



Original

Our experience in the treatment of incompetent perforating veins using radiofrequency ablation with the VEINEO® device

Nuestra experiencia en el tratamiento de venas perforantes insuficientes mediante ablación por radiofrecuencia (dispositivo VEINEO®)

Mariona Mas-Padilla, M.^a Carmen Aloy Ortiz, Robert Tejedor i Millos, Esteve Bramon Casademont, Gemma Guiu Gil, Laura Bayarri Costas, Quim Jubert Raventós, M.^a Dolores Lloret Cano

Joint Department of Angiology and Vascular Surgery. Hospital de la Santa Creu i Sant Pau. Hospital Dos de Maig. Barcelona, Spain

Abstract

Introduction and objective: radiofrequency ablation (RFA) has emerged as an alternative to sclerotherapy and subfascial ligation in the treatment of incompetent perforating veins (IPV). The objective is to present our experience in the treatment of IPV using RFA with the VEINEO® device.

Material and methods: observational prospective study of patients with CEAP 2-4 IPV, with perforating veins suitable for puncture (straight, ≥ 3 mm) treated between May-2021 and January-2025 with the VEINEO® device. Technical success was defined as the successful cannulation and ablation of the perforating vein. Postoperative follow-up visits were at 1, 6, and 12 months. Descriptive statistics were applied according to the distribution of the variables, and survival analysis using Kaplan-Meier curves (95 % CI), considering as an event the first detection of reflux, recanalization, or clinical worsening. The association between baseline variables and time to event was evaluated with log-rank test and univariate Cox regression ($p < 0.05$).

Results: 23 patients were included (13 men, 10 women) with a mean age of 48.7 ± 14 years and a median follow-up of 10.4 months (range 1-19). Intraoperative success was 100 %. Two complications related to phlebectomy were reported (hematoma and neuritis). In the survival analysis, the probability of maintained occlusion was 100 % (CI 95 % not-estimable [NE]) at 45 days, 87.5 % (58.6-96.7) at 6 months, and 51.6 % (21.1-75.4) at one year. The probability of remaining free of reflux was 100 % (CI 95 % NE) at 1 and 6 months, and 70.7 % (32.9-89.8) at one year. The probability of maintaining clinical improvement was 100 % (CI 95 % NE) at 45 days, 93.3 % (61.3-99.0) at 6 months, and 75.4 % (40.8-91.5) at one year.

Conclusions: RFA of perforating veins is a safe and effective technique for the treatment of IPV. Studies with a larger sample size and longer follow-up are necessary.

Keywords:

Perforator veins.
Chronic venous insufficiency.
Radiofrequency ablation. Endovenous ablation. VEINEO®.

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Correspondence:

Mariona Mas-Padilla / M.^a Carmen Aloy Ortiz.
Joint Department of Angiology and Vascular Surgery.
Hospital de la Santa Creu i Sant Pau. Carrer de Sant Quintí, 89. Horta-Guinardó. 08041 Barcelona, Spain
e-mails: mmasp@santpau.cat / caloy@santpau.cat

Resumen

Introducción y objetivo: la termoablación por radiofrecuencia (RFA) surge como alternativa a la escleroterapia y la ligadura subfascial en el tratamiento de la insuficiencia de venas perforantes (IVP). Nuestro objetivo es exponer nuestra experiencia en el tratamiento de IVP mediante RFA con el dispositivo VEINEO®.

Material y métodos: estudio observacional prospectivo de pacientes con IVP CEAP 2-4, con perforantes aptas para punción (rectilíneas, ≥ 3 mm) intervenidos entre mayo de 2021 y enero de 2025 con el dispositivo VEINEO®. El éxito técnico se definió como canalización y ablación de la perforante. Se controlaron posoperatoriamente al 1, 6 y 12 meses. Se aplicó estadística descriptiva según la distribución de las variables y análisis de supervivencia con curvas Kaplan-Meier (IC 95 %), considerando como evento la primera detección de reflujo, reperfmeabilización o empeoramiento clínico. La asociación entre variables basales y el tiempo hasta evento se evaluó con prueba de *log-rank* y regresión de Cox univariante ($p < 0,05$).

