can be compressed. Therefore, the working group suggested the vein diameter for RFA should be from 2 mm to 20 mm.

3) Reflux time

Reflux can be demonstrated either using a Valsalva maneuver or by augmentation of flow by squeezing the calf. Valsalva is useful for proximal veins close to the abdomen. Further distally, manual compression is more useful as abdominal pressure on the vein may not be forcefully transmitted distally, especially if some intervening valves remain competent. Cuff inflator is a useful adjunct for a more consistent pressure.

International consensus documents recommended 0.5 seconds as a cutoff value for all refluxes in veins of the lower extremity [14-16]. This value is, however, longer, 1 second, for the femoral and popliteal veins [17]. Therefore, the working group recommended 0.5 seconds as a cutoff value of saphenous vein reflux which needs treatment.

Some patients may have no symptoms related to CVI but only cosmetic problems. Treatment can be done if the saphenous vein shows a reflux higher than thecutoff value of 0.5 seconds. The working group suggested that it is not an indication for treatment for patients who have varicosity without reflux (reflux time less than 0.5 seconds). For these patients, it is necessary to evaluate thoroughly other veins such as perforating veins, accessory saphenous veins, or pelvic-originated veins, among others.

4) Shallow saphenous vein

Shallow location of the saphenous vein from the skin can be a risk of skin burn and phlebitis. However, skin burn as a complication after endovenous treatment was rarely reported [18]. It is suggested that the low incidence of skin burn was attributed to the appropriate use of tumescent solution. The appropriate techniques according to instruction for use (IFU) of the ClosureFast catheter are to be followed. When the vein to be treated is located near the skin surface, a subcutaneous distance of greater than or equal to 1 cm between the anterior vein wall and skin should be created by tumescent infiltration of saline or dilute anesthetic solution.

When the saphenous vein to be treated is located near the skin surface, formation of cord-like mass or pigmentation on the skin after ablation is another complication [19]. The working group recommends that RFA should be performed when a subcutaneous distance between the anterior vein wall and skin is greater than or equal to 0.5 cm or when the saphenous vein is located below the superficial fascia.

5) Secondary varicose vein due to chronic deep vein thrombosis

Varicose veins in patients with deep vein thrombosis was a contraindication for RFA in many studies [7,8,20]. However, the symptomatic patient with secondary varicose veins due to chronic deep vein thrombosis can be treated with RFA if the deep venous flow is maintained with partially recanalized deep vein or collateral channels.

6) Patients with anticoagulation

When the varicose vein surgery is performed in patients who are taking anticoagulants such as warfarin, it is a common practice to discontinue therapy at least 3 days (with or without heparin covering) prior to operation. Unlike conventional surgery, RFA ablates the target incompetent saphenous vein without the need for surgical incisions. Another concern of anticoagulation for patients who perform RFA is the risk of non-occlusion of the saphenous vein after the procedure. Sharifi et al. [21] compared 88 limbs of patients on warfarin who underwent endovenous thermal ablation for great saphenous vein (GSV) reflux disease with 92 limbs in patients receiving no anticoagulation or antiplatelet agents. The authors concluded that no differences were found in periprocedural risk of major bleeding or closure rate of the treated venous segments. Gabriel et al. [22] reported 45 patients receiving long-term anticoagulation therapy who underwent 71 endovenous ablation procedures. They concluded that patients with severe CVI who were receiving long-term warfarin therapy could be treated safely and effectively with RFA for incompetent GSV, small saphenous vein (SSV), and perforator veins. The working group suggests that symptomatic patients with anticoagulation therapy can be safely treated with RFA.

HOW TO ACCESS

1) Access site

The decision about the access site is important to reduce the heat-related complications such as skin burn, nerve damage and to increase the success of puncture. It is generally accepted that puncture at or above the knee joint should be done for the ablation of GSV. It is related with the anatomic characteristic of the saphenous nerve which accompanies the GSV. Holme et al. [23] demonstrated the anatomic relationship between the GSV and saphenous nerve with cadaveric dissection. According to this report, there is a close relationship between two structures from immediately below the knee to the ankle. For ablation of SSV, it is recommended to puncture at the level of the mid-calf or above this level. This is also related to the anatomic course of the SSV and sural nerve. The SSV mainly runs a course between the superficial (saphenous) and the deep crural (muscular) fascia of the lower leg [24]. At the ankle, the origin of the SSV is often plexiform, located deep below the fascia, and the sural nerve at this level is really stuck to the vein [25]. The proximal part of the sural nerve, however, courses under the deep fascia; therefore, it could well function as a natural barrier to prevent the sural nerve from the excessive heat during RFA. The deep fascia could also prove to be a good barrier between the nerve and vein during the injection of tumescent anesthesia [26].

