



Endovenous Radiofrequency Ablation for the Treatment of Varicose Veins: A Single Centre Experience

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Abstract

Varicose veins are dilated, tortuous superficial veins which usually affect the lower extremities. They can be painful, itchy or unsightly, especially when patients are standing and/or walking. Purpose of this prospective single-centre study was to evaluate efficacy of endovenous Radio Frequency Ablation (RFA) in Great Saphenous Vein (GSV) and Small Saphenous Vein (SSV).

A total of 108 extremities were treated for vein incompetence in 98 consecutive patients aged 18-88 years from October 2014 to December 2015 at our Hospital. 96 extremities (88.9%) received treatment for reflux in GSV and 12 extremities (11.1%) for reflux in SSV. All patients were previously studied with duplex ultrasounds imaging to evaluate diameter and tortuosity of the vein to treat and to evaluate the clinical score according with the CEAP classification. During the follow-up we evaluated occlusion rate, clinical complications and CEAP score.

Technical success was 100% (108/108). Complete vein occlusion was observed in 100% of patients (108/108) after 1 month and in 95.4% (103/108) after 6 months. The incidence of deep venous thrombosis was 0.9% (1/108). 9 patients (8.3%) with residual varicose veins after the follow-up period needed sclerotherapy (8/9) or perforating vein surgical ligation (1/9). Improvement of CEAP score was demonstrated in 61.1% (66/108) cases at 6 months ($p < 0.001$). No minor complications such as hematoma, paraesthesia, haemorrhage, infection or pain have been observed.

Our experience suggests that RFA is a safe and effective treatment for the management of varicose veins with significantly improve in venous clinical score at six months.

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Introduction

The venous insufficiency of the lower limbs is a widespread condition, reaching affect about a third of the population aged between 18 and 64 years in the Western Countries [1]. It's a morphological and functional alteration of the superficial venous system of lower limbs with chronic course that is often associated with disabling symptoms and even severe complications. Signs and symptoms include visible varicose veins, calf pain or swelling, leg cramping or fatigue, and a sensation of heaviness [2]. The high prevalence of the disease burden in an important way in budget spending [3].

For many decades, the "gold standard" treatment was represented by open surgery that involves the removal and/or ligation of the insufficient veins [4]. Today in the Western world, endovenous thermal ablation is the most commonly technique used to treat patients with saphenous vein reflux. The therapeutic goal of this technique is to obliterate the treated vein segment by thermal injury to the venous wall [5]. The purpose of this study was to evaluate the effectiveness and clinical improvements in the short and medium term of percutaneous radiofrequency thermal ablation (ClosureFast™ Covidien llc, Mansfield, MA, USA) of the saphenous veins in the lower limbs insufficiency.

Methods

From October 2014 to December 2015, 98 patients (38 males, 60 females) were treated with radiofrequency ablation (RFA), with a total 108 treated veins (96 GSV and 12 SSV). One patient underwent a double synchronous treatment of GSV and SSV, both in the right lower limb; 9 patients were treated two times for two different veins.

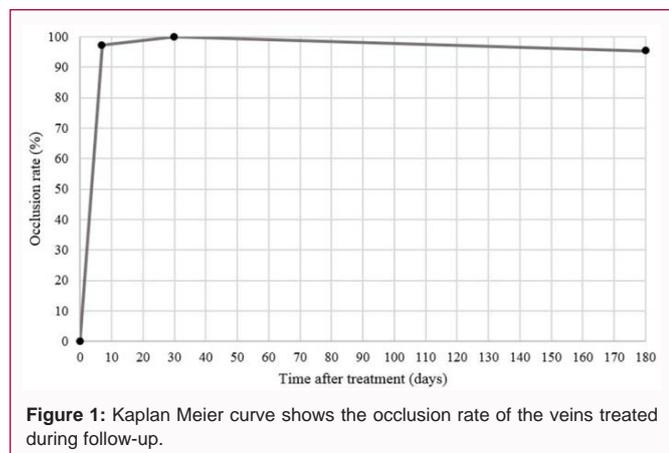
Patients with Great Saphenous Vein (GSV) and Small Saphenous Vein (SSV) insufficiency were screened with duplex scan; clinical score according with the CEAP classification was also evaluated (Table 1 and 2).

Table 1: Clinical components in CEAP classification.