Resultados: se incluyeron 23 pacientes (13 hombres, 10 mujeres) con edad media de $48,7 \pm 14$ años seguidos de mediana 10,4 meses (rango 1-19). El éxito intraoperatorio fue del 100 %. Se reportaron dos complicaciones relacionadas con la flebectomía (hematoma y neuritis). En el análisis de supervivencia, la probabilidad de oclusión mantenida fue del 100 % (IC 95 % no estimable [NE]) a 45 días, 87,5 % (58,6-96,7) a 6 meses y 51,6 % (21,1-75,4) al año. La probabilidad libre de reflujo fue del 100 % (IC 95 % NE) a los 1 y 6 meses, y 70,7 % (32,9-89,8) al año. La probabilidad de mantener mejoría clínica fue del 100 % (IC 95 % NE) a 45 días, 93,3 % (61,3-99,0) a 6 meses y 75,4 % (40,8-91,5) al año.

Conclusiones: la RFA de venas perforantes es una técnica segura y eficaz en el tratamiento de IVP. Son necesarios estudios con mayor tamaño muestral y seguimiento más prolongado.

Palabras clave:

Venas perforantes.
Insuficiencia venosa crónica. Ablación por radiofrecuencia. Ablación endovenosa. VEINEO®.

INTRODUCTION

Perforator vein insufficiency (PVI) is a relevant component of chronic venous disease and is hemodynamically defined by reflux lasting more than 0.5 seconds or by a venous diameter ≥ 3.5 mm (1-3). Traditionally, surgical treatment has been based on subfascial ligation and ultrasound-guided sclerotherapy with sclerosing agents such as polidocanol. However, both techniques show heterogeneous results, with non-negligible recurrence rates (4-6).

In recent years, thermoablative techniques such as radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) have become established as the treatment of choice for saphenous trunk insufficiency, and they have also been applied to the management of PVI, with initial occlusion rates of 60 % to 80 % and a favorable safety profile (4,7-10). In addition, in patients with active venous ulcers (CEAP C6), perforator RFA has been associated with accelerated healing and reduced recurrence, reinforcing its therapeutic usefulness (11,12).

However, the available evidence mostly comes from the ClosureRFS™ Radiofrequency Stylet device, which is more rigid and has a larger caliber than the VEINEO® catheter, for which virtually no published data are available. The latter is a small-caliber flexible catheter that enables segmental ablation after ultrasound-guided

cannulation and tumescence using a technique similar to that used for the saphenous trunks. Its smaller caliber and greater flexibility could facilitate perforator cannulation and reduce tissue injury.

The objective of this study was to present our center's experience in the treatment of PVI by RFA with the VEINEO® device, describing short- and mid-term hemodynamic and clinical outcomes, as well as its safety profile.

MATERIALS AND METHODS

We designed an observational study from a prospectively registered database.

Inclusion and exclusion criteria

We included patients with PVI who underwent intervention from May 2021 through January 2025 at our center (Hospital de la Santa Creu i de Sant Pau - Dos de Maig) using the VEINEO® RFA device with the CR40i fiber.

Patients were evaluated before surgery by Doppler ultrasound performed by an accredited vascular laboratory physician for selection and inclusion in the study.

The inclusion criterion was isolated PVI without associated saphenous trunk insufficiency and with a perforator suitable for cannulation and treatment, ie, straight and with a diameter ≥ 3 mm. Clinical stages according to CEAP ≥ 2 were included. All patients provided consent for the intervention and participation in the study.

Patients with concomitant saphenous trunk insufficiency, postthrombotic syndrome, anesthetic contraindication for surgery, or noncatheterizable perforators, ie, highly tortuous and small-caliber perforators, were excluded.

