

Endovenous ablation of incompetent perforating veins using the F Care Systems EVRF device and the CR30i catheter

**A minimal invasive way with an excellent cosmetic and functional
result**

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Abstract

Endovenous ablation using an F Care Systems EVRF device is an image-guided procedure that uses heat generated by radiofrequency to seal veins in case of venous reflux. Between June 2014 and February 2015, 20 cases of perforator incompetence were treated in a single centre. The CR30i catheter is connected to the EVRF device (both F Care Systems, Antwerp, Belgium). This catheter has a stainless steel tip of 1 cm length. Patients reported very low pain levels and only small local hematomas were noted at clinical evaluation the first week. No case of neuralgia was reported. A 100% occlusion rate is a very promising result and comparable to or even better than other techniques. The significant diameter reduction after only one month makes it an even better technique compared to others as found in literature

Introduction

Whether incompetent perforator veins require treatment is controversial. Duplex Ultrasound will find a large number of patients with varicose veins and often skin damage who have incompetent perforating veins as the only cause – showing that incompetent perforating veins are a problem in their own right. In addition, research has shown that there is a clear association between the presence of insufficient perforators and recurrent varicose veins.[1]

Ligation of an insufficient perforating vein is widely known and accepted as an isolated procedure or additional to an ablation or stripping of a great saphenous vein. In 1985, G. Hauer described the SEPS technique (sub fascial endoscopic perforating vein surgery) allowing perforators to be clipped through one small incision with the use of a laparoscope [2]

SEPS was superseded by a percutaneous endovenous procedure in 2001, called Transluminal Occlusion of Perforators (TRLOP) shown to be as effective as SEPS in a 5 year study.[3,4] As TRLOP can be performed under local anaesthesia and under ultrasound guidance,[5] the advantages over the more invasive and painful SEPS were clear.

Endovenous ablation using an F Care Systems EVRF device is an image-guided procedure that uses heat generated by radiofrequency to seal veins in case of venous reflux. A monopolar 4MHz generator (EVRF) conducts electrical current into radiofrequency waves. These waves cause friction between the molecules, creating heat and leading to cell fibrosis. An electrosurgical path creates a closed circuit between the patient and the generator, allowing for an optimal return of energy and a higher concentration of energy in the active part of the catheter. The energy itself spreads 3mm around the stainless steel tip of the catheter. This retrospective study aims to evaluate the clinical results of the use of radiofrequency-generated thermal energy. Primary outcome was the occlusion rates at 1 month and 6 months postoperatively.

Materials and methods

Population description

Between June 2014 and February 2015, 20 cases of perforator incompetence were treated in a single centre. The diagnosis of insufficiency was made using ultrasound in all patients. Patients who met the inclusion criteria had venous insufficiency with aesthetic or functional inconvenience. The ultrasound criteria to determine reflux were the presence of flow reversal for >0.5 to 1 second with proximal compression, the Valsalva manoeuvre or distal compression and release and a diameter of 0.4mm. Reasons for exclusion were deep venous insufficiency, hyper coagulopathy, previous venous surgery and the presence of major comorbidity (coronary artery disease, congestive heart failure, poor general health). Pregnant patients and patients younger than 18 years were also excluded.

Treatment technique

Prior to surgery, detailed duplex ultrasound mapping of the superficial and perforator system was performed including measurement of the diameter ([table 1](#)). Access to the perforator was obtained by puncture under ultrasound guidance followed by placement of a 20 Gauge needle (O.D. 1.1mm – L 32mm). The radiofrequency electrode was positioned just at the level of the fascia, again under ultrasound guidance. A small amount (3-5 cc) of tumescent anaesthetic fluid (20 ml Lidocaine 1 % diluted with 500ml NaCl 0.9 %) was injected around the perforator under ultrasound control. All patients were treated with single local tumescent anesthesia.

The CR30i catheter is connected to the EVRF device (both F Care Systems, Antwerp, Belgium). This catheter has a stainless steel tip of 1 cm length. The total length of the catheter is 27cm, with a 0,75mm diameter and a PTFE coating. An energy level of 16 Watt is reached instantly (0.01 sec). The pullback speed of the catheters has an average of 150Joule/6sec/1cm. The starting point is at the level of the fascia until the venous puncture site.

All patients were treated in an outpatient setting. Class 2 compression stockings were applied for one week, day and night. A prescription for paracetamol 1 g was given on discharge with the instructions to take it only in case of pain and with a maximum of 4 daily. All patients received DVT prophylaxis in the form of low molecular weight heparin (enoxaparin 40mg) for 10 days.

Clinical follow-up appointments were scheduled at 1 week, 1 month and 6 months postoperatively. Occlusion rate was determined at 1 week, 1 month and 6 months using the GELEV score (fig. 1).

