Endovenous saphenous ablation using F Care Systems radiofrequency device (EVRF) and CR45i catheter

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Introduction

Endovenous ablation using an F-care EVRF device is an image-guided procedure that uses heat generated by radiofrequency to seal off the great saphenous vein 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 outcomes were the amount of analgesics required, postoperative pain, the appearance of postoperative ecchymosis, patient satisfaction rate and postoperative quality-of-life score. Secondary outcomes were the occlusion rates at 1 month and 6 months postoperatively.

Materials and methods

Population description

Between June 2014 and February 2015, 50 cases of unilateral great saphenous vein (GSV) incompetence were treated in a single centre. The diagnosis of venous insufficiency was made using ultrasound in all patients. The clinical evaluation was made using the level II basic CEAP classification (Table 1) (1). We used the Chronic Venous Insufficiency Questionnaire -2 (CIVIQ-2) as a quality-of-life measuring tool (2). Patients who met the inclusion criteria had venous insufficiency with aesthetic or functional inconvenience. The ultrasound criteria to determine reflux was the presence of flow reversal for >0.5 to 1 second with proximal compression, the Valsalva manoeuvre or distal compression and release. Reasons for exclusion were deep venous insufficiency, venous diameter exceeding 15mm, hypercoagulopathy, 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.

TABLE 1

CEAP classification	Clinical description
C0	No visible or palpable signs of venous disease
C1	Telangiectasias or reticular veins
C2	Varicose veins; distinguished from reticular veins by a diameter of 3 mm or more
C3	Edema
C4	Changes in skin and subcutaneous tissue secondary to CVD, divided into 2 subclasses to better define the differing severity of venous disease: C4a: pigmentation or eczema C4b: lipodermatosclerosis or atrophie blanche
C5	Healed venous ulcer
C6	Active venous ulcer

Treatment technique

Prior to surgery, detailed duplex ultrasound mapping of the superficial and perforator system was performed including measurement of the diameter of the incompetent saphenous vein at two reference points (2 cm distal to the saphenofemoral junction (SFJ) and at the knee). From these measurements, we calculated the average diameter of the vein. The incompetent tributaries and perforating veins were marked on the skin.

Access to the GSV was obtained by puncture under ultrasound guidance at the most distal reflux site followed by placement of a 6F sheath. The radiofrequency electrode was positioned 2 cm distally to the SFJ, again under ultrasound guidance. An abundant quantity (approximately 500cc) of tumescent anaesthetic fluid (20 ml Lidocaine 1% diluted with 5000ml NaCl 0.9%) was injected around the GSV under ultrasound control. Two patients were treated with single local tumescent anaesthesia. The remaining patients received additional general anaesthesia.

The CR45i catheter (6F) is connected to the EVRF device (both F-care, Antwerp, Belgium). This catheter has a stainless steel tip of 0.5cm length. The total length of the catheter is 120cm, with a 2mm diameter and a PTFE coating. An energy level of 25 Watt is reached instantly (0.01 sec). The pullback speed of the catheters has an average of 150Joule/6sec/0.5cm. The starting point of ablation is 2cm below the SFJ until 2.5 cm above the puncture site (distance between distal marking of the catheter and the catheter tip). GSV ablations were accompanied by a Muller phlebectomy if necessary.

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. The visual analogue pain score was completed at 1 week, 1 month and 6 months, and the satisfaction score and QoI score at 1 month and 6 months. The ecchymosis was measured in square centimetres

at 1 week and 1 month. 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

50 incompetent GSVs were treated. The mean age was 51 years (table 2). Female predominance was 72%.

Patient characteristics in terms of CEAP classification are shown in Table 3. The average energy used was 165j/cm (range 980j-8625j; 98j/cm-191j/cm).

Postoperative ecchymosis was mainly due to vein wall perforation. As no preoperative compression was needed with this system, we only encountered 31 cases of ecchymosis (average square centimetres/mean length of vein: 11.48cm²/24.06cm).

17 patients needed analgesics with an average of 5.79 (number of tablets/n patients) for a period of 2.89 days.

The pain score was evaluated at 1 week (<1), 1 month (<1) and 6 months (0).

PAIN SCORE		
Week	Month	6 Months
0.68	0.32	0

Qol and satisfaction rate revealed an excellent result of 9.36 at 6 months.

The occlusion rates are summarized in Table 5.

TABLE 2

	Mean	Range
Age	51	29-81
BMI	24.3	16-31

TABLE 3

CEAP	N
C0	
C1	6 (12%)
C2	17 (34%)
C3	15 (30%)
C4	8 (16%)
C5	1 (2%)
C6	3 (6%)

TABLE 4

Mean diameter proximal	Range	Mean diameter distal	Range	Average diameter	Mean Length of vein	Range
6.47	4-9	5.73	5-10	6.082	34.24	10-50

TABLE 5

	1 month	6 months
Level 0		
Level 1a		
Level 1b	2 (4%)	1 (2%)
Level 2a	17 (34%)	1 (2%)
Level 2b	22 (44%)	10 (20%)
Level 3	8 (16%)	23 (46%)
Level 4	1 (2%)	5 (10%)

Discussion

This study was designed to assess the clinical efficacy and verify the safety of the procedure of EVRF. The technical aim is endothelial destruction due to heating of the vein wall. The vein contracts and fibrotic sealing of the vessel occurs. Great saphenous veins from 3 to 12mm can be treated. Even slight tortuosity is acceptable, as the catheter is very flexible and ends in a shapeable tip. To interpret the occlusion rates we used the GELEV score. No partial occlusion with reflux was reported. 2 cases of partial occlusion without reflux at 1 month, evolving to only 1 case at 6 months. Particular attention was paid to complete occlusions, where diameter reduction as marked shrinkage due to fibrotic organization can guarantee good long term results. At 1 months there were already 31 out of 50 cases with shrinkage, and 96% at 6 months. In terms of occlusion rates with and without diameter

reduction, we obtained technical success of 96% at 1 month and 98% at 6 months postoperatively. In the least case we did not find any proximal recanalization.

Other clinical outcomes were evaluated, such as relief of presenting symptoms and improvement of quality of life, ulcer healing and improvement in cosmesis. All 3 ulcers healed uneventfully within 3 weeks. We obtained a very high satisfaction score mainly due to the combination of symptomatic relief, very low pain and a good cosmetic result. The treatment led to marked reduction of varicose veins, leaving no discoloration or skin burn. No cases of paresthesia or periphlebitis were reported.

In terms of early and late complications we observed no infectious complications, no deep vein thrombosis or nerve injuries. We believe that the prevention of infectious complications derives from the very few ecchymoses and hematomas encountered with this technique. This might be due to the flexible catheter and stainless steel tip and the fact that no compression is needed during ablation. This avoids vein wall perforation, bleeding and local ulceration. The positioning of the catheter 2cm from the axis and the systematic thromboprophylaxis eliminated the occurrence of deep vein thrombosis in this study.

Conclusion

Considering the low pain scores, the diminished complication rate and the high quality of life, EVRF can be considered a safe technique that is very well tolerated by patients. An occlusion rate of 98% at 6 months also makes it a very effective treatment modality.

References

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