Procedure, data collection, and follow-up

The VEINEO® system consists of a flexible 1.1-mm-diameter catheter divided into 7-mm white and black bands, with a 5-mm tip that emits radiofrequency waves. The procedural steps are similar to RFA of the saphenous veins. First, ultrasound-guided puncture of the perforator is performed with a 16-gauge Abbocath, the catheter is introduced, and its tip is placed 5 mm from the deep venous system. Tumescence anesthesia is then administered using Klein solution (10 mL of 5 % lidocaine in 500 mL of cold saline), the patient is placed in the Trendelen-

burg position, and ablation cycles are started. The procedure is detailed in figure 1.

Technical success was defined as successful completion of the procedure, ie, cannulation and ablation of the perforator. All procedures were performed by the same female surgeon.

At the end of the procedure, class 2 elastic compression stockings (23-32 mmHg) were prescribed for 1 month, together with prophylactic heparin for 10 days.

Demographic data, baseline clinical grade according to CEAP, location of the treated perforator, and previous varicose vein surgery were collected for each patient. Postprocedural complications recorded during postoperative visits were also documented.

Patients were followed up at 3 visits, at 1 month, 6 months, and 1 year, with Doppler ultrasound performed by an accredited vascular surgeon to assess the degree of perforator occlusion and the presence of reflux, together with clinical evaluation according to the CEAP classification.

Statistical analysis

The variables described were collected in a Microsoft Excel® database and exported to Jamovi statistical software for analysis.

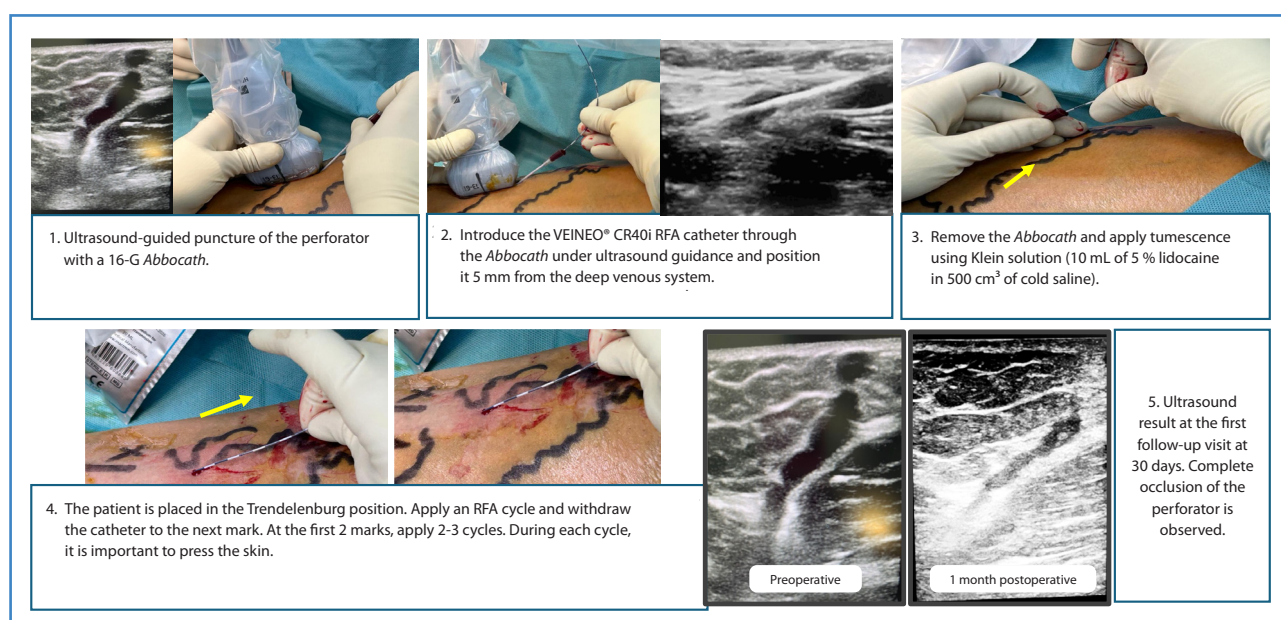


Figure 1. Step-by-step procedure for radiofrequency ablation of perforator veins. Own images. RFA: radiofrequency ablation.

