PHLEBOGRIFFE – A NEW DEVICE FOR MECHANOCHEMICAL ABLATION OF INCOMPETENT SAPHENOUS VEINS: A PILOT STUDY

Piotr Ciostek[1], Marcin Kowalski[1], Witold Woźniak[1], Tomasz Miłek[1], Piotr Myrcha[1], Bartosz Migda[2]

[1]1st Chair and Clinic of General and Vascular Surgery, 2nd Faculty of Medicine, Medical University of Warsaw, Warsaw, Poland
[2]Diagnostic Imaging Facility, Medical University of Warsaw, Warsaw, Poland

ORIGINAL PAPER

Phlebological Review 2015; 23, 3: 72–77
DOI: 10.5114/pr.2015.57466

Submitted: 15.11.2015
Accepted: 30.11.2015

ADDRESS FOR CORRESPONDENCE
Prof. Piotr Ciostek
Mazowiecki Szpital Brodnowski
Kondratowicza 8, 03-242 Warszawa
e-mail: piotr.ciostek@gmail.com

ABSTRACT

Objectives: The aim of this study was to evaluate the feasibility, safety and early results of mechanochemical ablation of incompetent varicose veins using a special catheter: the Phlebogriffe.

Material and methods: The design of this catheter is based on a typical diagnostic catheter. Into this catheter a metal shank, attached to which are 5 thin, curved, springy wires with sharpened ends, is introduced. After being pushed out of the catheter, these wires deploy into a cat's claw pattern. When the whole device – the catheter and shank with open claws – is being pulled out, sclerosing foam is administered. In this pilot study, which was performed in the years 2011-2013, we evaluated 40 patients with varicose veins. Efficacy of the procedure, defined as closure of the treated vein, and clinical result evaluated using the Venous Clinical Severity Score (VCSS) were assessed after 1, 3, 6 and 12 months.

Results: Efficacy of the procedure after 1, 3, 6 and 12 months was 97.4%, 94.9%, 89.7% and 89.7%, respectively. Statistical analysis of the VCSS before the procedure and after 12 months revealed statistically significant improvements regarding pain, presence of varicose veins, oedema, number and size of active ulcers, their duration, size of active ulcers and the use of compression therapy. The average improvement in VCSS scores was 3.56 points.

Conclusions: The Phlebogriffe is a device that offers new opportunities for safe and efficient treatment of varicose veins associated with incompetence of saphenous veins.

Key words: varicose veins, chronic venous insufficiency, mechano-chemical ablation.

Incompetence of the great and/or small saphenous vein is the most common manifestation of chronic venous disease [1]. Chemical ablation of incompetent superficial veins using a foamed sclerosant remains the most often used treatment modality in Europe. Still, even if foam sclerotherapy offers many advantages, it is not free of complications, comprising thrombophlebitis, inflammation of the skin and hyperpigmentation [2]. All these complications seem to be related to thrombosis of the treated vein. Furthermore, the high postprocedural efficacy of foam sclerotherapy, which is reported as an occlusion of the treated vein, results from immediate thrombosis of such a vein, which precedes a slow process of inflammatory-driven fibrosis evoked by chemical irritation [3].

On one hand, thrombosis is a desired process, since it augments inflammation that in turn leads to permanent obliteration of the treated vein. On the other hand, thrombosis is a reversible process – hence the high rate of late recanalisations of previously occluded veins, even as high as 20-30% after 12 months [4].

Based on our own experience and taking into account the pathophysiology of obliteration and fibrosis of the vein, we have focused on mechanical injury, which appears as the initial and pivotal event that initiates damage of the endothelium and enables penetration of the sclerosant into deeper layers of the venous wall. This idea inspired the first author of this paper to develop a unique catheter capable of mechanical injury of the venous endothelium prior to administration of the sclerosant. Theoretically, such mechanochemical obliteration should be more effective in comparison with standard chemical ablation, since the former should result in more severe and diffuse inflammatory process that leads to fibrosis of the vein.

AIM OF THE STUDY

This study was aimed at evaluation of feasibility, safety and early result of mechanochemical ablation of incompetent varicose veins with the use of special catheter, which was invented by the first author of this report.

TECHNIQUE OF THE PROCEDURE

The Phlebogriffe catheter was invented in collaboration with a manufacturer of medical equipment: Balton Sp. z o.o. (Balton, Warsaw, Poland). The design of this catheter is based on a typical 5F 100 cm long single-channel diagnostic catheter (Fig. 1). Into this catheter a metal shank, attached to which are 5 thin, curved, springy wires with sharpened ends, is introduced. After being pushed out of the catheter, these wires deploy into a cat's claw pattern (Fig. 2).

