

Title: **EVRF** —fCare Systems® a new radiofrequency method applicable to venous pathologies.

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ABSTRACT

The novelty of the EVRF-f Care Systems® consists in having a single work station for the administration, on an outpatient basis, of a whole range of treatments for the diverse clinical manifestations of Chronic Venous Disease (CVD) of the lower limbs. This device, thanks to a radiofrequency (RF) generator connected to various "kits" helps treat the saphenous trunks, the collateral veins and the perforator veins endovenously, and the telangiectasias transcutaneously.

The CR45i catheter is used for the thermal ablation of the saphenous trunks with the Seldinger technique. The procedure is quite easy, can be carried out with only tumescent anaesthesia and sedation; post-operative pain is, in our limited experience, practically absent.

The CR12i and CR30i hand pieces emit RF through a 10 cm long fibre, whose active distal segment is 1 cm long; the fibre comes out of one hand piece, is introduced in the vein through a cannula with a 24 or 21 gauge. The sets can be used for vessels with diameters between 1 and 5 mm. The procedure requires tumescent anaesthesia and can be considered an alternative to multiple phlebectomies and sclerotherapy.

The percutaneous treatment of telangiectasias is, in our opinion, a valid and handy alternative to laser therapy. It is independent from the patient's skin phototype and has practically no complications. RF are emitted by needles with a variable gauge between 0.075 and 0.15 mm, in a power range of between 5 and 16 Watt, according to the diameter of the small vessel to be treated (from 0.3 to 1 mm). The heightened efficiency of this treatment is obtained by coupling this method with sclerotherapy.

Our experience is at the beginning and our opinion to date is based on a limited number of cases. It should be noted that there is no reference bibliography. Our opinion, however, is quite positive and we intend therefore to increase the case studies and to ask for a critical follow-up review of the results to date.

KEY WORDS Radiofrequency, thermal ablation, varicose veins of the lower limbs

INTRODUCTION

In the last fifteen years, radiofrequency (RF) thermal ablation of the saphenous trunks has become increasingly popular and has developed as a valid alternative to stripping (1,2), as have endovenous laser treatment and ultrasound guided foam sclerotherapy.

The recent North American SVS and AVS guidelines, partially implemented by the Italian College of Phlebology in 2013, consider laser or Rf thermal ablation treatments the gold standard in the treatment of the great and small saphenous veins reflux, or at least they consider these therapies at least as effective as traditional surgery (3,4).

After checking, in clinical practice, the safety, manageability and results in the obliteration of the main venous trunks, the same technologies have been applied, adjusting the relevant devices, to the treatment of collateral veins varicosity and perforator veins insufficiency. A further indication for laser therapy in Chronic Venous Disease (CVD) predates this method and consisted in the transcutaneous treatment of telangiectasias: the FDA has authorised the use of RF in that field in 2009.

The rationale at the basis of the use of thermal ablation procedures is the goal to minimise the invasiveness of the treatment of varicose syndromes and to administer it exclusively on an outpatient basis. This is the framework in which we decided to use the EVRF-fCare Systems® device, approved by the FDA in 2013, which, with a single RF generator makes it possible to carry out a wide range of treatments of the various types of CVDs, from telangiectasias and reticular veins, to perforator and collateral veins insufficiency, to saphenous trunk reflux.

MATERIALS AND METHODS

In this study we used EVRF f-Care Systems® since October 2012: the device comprises a RF (total) generator with which, through the use of specific "kits", it is possible to treat the saphenous trunks, the collateral veins and the perforator veins endovenously, and the telangiectasias transcutaneously.

The RF emission parameters for the different types of treatment are programmed straight in the touch-screen display on the console (picture 2).

The CR45i catheter, used with the Seldinger technique (with a 6F introducer needle) is used for the thermal ablation of the saphenous trunks (with a diameter of between 6 and 18 mm); the RFs are emitted radially from the distal end of the probe (the active radiating segment has a length of 0.5 cm) usually, the power used varies from 16 to 25 Watt. The procedure usually lasts 5-6 minutes. The procedure is quite easy, and be carried out with only tumescent anaesthesia and sedation; post-operative pain is, in our limited experience, practically absent.

The CR12i and CR30i hand pieces emit RF through a 10 cm long fibre, whose active distal segment is 1 cm long; the fibre comes out of one hand piece, is introduced in the vein through a cannula with a 24

or 21 gauge. The sets can be used for vessels with diameters between 1 and 5 mm. The procedure requires tumescent anaesthesia and can be considered an alternative to multiple phlebectomies and sclerotherapy in an outpatient setting.

The percutaneous treatment of telangiectasias is the heir of the Veinwave® method, which has long been used not only for the treatment of lower limb lesions, but also for couperose. RFs are emitted by needles with a variable gauge between 0.075 and 0.15 mm (a 30 G needle has a 0.3 mm gauge), in a power range of between 5 and 16 Watt, according to the diameter of the small vessel to be treated (from 0.3 to 1 mm). Needles are mounted on a hand piece that is connected to the generator, and release a very high frequency wave (4 million Hertz), which, in turn, generates a progressive thermal lesion of the microvaricosity, with its consequent sclerosis and disappearance. This method has always been associated with sclerotherapy in this study.