Quantitative variables were described using the mean or median and measures of dispersion according to their distribution (Shapiro-Wilk test). For qualitative variables, absolute and relative frequency distributions were used for each category.

We conducted a survival analysis with Kaplan-Meier curves with 95 %CIs for freedom from repermeabilization, freedom from reflux, and freedom from clinical worsening. The event date was assigned to the visit at which the event was first detected, using a conservative approach. Given the variability in the timing of follow-up visits, estimates were reported at representative times, ie, the medians of each visit. Patients without events were censored at the last available follow-up visit.

The association between baseline variables, sex, age, previous recurrence, and type of perforator, and time to event was assessed using the log-rank test for categorical variables and univariable Cox regression models for age as a quantitative variable. *p* values < 0.05 were considered statistically significant.

RESULTS

A total of 23 patients, 13 men and 10 women, aged 27 to 79 years, with a mean age of 48.7 ± 14 years,

underwent intervention between May 2021 and January 2025. A single perforator vein was treated in each patient.

The median follow-up was 10.4 months; the minimum follow-up was 1 month and the maximum was 19 months. Three patients did not attend any postoperative follow-up visit and were excluded from the follow-up analysis.

Regarding baseline patient characteristics (Table I), 5 patients had recurrence after previous sclerotherapy, and most patients (*n* = 16) had CEAP C2 disease. The anatomical distribution was 12 popliteal perforators, 8 Hunter perforators, and 3 Cockett perforators.

The main results are shown in tables II and III and in figures 2 and 3.

Descriptive analysis

Intraoperative technical success was 100 %, defined as perforator cannulation and ablation. In all cases, adjunctive phlebectomy was also performed in addition to RFA.

Two postoperative complications were recorded, posterior tibial nerve neuritis and hematoma, both related to phlebectomy.

Table I. Baseline characteristics of the patients included in the study

Baseline patient characteristics (<i>n</i> = 23)		
Sex	Men	56.5 % (13)
	Women	43.5 % (10)
Age, years	Mean	48.7
	SD	14
	Minimum	27
	Maximum	79
	Shapiro-Wilk <i>p</i> value	<i>p</i> = 0.702
Type of perforator, %, <i>n</i>	Cockett	13 % (3)
	Hunter	34.8 % (8)
	Popliteal	52.2 % (12)
Initial CEAP, %, <i>n</i>	C2	69.6 % (16)
	C3	17.4 % (4)
	C4	13 % (3)
Previous recurrence, %, <i>n</i>		21.7 % (5)

Table II. Main results: technical success, postoperative complications, ultrasound and clinical variables at 1-month, 6-month, and 1-year follow-up, and survival analysis

Periprocedural results					
Intraoperative technical success, <i>n</i> , %		100 % (23)			
Postoperative complications, <i>n</i> , %		8.69 % (2)			
Results during follow-up		1 month	6 months	1 year	Total
<i>n</i>		18	10	12	20
Losses to follow-up		5	13	11	3
Median, days		45	214.5	367.5	313
IQR, days		12.5	46.3	98.0	200
Minimum follow-up, days		31	120	307	36
Maximum follow-up, days		97	312	585	585
Shapiro-Wilk <i>p</i> value		<i>p</i> = 0.002	<i>p</i> = 0.922	<i>p</i> = 0.048	<i>p</i> = 0.049
Degree of occlusion, %, <i>n</i>	Complete occlusion	83.3 % (15)	50 % (5)	41.7 % (5)	-
	Partial occlusion	11.1 % (2)	30 % (3)	0 % (0)	-
	Patent without reflux	5.6 % (1)	20 % (2)	25 % (3)	-
	Patent with reflux	0 % (0)	0 % (0)	33.3 % (4)	-
Freedom from complete repermeabilization probability, K-M	At risk, <i>n</i>	18	14	5	-
	% free from repermeabilization, 95 %CI	100.0 (95 %CI NE)	87.5 (58.6-96.7)	51.6 (21.1-75.4)	-
Presence of reflux, %, <i>n</i>	Sufficient	100 % (18)	100 % (10)	66.7 % (8)	-
	Insufficient	0 % (0)	0 % (0)	33.3 % (4)	-
Freedom from reflux probability, K-M	At risk, <i>n</i>	18	15	6	-
	% free from reflux, 95 %CI	100.0 (95 %CI NE)	100.0 (95 %CI NE)	70.7 (32.9-89.8)	-
Clinical improvement rate, CEAP >1 point, %, <i>n</i>		100 % (20)	80 % (8)	66.7 % (8)	-
Freedom from clinical worsening probability, K-M	At risk, <i>n</i>	18	14	5	-
	% free from clinical worsening, 95 %CI	100.0 (95 %CI NE)	93.3 (61.3-99.0)	75.4 (40.8-91.5)	-