C: Clinical Classification	
C0	No visible or palpable signs of venous disease
C1	Telangiectases or reticular veins
C2	Varicose veins
C3	Edema
C4a	Pigmentation or eczema
C4b	Lipodermatosclerosis or atrophie blanche
C5	Healed venous ulcer
C6	Active venous ulcer

Table 2: Characteristics of treated patients.

	n	%
Total patients	98	
Female	60	61
Male	38	39
Total treated veins	108	
Great saphenous vein	96	89
Right	54	50
Left	42	39
Small saphenous vein	12	11
Right	7	6.5
Left	5	4.6



All procedures were performed in angiographic suite. Inclusion criteria were age of 18 years old (y.o.), vein insufficiency (GSV or SSV), minimum diameter of affected vein ≥ 5 mm, subcutaneous thickness ≥ 5 mm, absence of severe tortuosity of the vessel to be treated and no previous treatments (surgical and/or endovascular) of the affected vein. Patients with deep venous thrombosis or superficial thrombophlebitis, agenesis of the deep venous system or vascular malformation syndromes, post-thrombophlebitic syndrome, pregnancy, immobility, allergy to local anaesthetics (lidocaine, mepivacaine), insufficiency of collateral vessels (with saphenous trunk continent), vein diameter less than 5 mm, peripheral arterial insufficiency, severe tortuosity of the vein interested, platelet deficiency ($<50,000/\mu\text{L}$), altered coagulation parameters ($26\text{s} < \text{aPTT} < 38\text{s}$; $0.8 < \text{INR} < 1.2$) were excluded. Informed consent was obtained from all individual patients before each treatment. The mean age of the population was 57 y.o. (range: 18-88 y.o.). All

patients were treated under local anaesthesia and outpatient settings. No patient needed hospitalization. Primary endpoints were technical success and complete vein occlusion rate at the follow-up. Secondary endpoints were average procedure time, return to normal daily activities, clinical changing according CEAP score and complications. Follow-up included clinical control and duplex scans at 7 days, 1 and 6 months.

Statistical analysis

Data were collected and analyzed using SPSS 15.0 software (SPSS Inc, Chicago, Ill).

Outcomes were analyzed by a paired t test to compare the CEAP clinical score of varicose veins during serial follow ups. The clinical characteristics were summarized.

Results

All interventions were carried out without complications, with a technical success rate of 100%.

The average duration of treatment was 35 minutes (SD:12). In all cases, patient has resumed normal activities immediately following the intervention. In 105 interventions of 108, (97.2%), the treated veins were occluded at duplex scan control performed 1 week after treatment, while the occlusion rate after 1 month with was 100%. All patients completed the follow-up after 6 months; the occlusion rate was 95.4%. Regarding the CEAP clinical score we observed an improvement in 12cases (11.1%) the first week after treatment, in 39 cases (36.1%) after 1 month and in 66 cases after 6 months (61.1%) (Table 3). We observed 1 case of deep venous thrombosis (0.9%) at 1 month, while among the minor complications were documented 42 cases of ecchymosis (38.9%), 1 case of haematoma (0.9%) and 1 episode of pain (0.9%) (Table 4); 9 patients (8.3%), with residual varicose collateral veins after the follow-up period, needed sclerotherapy (8/9) or perforating vein surgical ligation (1/9) to complete the treatment (Figure 1).

Discussion

In recent years, RFA has emerged as a minimally invasive and effective alternative to surgery in the treatment of varicose veins of the lower limbs [6-8].

Our study shows that this approach is able to achieve excellent occlusion rate in veins treated, at short and medium term, with very low incidence of procedure failure and early complications, mostly represented by discolouring and ecchymosis that have rapid resolution. The only case detected of deep venous thrombosis occurred to the only patient undergoing a double synchronous intervention of the great saphenous vein and small of the same limb, with no evidence, however, in this patient, of a thrombophilic state. Thrombosis was detected in a few days and readily resolved with anticoagulant medical therapy.

We obtained a progressive improvement of clinical score of the CEAP classification during six months follow-up.

Data shows that patients with symptomatic varicose veins (e.g. related to the presence of lower limb edema) particularly benefited from treatment: in fact, the percentage of this type of patients (score C3) is gradually decreased during the follow-up (27.8% at treatment vs. 1.9% after 6 months) to lower score (C2 or C1). Proebstle et al. [9], assessed efficacy and safety of RFA with results obtained in the short and medium term. The duration of his procedures is apparently

Table 3: Comparison of clinical CEAP score during serial the follow-up.