RESULTS

We treated 4 patients with great saphenous vein reflux at thigh level. In all 4 cases we obtained the immediate and complete obliteration of the saphenous trunk (A-P diameter at thigh level in supine position varied between 0.6 and 0.8 cm). The procedure was carried out in the operating theatre with tumescent anaesthesia and sedation. We used various power levels, from 20 to 25 W; the duration of the treatment varied between 5 and 9 minutes. The post-operative progress was regular in all cases, with no pain at all. After more than 1 year from the procedure, no recanalization could be found.

The CR12i and CR30i hand pieces have been used on 15 patients for the treatment of varicose collateral veins with a diameter ranging from 1 to 5 mm. It is necessary to administer tumescent anaesthesia along the vessel (with a 0.9% NaCl saline solution, administered cold at -4°C, with 0.2% lidocaine). The procedure was carried out in the outpatient department; the same device can be used on the same patient on multiple vessels. In all cases the result was the obliteration of the treated segment, using emission power that varied from 6 to 12 Watt. Only one complication arose, in the form of a small 3 mm scar in a female patient for whom the tumescence had been insufficient.

The treatment of telangiectasias, administered here to around fifty patients in association with sclerotherapy, is relatively simple but requires precision and a rigorous procedure. We recorded the following advantages: immediate disappearance of microvaricosities, no allergic manifestations, no lasting pigmentation, no necrosis, applicability to all skin types and colours. The pain caused by the procedure was usually well tolerated, and disappeared completely at the end of the application. There are very few contraindications presence of a pacemaker, allergy to nickel (in this case, a gold needle is used), skin infections.

DISCUSSION

The novelty in the EVRF-fCare Systems® method does not consist in the use of RFs for the therapy of varicosity, which is really quite common and with substantiated effectiveness in phlebological practice, but rather in having a single work station, small and easily moved, for the administration, on an outpatient basis, of a whole range of treatments for the diverse clinical manifestations of CVD.

The endovascular treatment of the saphenous trunks seems to us to be effective, well tolerated and safe, even in comparison with the gold standard represented by the VNUS Closure Fast® (5) method. Endovenous obliteration has a duration of a few minutes, and is easily controlled by ultrasound guidance. Patients report the absence of significant pain afterwards.

Endovenous obliteration of varicose collateral veins can be an alternative to sclerotherapy and phlebectomy. In comparison to sclerotherapy, it does not trigger allergic reactions, nor does it cause residual hyperchromia; however, it is more expensive and requires tumescent anaesthesia. As against multiple phlebectomies according to Müller's technique, it can be advantageous in vessels with a substantially straight course.

The treatment of lower limb telangiectasias is an area of overlapping in which phlebologists, dermatologists and aesthetic medicine practitioners all operate with various degrees of success. Sclerotherapy is the more popular treatment and the benchmark against which other therapies need to be compared.

The need to offer alternative therapies derives from the fact that, in a fair percentage of cases (about 20-30%) sclerotherapy does not achieve the desired results and is not free from adverse reactions (6).

Scholars have been trying for decades to find alternatives to injective pharmacological procedures. Microelectrosclerotherapy, laser treatments and pulsed light treatments are all attempts at eliminating telangiectasias (7) by physical means (substantially, through heat damage). RFs, too, have been used in this sense since 1998 in this field. The first RF device to be used in clinical practice was the Veinwave™, followed by the Thermavein, both used for the treatment of face and lower limb telangiectasias. The EVRF-fCare Systems® device follows in their wake.

This device is easy to use and offers the following advantages over sclerotherapy: immediate disappearance of microvaricosities, absence of ecchymoses, allergic reactions only in exceptional cases, absence of long-lasting residual pigmentation, absence of necrosis; moreover, it can be used on all skin types and colours. The pain of the procedure is usually well tolerated and disappears completely after the RF session is concluded. No medication or elastic compression are necessary; the treatment can be carried out also in hot weather. There are very few adverse effects; rushes, rarely, or, even more rarely, hyperpigmentation.

It should be underscored, however, that, in order to optimize results, the percutaneous treatment

with RF should be used in addition to traditional sclerotherapy. The percentage of failed treatments is still difficult to assess; actually, we used RFs mainly on telangiectasias whose calibre made them ineligible for sclerotherapy, and so any comparison is problematic.

CONCLUSIONS

EVRF-fCare Systems® is an interesting method, that makes it possible to administer a wide range of treatments for lower limb varicose veins; it is relatively easy to use and safe; its effectiveness is not absolute, and still needs to be demonstrated in full; results, of course, depend on the skill and clinical know-how of the operator; it is an ideal addition to sclerotherapy of telangiectasias and, in some cases, a valid substitute thereof.

Our experience is at the beginning and our opinion to date is based on opinions and suggestions, rather than a large case history and bibliographic data.

Our opinion, however, is quite positive and we intend therefore to increase the case studies and to ask for a critical follow-up review of the results to date.

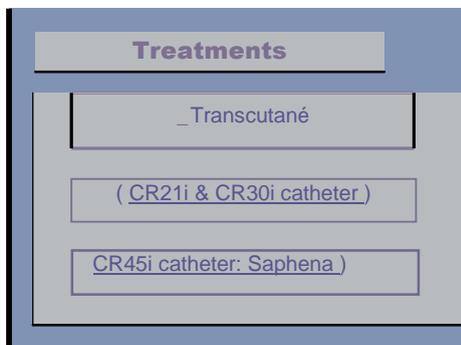
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(Foto 1: operating system EVRF (EndoVenousRadioFrequency)- fCareSystems®)



(Foto 2:image of the console display with the visualization of the three treatment options.