2) Minimum diameter for access

This issue is directly related to the indication for RFA in terms of diameter criteria. Therefore, the working group suggested 2 mm of saphenous vein as the minimum diameter for access.

3) Fixation of the introducer sheath

During the pull-back of the ClosureFast catheter, the introducer sheath is the guide for pull-back length. It may be possible to move the position of the introducer sheath during the pull-back of the catheter. It is useful to fix the introducer sheath at the skin, using adhesives such as Steri-strips.

4) Failed access

Limitations with saphenous vein access during RFA have been reported [27]. The possible causes of access failure are a small diameter of the saphenous vein or vasospasm. Although uncommon, this may result in a delay in treatment or venous cut-down. Small vessel diameter and vasospasm can be overcome by a more proximal puncture and open access.

CATHETER PLACEMENT

1) Strategies for the difficult advancement

There are 4 stages with difficulty in performing endovenous treatment for varicose veins: cannulation of a vein, advancement of the working part to the saphenofemoral or saphenopopliteal junction, visualization of the tip of the working part at the saphenofemoral or saphenopopliteal junction, and difficulty in performing the ablation and delivering the planned linear energy density. Although the delivery of a working part to the junction was the least problematic [28], it is important to have strategies for overcoming this complexity. The strategy for overcoming a difficult advancement includes guiding the catheter with manual external compression, extending or bending the knee joint, advancing a guidewire though the tortuous segment under ultrasound guidance and then advancing a catheter over the wire, and the double puncture above the tortuous segment with excision of tortuous segments.

2) Position of the catheter tip

In experimental tests, forward heating beyond the catheter tip occurs due to ejection of luminal fluid from the catheter lumen upon heating. Vein occlusion up to 1.75 cm has been observed. Manufacturer's IFU does emphasize the verification of the catheter tip location using ultrasound. When treating the GSV, the catheter tip should be placed 2.0 cm inferior to the saphenofermoral junction. For SSV ablation, 2.0 cm inferior to the saphenopopliteal junction is the optimal point for the catheter tip. The position change of patients and infiltration of tumescent solution may result in the position change of the catheter. Therefore, the working group recommends that the catheter tip should be rechecked using ultrasound whenever the patient's position is changed or after infiltration of tumescent solution.

3) Treatment of endovenous heat-induced thrombosis

Endovenous heat-induced thrombosis (EHIT) is thrombus extending from the superficial venous system into the deep venous system at, or proximal to, a site of recent thermoablation; most commonly thrombus extending from the GSV into the common femoral vein [29]. A classification system based on the level of EHIT in relation to the saphenopopliteal junction is reported [30]. Clinical course of EHIT is benign, usually resolving within 2 to 4 weeks in

most patients [31]. Until now, there was no consensus for the proper treatment of EHIT. However, in most centers, patients with EHIT involving more than 50% of the deep vein diameter were managed with low-molecular weight heparin (LMWH). The LMWH was discontinued when the thrombus had retracted to the superficial vein. No further anticoagulation was recommended after retraction was confirmed sonographically [30].

INFILTRATION OF TUMESCENT SOLUTION

Infiltration of tumescent solution allows the vein to be displaced further from the underlying skin. This solution provides a fluid bath "heat sink" to displace heat radiating up to 1.5 mm beyond the vein wall. This results in decreased skin burns and sensory nerve injury rates [32].

1) Composition of solution

There are several reports about the composition of the tumescent solution. Manufacturer's IFU suggested using a tumescent solution of dilute local anesthetic or saline injected into the perivascular space to create a fluid layer around the vessel to be treated. The working group recommends the composition of the solution as 2% lidocaine 20 mL+500 mL normal saline+sodium bicarbonate 2.5 mL with/without epinephrine. Although this composition is appropriate, other compositions may be used, depending on the institute's protocol.

2) Infiltration of solution

The topical application of lidocaine cream on the infiltration site can reduce the pain. When the tumescent solution is infiltrated properly into the saphenous compartment between the superficial and deep fascia, the temperature around the catheter should be decreased. Therefore, the working group recommends that the temperature on the generator should be elucidated just after infiltration of solution.

The direction of infiltration is another issue. Mostly, infiltrations may be performed from distal to proximal direction. It results in the effect of emptying the blood within the saphenous vein. Another direction, from proximal to distal, also has a role. After infiltration of tumescent solution at the proximal segment, the pain may be relieved at the time of distal infiltration due to proximal anesthetic effects. The working group recommends going with the physician's preference for the direction of infiltration.