	Total patients	Initial average clinical CEAP score	Average clinical CEAP score during follow-up	p (paired t test)
Preoperative vs.1 week	n = 108	2,63 ± 0.97	2.52 ± 0.99	0.406
Preoperative vs. 1 month	n = 108	2,63 ± 0.97	2.23 ± 0.94	0.003
Preoperative vs. 6 months	n = 108	2,63 ± 0.97	1.88 ± 1.12	<0.001

Table 4: Post-operative complications.

	n	%
Major complications	1	0.9
Deep venous thrombosis	1	0.9
Paraesthesia	0	0
Cutaneous necrosis	0	0
Infection	0	0
Phlebitis	0	0
Minor Complications	44	41
Ecchymosis	42	39
Haematoma	1	0.9
Pain	1	0.9

less than our study (16 ± 8 minutes vs. 35 ± 12 minutes), but in this case it was considered only the time from the insertion of the catheter and its removal at the end of the procedure, while in our case the values obtained refer to the entire duration of the intervention (from puncture to shaft removal). The return to normal activities occurred in very short times. The rate of veins occlusion during six months follow-up was 99.6%, with post-procedural complications not dissimilar to those found in our study.

Another study of the same Author [10], based on a median follow-up of 5 years, has shown that even in the long term the occlusion rate is very high (91.9%), with no sign of venous reflux at duplex scan. Even Merchant et al. [11] evaluated the long-term efficacy of RFA, with a follow-up of 4 years. The rate of vein occlusion after 1 week and after 6 months from the procedure was in line with what was observed in our study (respectively 97.4% vs. 97.2% and 91.0% vs. 95.4%). We can observe how the occlusion rate is slightly decreased during the annual follow-up (88.8% after 1 year, 86.2% after 2 years, 84.2% after 3 years, 88.8% after 4 years), however maintaining excellent results. The percentages of complications registered after 1 week from the procedure do not differ from what was observed in our study, except for a greater rate of paraesthesia (12.1%) and phlebitis (3.3%). Choi et al. [12] have primarily assessed the rate of venous occlusion after 1 week from treatment (94.6%). They also focused on the clinical development of the treated patients, evaluating clinical score of the CEAP classification and showing a statistically significant improvement of this value. Concerning complications, they found fewer rate of ecchymosis (3%, 4%) and a great number of paraesthesia (8%, 1%).

The study of Broe et al. [13] demonstrated also in this case a high rate of venous occlusion (99%), with a significant improvement of the clinical score of the CEAP classification, up to 81%, after 3 months from the procedure. It also assessed the occurrence of complications during follow-up after RFA and they detected cases of paraesthesia (4%) and hematoma (1%, 7%), but no cases of deep venous thrombosis (0%).

The study conducted by Tolva et al. [14] evaluated the percentage

of technical success of the procedure (100%), the return of normal activities after treatment (100%) and the percentage of venous occlusion to one week after procedure (100%). The latest value was also maintained constant after 6 and 12 months from the intervention. A bout complications, it has been found a case of paraesthesia (0.4%), no cases of deep venous thrombosis (0%) and three cases of thrombophlebitis (1%, 2%).

The Recovery Study [15], thought to compare laser and radio frequency ablation, has detected a percentage of ecchymosis similar to our result (35% vs. 38.9%) and a greater number of paraesthesia (2.2% vs. 0%) after 1 week from the intervention. They didn't found cases of deep venous thrombosis (0% vs. 0.9%), infection (0% vs. 0%) or phlebitis (0% vs. 0%).

Conclusion

Literature has shown that radiofrequency ablation of varicose veins is an efficacy, short and safe procedure, with an early venous occlusion rate next to the 100%. It is easy to be performed as office technique, avoiding patient hospitalization with early return to daily activities and work. Moreover, because of the mini-invasive nature of the procedure, avoids the need for surgical sutures, reducing drastically the risk of infections and ensuring a better aesthetic result. The early complications are minimal and reversible. Limit of the procedure consists in the difficulty to treat veins with marked tortuosity, for that is preferable traditional surgery.

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