K-M: Kaplan-Meier; IQR: interquartile range; CI: confidence interval; NE: not estimable.

Table III. Association analysis between baseline variables, sex, age, previous recurrence, and type of perforator, and time to event using the log-rank test for categorical variables and univariable Cox regression models for age as a quantitative variable

Event	Baseline variable	Groups, <i>n</i> ; events	Log-rank χ^2 (df), <i>p</i>	Cox, age, HR, 95 %CI, <i>p</i>
Reflux	Sex	Men (12; 3) vs women (8; 1)	0.981 (1); <i>p</i> = 0.322	—
	Previous recurrence	No (16; 3) vs yes (4; 1)	0.353 (1); <i>p</i> = 0.553	—
	Type of perforator	Popliteal (10; 2), Cockett (3; 0), Hunter (7; 2)	2.02 (2); <i>p</i> = 0.363	—
	Age	—	—	HR, 1.00 (95 %CI, 0.90-1.11); <i>p</i> = 0.982

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Tabla III (cont.). Association analysis between baseline variables, sex, age, previous recurrence, and type of perforator, and time to event using the log-rank test for categorical variables and univariable Cox regression models for age as a quantitative variable

Event	Baseline variable	Groups, n; events	Log-rank χ^2 (df), p	Cox, age, HR, 95 %CI, p
Complete repermeabilization	Sex	Men (12; 6) vs women (8; 2)	1.11 (1); $p = 0.291$	—
	Previous recurrence	No (16; 7) vs yes (4; 1)	0.0325 (1); $p = 0.857$	—
	Type of perforator	Popliteal (10; 2), Cockett (3; 1), Hunter (7; 5)	0.269 (2); $p = 0.874$	—
	Age	—	—	HR, 0.97 (95 %CI, 0.91-1.03); $p = 0.340$
CEAP worsening	Sex	Men (12; 3) vs women (8; 1)	1.16 (1); $p = 0.282$	—
	Previous recurrence	No (16; 4) vs yes (4; 0)	0.909 (1); $p = 0.340$	—
	Type of perforator	Popliteal (10; 1), Cockett (3; 2), Hunter (7; 1)	6.09 (2); $p = 0.047$	—
	Age	—	—	HR, 0.91 (95 %CI, 0.82-1.02); $p = 0.104$

Df: degrees of freedom; HR: hazard ratio; CI: confidence interval.