FIGURE 1

Lev 0: no occlusion, refluxing vein, unchanged vein

Lev 1a: partial occlusion with proximal reflux

Lev 1b: partial occlusion without reflux

Lev 2a: complete occlusion with unchanged or larger diameter

Lev 2b: complete occlusion with diameter reduction >30%

Lev 3: complete occlusion with diameter reduction >50%

Lev 4: fibrotic cord, vein not visible

Results

20 incompetent perforating veins were treated. The mean age was 50 with a clear female predominance 19 versus 1. Patient characteristics in terms of CEAP classification are shown in Table 2. The occlusion rates are summarized in Table 3. Patients reported very low pain levels and only small local hematomas were noted at clinical evaluation the first week. No case of neuralgia was reported.

Discussion

Dissection of incompetent perforator veins even when using the sub fascial endoscopic perforator surgery technique is associated with substantial side effects. The objective of our study was to evaluate the feasibility of endovenous ablation using EVRF. All incompetent perforator veins were occluded, with a significant diameter reduction as early as after 1 month. Side effects were very moderate.

A 100% occlusion rate is a very promising result and comparable to or even better than other techniques (6,7,8,9). The significant diameter reduction after only one month makes it an even better technique compared to others as found in literature (6,7,8,9).

We never use sclerotherapy for incompetent perforating veins, as we are concerned about the risk of reflux of the solution into the deep system and development of deep vein thrombosis. Compared to sclerotherapy, endovenous ablation has a more predictable outcome with a lower risk.

One important principle in this study is the selection of patients. This is critical to maximize the effect of perforant ablation. In case of varicosities, superficial venous insufficiency must be excluded. In case of oedema, other lymphovascular pathology must be investigated with a CT scan of the abdomen and scintigraphy of the lymphatic system. Patients with non-healing venous ulcers or impending venous ulcers must be in excellent compliance with compression therapy and wound care in order to benefit from this treatment. Overall, patients with varicose veins and/or skin damage due to incompetent perforating veins as the only cause are most likely to benefit from endovenous ablation of incompetent perforators.

This procedure is technically challenging; however, the CR30i catheter, (F Care Systems, Antwerp, Belgium) has a very flexible tip and no stiff stylet as compared to other currently available devices. The catheter itself is very easy to push and has excellent visibility of its tip, allowing accurate placement at the level of the fascia.

Conclusion

After 6 months of follow-up we noticed no ulcer recurrence, no impending ulceration or progression of lipodermatosclerosis, while oedema decreased. EVRF can be considered a safe technique that is very well tolerated by patients. An occlusion rate of 100% and no occurrence of deep vein thrombosis are very promising results.

References

1. Rutherford EE, Kianifard B, Cook SJ, Holdstock JM, Whiteley MS (May 2001). "Incompetent perforating veins are associated with recurrent varicose veins". *EJVS* **21** (5): 458–60.
2. Endoscopic sub fascial discussion of perforating veins--[preliminary report]. *VASA* (in German) **14** (1): 59–61.
3. Kianifard B, Browning L, Holdstock J M, Whiteley MS. "Surgical technique and preliminary results of perforator vein closure - TRLOPS (Transluminal Occlusion of perforators)". in "Vascular surgical society of Great Britain and Ireland abstracts". *BJS* 89 (4): 507–26. April 2002.
4. Bacon JL, Dinneen AJ, Marsh P, Holdstock JM, Price BA, Whiteley MS (April 2009). "Five-year results of incompetent perforator vein closure using TRans-Luminal Occlusion of Perforator". *Phlebology* 24 (2): 74–8.
5. The College of Phlebology (December 14, 2012). "TRLOP closure of incompetent perforating vein (IPV)". The College of Phlebology. Retrieved August 25, 2014.
6. Proebstle TM1, Herdemann S. Early results and feasibility of incompetent perforator vein ablation by endovenous laser treatment. *Dermatol Surg.* 2007 Feb;33(2):162-8.
7. Seren M1, Dumantepe M2, Fazliogullari O2, Kucukaksu S2. Combined treatment with endovenous laser ablation and compression therapy of incompetent perforating veins for treatment of recalcitrant venous ulcers. *Phlebology.* 2015 Jun 30
8. Boersma D, Smulders DL, Bakker OJ, van den Haak RF, Verhoeven BA, Koning OH. Endovenous laser ablation of insufficient perforating veins: Energy is key to success; *Vascular.* 2015 May 12
9. Lawrence P, Alktaifi A, Rigberg D, DeRubertis B, Gelabert H, Jimenez J, Endovenous ablation of incompetent perforating veins is effective treatment for recalcitrant venous ulcers *Journal of Vascular Surgery* 54, 3, Sept 2011, 737–742

TABLE 1

Perforator	Number	main diameter (mm)	Range
Dodd	1	5.2	5.2
Cockett 1	2	4.05	4-4.1
Cockett 2	8	4.3	4-5
Cockett 3	2	4.8	4.4-5.2
paratibial	7	5.28	4-6.2

TABLE 2

CEAP	N	%
C0	0	
C1	0	
C2	4	20
C3	6	30
C4	6	30
C5	4	20
C6	0	

TABLE 3

	1 month	6 months
Level 2b	0	0
Level 3	20 (100%)	1 (5%)
Level 4	0	19 (95%)