ABLATION

Ablation can be started by pressing the "RF power" button on the generator to begin RF energy delivery. This will cause the RF power button to start blinking. If the button does not light or start blinking, observe any displayed message and respond. RF energy can be delivered by pressing the button on the catheter handle or by pressing the "Start RF" button below the screen on the RF generator. Some authors suggest that 2 cycles of RFA treatment in all segments of the GSV achieve quicker and greater vein shrinkage of the medium diameter without an increase in side effects [13]. Manufacturer's IFU suggests 2 cycles of ablation to the segment closest to the saphenofermoral junction. Therefore, the working group recommends 2 cycles of ablation for the first segment of saphenous vein and the segment where the incompetent perforators are located. The other segments should be ablated once.

During RF energy delivery, it is recommended that a near bloodless field is created by applying external compression along the full length of the heating element using the ultrasound transducer, longitudinally aligned with the heating element, or external manual compression. Some friction between the vein wall and catheter after a heating cycle is normal and may be noticed while withdrawing the catheter. If withdrawing the catheter is difficult, it may be overcome by rolling the catheter back and forth and slowly withdrawing. It is prohibited to re-advance the catheter through an acutely treated vein segment. Although the introducer sheath is inserted below the knee joint or mid-calf level, ablation should be stopped at the level of the knee joint for GSV and above the mid-calf level for SSV.

CONCOMITANT PROCEDURE

1) Phlebectomy or sclerotherapy

RFA of varicose veins may be performed simultaneously with ambulatory phlebectomy of tributaries or as a delayed stand-alone procedure. Many practitioners routinely perform ambulatory phlebectomy or sclerotherapy, or both of tributaries in conjunction with endovenous ablation [33,34]. Some authors insist that many branch varicosities diminish in size or resolve completely once the saphenous reflux has been eliminated by endovenous ablation [35,36]. However, recent trials demonstrated that concomitant phlebectomy along with saphenous ablation reduced the need for secondary procedures and significantly improved clinical outcome as well as early quality of life improvements [37,38]. Harlander-Locke et al. [39] suggested that the

great majority of patients with refluxing tributary veins greater than 3 mm in diameter required phlebectomy in addition to saphenous ablation. These patients may benefit from concomitant phlebectomy along with endovenous saphenous closure. The working group recommends simultaneously carrying out ambulatory phlebectomy with RFA. For sclerotherapy, it is recommended to defer at least 2-4 weeks. For delayed stand-alone procedures, some authors recommend 6 months-waiting periods following endovenous procedures [35,36].

POST-PROCEDURAL MANAGEMENT

1) Compression

Currently, there is little knowledge on the optimal duration of compression stocking use after endovenous ablation of varicose veins in terms of efficacy and patient satisfaction. One study prospectively evaluated the effect of eccentric compression applied by a crossed-tape technique on procedure-related pain occurrence after endovenous ablation of the GSV. It showed that the intensity of postoperative pain was significantly reduced in the eccentric compression group compared with the non-compression group [40]. Bakker et al. [41] reported the effect of a compression stocking with a prospective randomized control trial. This study demonstrated that pain was significantly reduced during the first week in the group of patients wearing the stockings for 7 days when compared with 2-day use. Also, physical function and vitality were better in the group of patients with a 7-day use of stockings. According to the guidelines of the Society for Vascular Surgery and the American Venous Forum, post-procedural compression is recommended for at least 7 days [10]. National Institute for Health and Care Excellence guidelines recommended compression for at least 7 days after ablation [42]. The working group recommends that compression stocking should be maintained for at least 7 days after RFA.

2) Ambulation

Post-procedural ambulation is encouraged to reduce the thrombotic complications in most centers. The working group recommends frequent ambulation after RFA.

3) Daily activity

Currently, there is little information on the limitation of daily activities after RFA. The working group suggests the daily activities after RFA as following. Try to elevate the legs when the patients are sitting or sleeping for the first 24 hours after the procedure. Carry on all daily activities including aerobic, jogging, cyclingetc. Take a shower 24 hours after procedure with water-proof adhesives. No baths, swimming, or soaking in water for 2 weeks to prevent infection. Avoid core/abdominal exercise or strenuous activities for 2 weeks.

CONCLUSION

Although RFA might be a simple procedure, the best results can be achieved with a standardized, algorithmic approach. This consensus is expected to help operators to support and provide stepwise concrete information when performing RFA procedures.

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