The purpose of these "claws" is to carve deep bruises on the internal wall of the vein when the catheter is pulled out of the vessel. The thickness and elasticity of the wires constituting the claws were adjusted to make possible deep bruising of the endothelium while minimizing the risk of puncture into the deep layers of the venous wall. Such a design was optimised during an in vitro study, using veins previously removed during classic varicose vein surgery (Figs. 3 and 4). The distance between fully expanded claws of the Phlebogriffe is about 20 mm, which in the authors' opinion is sufficient to manage veins up to 15-17 mm in diameter.

In January 2011 we constructed a functioning prototype of the device and obtained approval to conduct the study from the local Bioethical Committee.

The use of the Phlebogriffe catheter is simple. After disinfecting the skin and draping the surgical field, the great saphenous vein (GSV) is punctured with an 18G needle, distally from its incompetent segment, or in the most distal part of the incompetent vein. In a case of unsuccessful puncture, a venesection can be performed. Then, a 0.035" J-type guidewire is introduced into the vein and over this guidewire an introducer sheath is introduced. Through this introducer, over the guidewire, the Phlebogriffe is inserted. The catheter is clearly visible on ultrasound, enabling precise placement of its terminal part in the saphenofemoral junction (Figs. 5 and 6). While the metal shank of the Phlebogriffe remains in the desired location, the catheter is pulled distally, which enables deployment of the claws in the saphenofemoral junction. Then, the whole device – catheter and shank with open claws – is pulled distally with a constant speed of about 1 cm per second. Simultaneously, beginning at the level of about 3 cm distally from the saphenofemoral junction, sclerosing foam is administered (1-3%

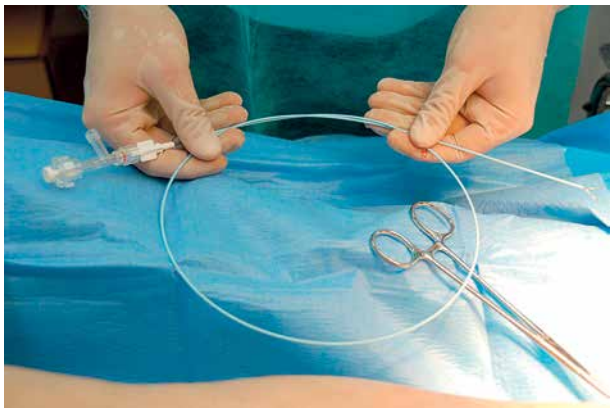

Fig. 1. Phlebogriffe

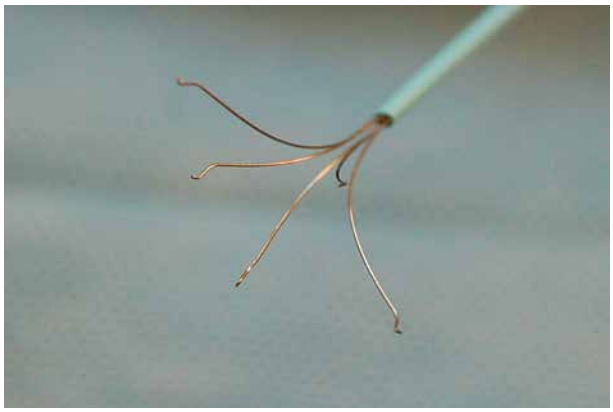

Fig. 2. Phlebogriffe – sharply terminated metal claws

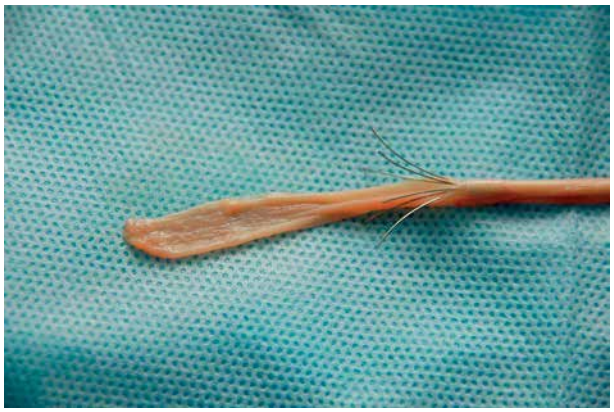

Fig. 3. Prototype of intravenous catheter in the lumen of a removed great saphenous vein. Visible damaged vein wall, macroscopic view