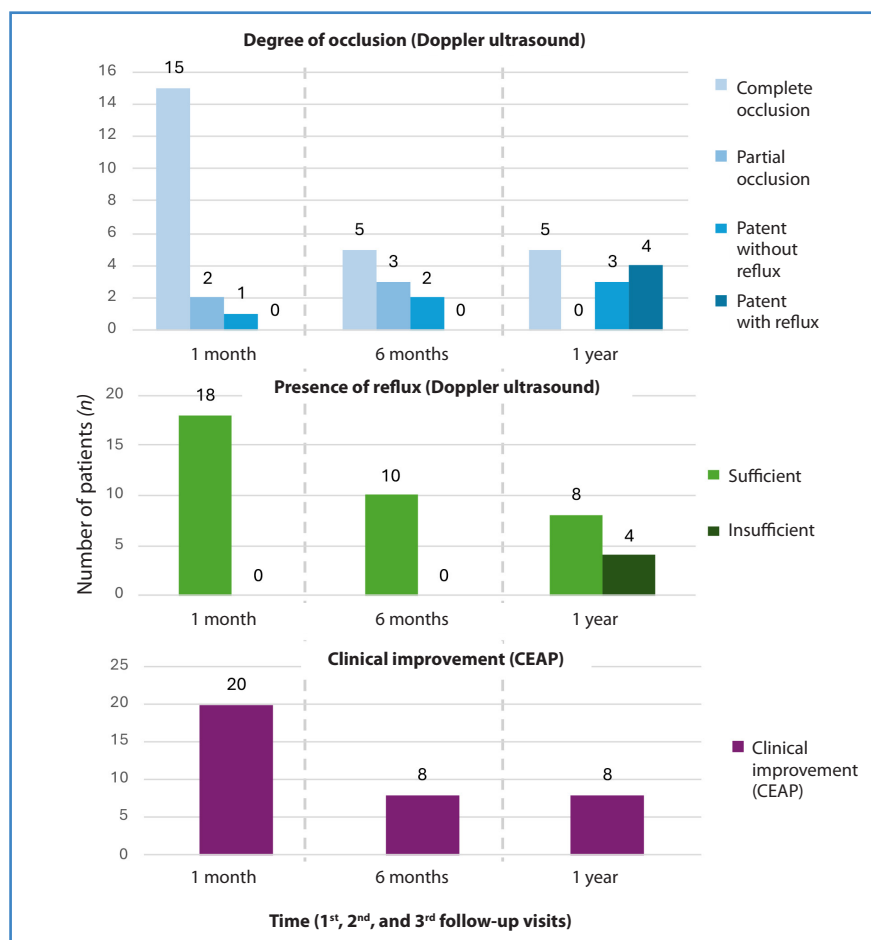


Figure 2. Graphic representation of outcomes during follow-up at the first visit (1 month), second visit (6 months), and third visit (1 year), expressed as number of patients. Blue: degree of occlusion; green: presence of reflux; purple: clinical improvement from baseline CEAP.

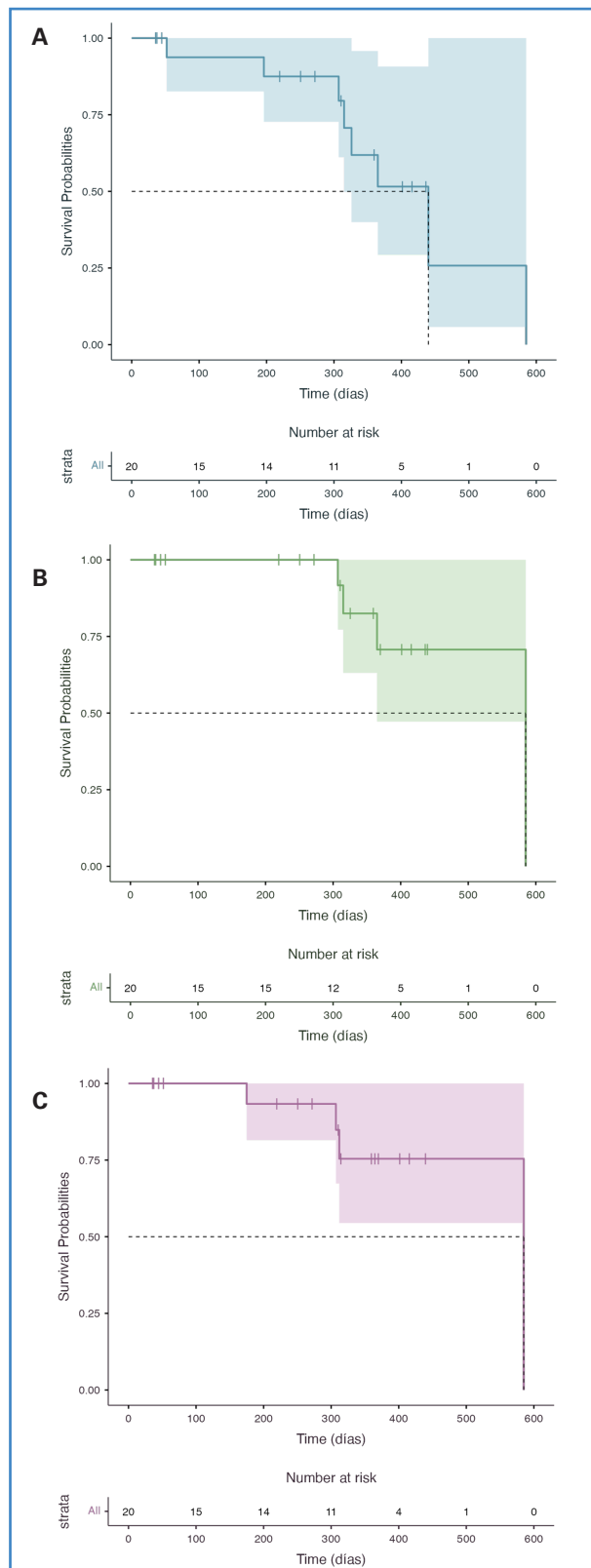


Figure 3. Kaplan-Meier curves of: A. Freedom from complete repermeabilization (days). B. Freedom from reflux (days). C. Probability of absence of clinical worsening according to the CEAP scale (days). The 95 %CIs are represented as colored shading around the line.

At the first postoperative month, 83.3 % (15/18) of patients had complete perforator occlusion, 11.1 % (2/18) had partial occlusion, and 5.6 % (1/18) had repermeabilization without reflux. No patient with reflux was reported. At the 2nd follow-up visit, at 6 months, all patients-maintained absence of reflux, and 20 % (2/10) had perforator repermeabilization. At 1 year, 66.7 % (8/12) maintained absence of reflux, and 41.7 % (5/12) maintained complete perforator occlusion.

Among patients who had previously undergone sclerotherapy, 3 had complete occlusion at 1 month, which was maintained in 2 of them at 1 year, while 1 patient showed partial occlusion at 1 month and recanalization with reflux at 1 year.

All patients showed improvement in baseline CEAP class during the first postoperative month, with a decrease of 1 to 2 points. At 6 months, 80 % (8/10) maintained clinical improvement, and 2 patients had recurrence, 1 of them due to the presence of truncal varicose veins in another territory. At 1 year, 66.7 % (8/12) of patients-maintained improvement in CEAP class.

Survival analysis

In the survival analysis, given the variability in the timing of follow-up visits, estimates were analyzed at the median of each visit, namely days 45, 214, and 367.

The probability of maintained occlusion, or freedom from repermeabilization, estimated by Kaplan-Meier analysis, was 100 % at 45 days (95 %CI not estimable because of the absence of events), 87.5 % at 214 days (95 %CI, 58.6-96.7), and 51.6 % at 367 days (95 %CI, 21.1-75.4).

In contrast, the probability of remaining free from reflux was 100 % at 45 days and 214 days (95 %CI not estimable because of the absence of events) and 70.7 % at 367 days (95 %CI, 32.9-89.8). This corresponds to an estimated occurrence of reflux of 29.3 % up to 367.5 days.

Furthermore, Kaplan-Meier curves were used to estimate the probability of maintaining clinical improvement, or absence of clinical worsening, which was 100 % at 45 days (95 %CI not estimable because of the absence of events), 93.3 % at 214 days (95 %CI, 61.3-99.0), and 75.4 % at 367 days (95 %CI, 40.8-91.5).

Association analysis

We conducted an association analysis among baseline variables, sex, age, previous recurrence, and type of perforator, and time to event, repermeabilization, reflux, and clinical worsening, with no significant associations found (see table III).

However, a significant association was observed between time to clinical worsening and the type of perforator treated (log-rank chi-square test = 6.09; $df = 2$; $p = 0.047$), with a less favorable course in Cockett perforators. Nevertheless, given the small number of events, 2 events in 3 patients, and the high number of censored patients, these findings are not robust.