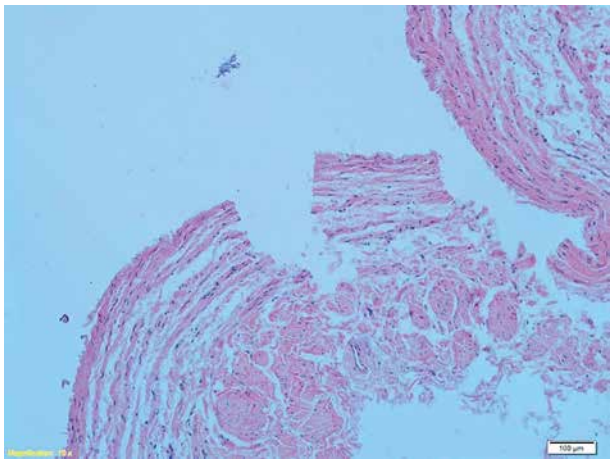

Fig. 4. Microscopic image of damaged internal wall of the great saphenous vein

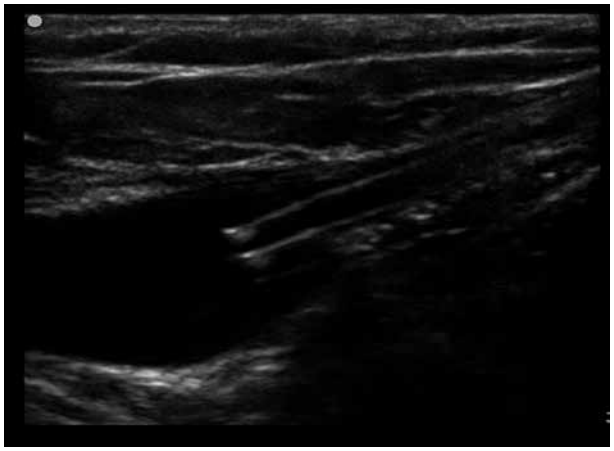

Fig. 5. Intraoperative USG image, Phlebogriffe catheter visible in the saphenofemoral junction prior to "opening"

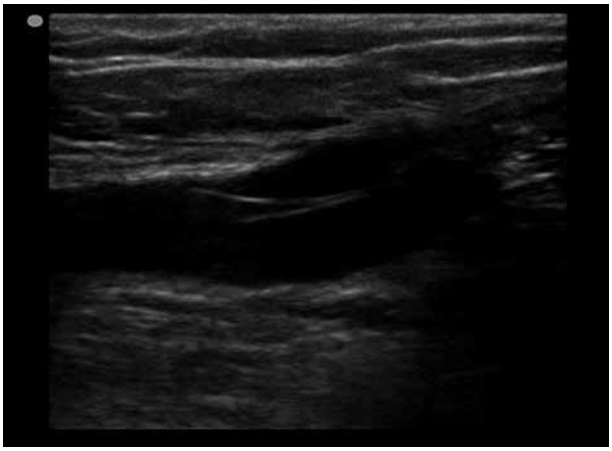

Fig. 6. Intraoperative USG image, "open" Phlebogriffe catheter in the saphenofemoral junction

polidocanol made using the Tessari method), similarly to the standard foam sclerotherapy using a long catheter. During injection of foam, pressure should be applied at the bulb of the GSV in order to reduce the risk of rapid migration of foam to the femoral vein. Mechanical injury of venous endothelium combined with administration of sclerosing foam is continued along the entire treated vein, if necessary up to the area of vascular access. Finally the catheter is removed, manual pressure is applied at the area of venous puncture, and when there is no more bleeding a slightly compressing dressing is applied. A similar technique can be used for ablation of the small saphenous vein (SSV). Mechanochemical ablation of saphenous veins should be completed with standard foam sclerotherapy of visible varicosities. After the procedure an elastic bandage or class 2 compression stocking is applied. Immediately after the procedure patients are mobilised and a short (15-minute) walk is recommended.

MATERIAL AND METHODS

A pilot study of the Phlebogriffe catheter in clinical settings was performed in the years 2011-2013.

We included 40 patients presenting with class C2-C6 of chronic venous disease and with incompetence of the great or small saphenous veins demonstrated by duplex Doppler. All patients underwent colour duplex scanning of the veins, which was performed in a warm and comfortable examination room. Diameters of the great and small saphenous veins were measured in the supine position. Diameter of the GSV was measured 3-5 cm distally from the saphenofemoral junction using B-mode imaging, and the inner anechoic part of the vein was used for the measurements. Diameter of the SSV was measured in the same manner, 3-5 cm distally from the saphenopopliteal junction. In a case of incompetent thigh extension of the SSV without connection with the popliteal vein, the diameter was measured at the popliteal fossa 5 cm distally from the knee crease. Mean diameter of the incompetent GSV was 6.2 ±2.0 mm, while mean diameter of the incompetent SSV was 5.6 ±2.7 mm.