DISCUSSION

In our experience, perforator RFA with VEINEO® proved to be a safe and effective technique, with 100 % technical success, a low complication rate, and a probability of maintained occlusion of 87.5 % at 6 months, with absence of reflux of 70.7 % at 1 year.

RFA has become established as a widely used technique in the treatment of chronic venous disease, both for saphenous trunks and in advanced stages combined with other techniques (13,14). Along these lines, our study reinforces the role of RFA as a versatile tool within the comprehensive management of chronic venous disease.

Patient selection appears to be a determining factor for achieving high technical success. In our study, cannulation and ablation were achieved in all cases thanks to precise ultrasound identification of straight perforators ≥ 3 mm. In the literature, success rates with RFA devices are also high, 88 % to 100 %, although data are available only for the ClosureRFS™ Radiofrequency Stylet device (15-17). Hingorani et al. reported a 12 % cannulation failure rate, attributed to the presence of multiple perforators treated during the same surgical procedure, in which the second perforator could not be cannulated because of vasospasm (16).

The low complication rate in our sample is consistent with that described in other studies. In their systematic review, Ho et al. reported an overall rate of 8.6 %; the most frequent complications were neu-

rological injuries and superficial phlebitis, with only 0.4 % deep vein thrombosis (8). In our study, only 2 mild events, neuritis and hematoma, were recorded, both related to phlebectomy, reinforcing the safety profile of the technique.

The occlusion rates obtained are within the range reported in other series, although the heterogeneity of occlusion criteria and variability in follow-up make direct comparisons difficult. In our series, survival analysis showed maintained occlusion of 100 % at 45 days and 87.5 % at 6 months, results comparable to those reported in other studies. However, at 1 year this rate decreased to 51.6 %, which may be influenced by the small number of patients with long-term follow-up. Studies with the ClosureRFS™ device show closure rates greater than 80 % to 97 % at 1 year and even 81 % at 5 years, according to Bacon et al (10,15,18,19).

Conversely, Hager et al. reported ultrasound occlusion rates of 73 % at 2 weeks after the procedure, which were significantly higher than those achieved with ultrasound-guided foam sclerotherapy (17). In that study, patients who had recanalization after foam sclerotherapy underwent a thermoablative technique, which improved secondary occlusion rates to 85 % to 89 %. The results obtained in our series of patients with recurrence after sclerotherapy were heterogeneous, and no association was found: 2 of them had maintained occlusion at 1 year, whereas 1 showed recanalization with associated reflux.

In most studies, ultrasound follow-up is performed to describe perforator occlusion or recanalization, without specifying hemodynamic parameters. In our series, freedom from reflux was 100 % up to 6 months and 70.7 % at 1 year, whereas a progressive reduction in occlusion was observed in the mid to long term. This dissociation between occlusion and functional competence suggests that absence of reflux could be a more relevant functional marker than occlusion.

Regarding clinical improvement, all patients showed a reduction of at least 1 grade in the CEAP classification during the first month, with a probability of maintained improvement of 93.3 % at 6 months and 75.4 % at 1 year. Adjunctive phlebectomy was performed in all patients, which may mask the results. In other series including patients with

more advanced stages (CEAP C5-C6), perforator RFA has been shown to accelerate ulcer healing and reduce recurrence (11,12).

This study has limitations inherent to its observational design and small sample size, which was conditioned by the low prevalence of PVI, strict case selection, and loss to follow-up. A probable masking of clinical improvement according to the CEAP clinical classification caused by phlebectomies associated with RFA should also be considered.

However, technical homogeneity, prospective recording, and protocolized hemodynamic assessment strengthen these preliminary results. Our study also provides novel data on the VEINEO® device, for which very few previous publications exist. Prospective studies with larger numbers of patients and longer follow-up are required to more precisely define the role of RFA in the treatment of PVI.

CONCLUSIONS

Our results suggest that perforator RFA with VEINEO® combined with phlebectomy is an effective and safe technique in selected patients and represents a valid alternative in the management of PVI. In our series, the procedure showed 100 % technical success, with acceptable mid-term occlusion rates. The low complication rate and adequate hemodynamic response support its use in centers with experience in endovascular techniques.

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