Table 1. Characteristics of patients in the study group

Age (years)	51.82 ±15.78
Sex (F/M)	34/6
Max/avg. GSV diameter (mm)	15/6.2 ±2.0
Max/avg. SSV diameter (mm)	13/5.6 ±2.7
Length of ablated GSV (cm)	42 ±7
Length of ablated SSV (cm)	22 ±6

Mechanochemical ablation of incompetent saphenous veins was performed with the Phlebogriffe catheter and 2% polidocanol foam, using the above-described technique. The average volume of foam used to occlude the GSV was 13 ml (minimal volume: 8 ml, maximal volume: 20 ml) and 5.5 ml (minimal volume: 2 ml, maximal volume: 10 ml) to occlude the SSV.

After the procedure patients were recommended to wear compression hosiery for 3-4 weeks. Efficacy of the procedure, defined as closure of the treated vein, and the clinical result evaluated using the Venous Clinical Severity Score (VCSS) were assessed after 1, 3, 6 and 12 months. Sonographic assessment was particularly focused at possible segmental or total recanalisation of the treated vein.

RESULTS

Thirty-nine patients completed the study. One female patient did not show up at any of the scheduled follow-up visits. Efficacy of the procedure assessed at follow-up visits, which was defined as occlusion of the treated saphe-

Table 2. Characteristics of 39 patients who completed the study according to "C" component of the CEAP classification (one patient who did not show at follow-up presented with C2 class)

	C2	C3	C4	C5	C6
Number of patients	5 (–1)	9	12	7	6

nous vein, was: after one month 97.4% (38/39), after 3 months 94.9% (37/39), after 6 months 89.7% (35/39) and after 12 months 89.7% (35/39). Detailed results are presented in Table 3.

There were no significant complications related to the procedure. Still, the majority of patients complained of aching along the course of the treated vein. Only 8 patients (20.5%) required administration of analgesics (e.g. paracetamol) for pain relief. Such aching was present for 57 days on average (±6.07 days). In 14 patients (35.9%) there were signs of phlebitis and inflammation of adjacent tissues, such as palpable induration and redness of the skin (Table 4). In order to speed up the recovery and reduce the risk of hyperpigmentation in 6 patients during the first 2 weeks after the procedure we performed needle puncture and extraction of the thrombi from the occluded veins. After 12 months hyperpigmentation was found in 2 patients (5.1%). Within 3 months after the procedure 3 patients developed telangiectasias, primarily on the shins. There were no other complications related to sclerotherapy that have been described in the literature, such as pruritus, urticaria, paraesthesia, metallic taste in the mouth, skin necrosis, deep vein thrombosis or pulmonary embolism.

Clinical outcome after 12 months evaluated using the VCSS is presented in Table 5. Statistical analysis using Student's t test for paired groups (paired data) of the VCSS scores before and after the procedure revealed statistically significant improvements regarding pain, presence of varicose veins, oedema, number and size of active ulcers, their duration, size of active ulcers and the use of compression therapy. The average improvement in VCSS scores was 3.56 points.

DISCUSSION

The Phlebogriffe appears to be an easy-to-use and operator-friendly device. This pilot study demonstrated

Table 3. Efficacy of venous ablation with the use of Phlebogriffe

		Phlebogriffe group (*n* = 39)
1 month	Full occlusion of the treated vein over its entire length	97.4% 38/39
	Segmental recanalisation	2.5% 1/39
	Recanalisation of the treated vein over its entire length	0% 0/39
3 months	Full occlusion of the treated vein over its entire length	94.9% 37/39
	Segmental recanalisation	5.1% 2/39
	Recanalisation of the treated vein over its entire length	0% 0/39
6 months	Full occlusion of the treated vein over its entire length	89.7% 35/39
	Segmental recanalisation	10.3% 4/39
	Recanalisation of the treated vein over its entire length	0% 0/39
12 months	Full exclusion/occlusion of the treated vein over its entire length	89.7% 35/39
	Segmental recanalisation	10.3% 5/39
	Recanalisation of the treated vein over its entire length	0% 0/39

Table 4. Frequency of complications

Complications	% (*n*)
Ache along the course of the vein	20.5% (8/39)
Thrombophlebitis with swelling, palpable induration and reddening of the skin along the course of the vein	35.9% (14/39)
Hyperpigmentation (at the injection areas and along the course of treated vein)	5.1% (2/39)
Telangiectasia	7.7% (3/39)

Table 5. Venous Clinical Severity Scoring (VCSS) before and 12 months after the procedure

VCSS scale parameter	Before treatment (pt)	After treatment (pt)	*p*
Pain	1.23 ±0.71	0.28 ±0.46	< 0.001
Presence of varicose veins (diameter > 4 mm)	0.82 ±0.60	0.13 ±0.34	< 0.001
Oedema	1.18 ±0.64	0.31 ±0.52	< 0.001
Skin hyperpigmentation (does not concern skin above the varicose vein)	0.77 ±0.67	0.74 ±0.64	sid
Inflammatory infiltration	0.38 ±0.67	0.33 ±0.58	sid
Lipodermatosclerosis (LDS)	0.28 ±0.56	0.28 ±0.56	–
Number of active ulcers	0.23 ±0.58	0.03 ±0.16	0.031
Duration of ulcers	0.23 ±0.58	0.05 ±0.32	0.033
Size of active ulcers	0.18 ±0.45	0.03 ±0.16	0.032
Use of compression therapy	0.61 ±0.67	0.18 ±0.39	< 0.001
Total points	5.92 ±4.76	2.36 ±2.89	< 0.001

Pt – points; sid – statistically irrelevant difference

high efficacy of mechanochemical ablation for the treatment of incompetent saphenous veins. The small number of minor complications typical for standard chemical ablation confirms the high level of safety of this technique. Because both the device and the method are innovative, the likely next step of the research will consist of direct evaluation of the Phlebogriffe compared to another already established surgical technique.

There is a similar device that utilises the concept of mechanochemical ablation of the veins: the ClariVein (Vascular Insights, Quincy, MA, USA). It should be emphasised that our team began the research on injuring the endothelium in addition to chemical ablation before the invention of the ClariVein system was released. Considering the good results of the ClariVein, our concept of mechanochemical ablation seems to be correct [5-7]. The mechanism of action of the Phlebogriffe has a solid pathophysiological basis [8-10]. The authors believe that the results of this pilot study will encourage further trials aimed at evaluation of this device. There are several advantages of the Phlebogriffe: its construction is simple (which means that cost of the device should not be high), it is easy to use, there is no need for anaesthesia (except for local anaesthesia at the access site), the treatment can be performed on an outpatient basis, and the procedure is highly effective.

CONCLUSION

The Phlebogriffe is a device that offers new opportunities for safe and efficient treatment of varicose veins associated with incompetence of saphenous veins.

The authors declare no conflict of interest.

References

1. Jawień A., Grzela T., Ochwat A. Prevelance of CVI in Poland. Phlebology 2003; 18: 110-122.
2. Biegeleisen K., Neilsen R.D., O'Shaughnessy A. Inadvertent intra-arterial injection complicating ordinary and ultrasound-guided sclerotherapy. J Dermatol Surg Oncol 1993; 19: 953-958.
3. Ikponmwosa A., Abbott C., Graham A., Homer-Vanniasinkam S., Gough M.J. The impact of different concentrations of sodium tetradecyl sulphate and initial balloon denudation on endothelial cell loss and tunica media injury in a model of foam sclerotherapy. Eur J Vasc Endovasc Surg 2010; 39: 366-371.
4. Hamel-Desnos C., Allaert F.A. Liquid versus foam sclerotherapy. Phlebology 2009; 24: 240-246.
5. Elias S., Lam Y.L., Wittens C.H. Mechanochemical ablation: status and results. Phlebology 2013; 1: 10-14.
6. Van Eekeren R., Boersma D., Elias S., Holewijn S., Werson D.A., de Vries J.P., Reijnen M.M. Endovenous Mechanochemical

Ablation of Great Saphenous Vein Incompetence Using the ClariVein Device: A Safety Study. J Endovasc 2011; 18: 328-334.
7. Vun S., Rashid S., Blest N., Spark J. Lower pain and faster treatment with mechanico-chemical endovenous ablation using ClariVein®. Phlebology 2015; 30: 688-692.
8. Coleridge Smith P. Sclerotherapy and foam sclerotherapy for varicose veins. Phlebology 2009; 24: 260-269.
9. Schneider W. Contribution to the history of the sclerosing treatment of varices and to its anatomo-pathologic study. Soc Fran Phlebol 1965; 18: 117.
10. Orsini C., Brotto M. Immediate pathologic effects on the vein wall of foam sclerotherapy. Dermatol Surg 2007; 33: 1250-1254.