VIA MEDICA

ORIGINAL ARTICLE

Acta Angiol
Vol. 25, No. 3, pp. 127–132
Doi: 10.5603/AA.2019.0008

ISSN 1234–950X
www.journals.viamedica.pl/acta_angiologica

The novel minimally invasive mechano-chemical technique of the saphenous vein ablation. Our center experience: results of 24 months follow-up

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Abstract

Introduction: *The aim of the study was to evaluate the efficacy of the endovascular ablation method of GSV/SSV superficial venous insufficiency using Flebogrif® catheter, the safety of the method, expressed in number and quality of observed complications in 24-month observation.*

Material and methods: *Initially, the observed group included 200 patients undergoing ablation of insufficient GSV/SSV. During 24 months of observation, this number decreased to 158, which seems to be a natural process. All patients signed the informed consent form approved by the Bioethics Committee of the Medical University of Lublin. Based on clinical evaluation, including ultrasound assessment, 200 patients, including 170 women and 30 men, were admitted to the study using the adopted criteria of inclusion/exclusion. In the studied group of patients, 172 great saphenous veins (GSV) and 28 short saphenous veins (SSV) were ablated. The treated inefficient veins were punctured at three levels depending on the length of the segment of insufficient GSV/SSV. Each patient was treated with a compression agent in the form of a second compression class elastic stockings (20–30 mm Hg). Control visits on the basis of the accepted protocol were established in 1, 3, 6, 12, 24, 36 months after the procedure.*

Results: *During 24 months of observation, the evaluation of the Flebogrif® catheter method was based on the analysis of results obtained in four categories: effectiveness of the method, expressed as the ratio of the number of successfully closed veins ablated with the Flebogrif® catheter to the number of observed cases of recanalization; clinical improvement of venous insufficiency symptoms, based on the VCSS, CEAP, VAPS scale; safety of the method, expressed in terms of quantity and quality of observed complications; technical characteristics of the method. The obtained results were analyzed statistically using tests for non-parametric variables. The effectiveness of the method based on the obtained results was 92%. A statistically significant decrease in the intensity of clinical symptoms in relation to the preoperative condition was observed. The number and quality of the observed complications allow considering the procedure of vein ablation with the use of Flebogrif® catheter as safe, possible to perform in ambulatory conditions.*

Conclusions: *Effectiveness of the method of 92% in 24-month observation; good cosmetic effect; a statistically significant decrease in the intensity of clinical symptoms in 24-month observation; the low incidence of complications allows to consider the method safe; the method of surgery allows to perform the procedure in ambulatory conditions.*

Key words: mechano-chemical ablation, Flebogrif®, sclerosant, endovascular treatment, ablation, varicose veins, great saphenous vein, short saphenous vein

Acta Angiol 2019; 25, 3: 127–132

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Introduction

Venous insufficiency is a problem affecting a large part of the world population. It is estimated that about 1/3 of the population in developed countries suffers from venous insufficiency. In Europe, the proportion of the population affected by this disease is at a level of about 39% [1, 2].

Despite the many methods proposed over the centuries, the problem of GSV/SSV insufficiency seems to persist. The method developed in 1905 by William W. Babcock, based on stripping the trunk of the insufficient vein with minor modifications, still remains the basic procedure in classical surgery of lower limb varicose veins [3]. A number of minimally invasive methods, such as EVLT, RFA, STIM introduced in the 1980s, constitute a compromise between patients' expectations and therapeutic possibilities proposed by physicians dealing with the treatment of superficial venous system insufficiency [4]. The method of mechano-chemical ablation with the use of Flebogrif® catheter, introduced by BALTON Sp. z o.o. seems to be an interesting proposal, extending the possibilities of effective solution of the problem of GSV/SSV insufficiency, perfectly matching the definition of the minimally invasive procedure [5, 6].

Material and methods

The observed group of patients consisted of 200 patients included in the study after signing the informed consent form approved by the Bioethics Committee of the Medical University of Lublin. Each patient met the exclusion criteria. The basis for qualification for the mechano-chemical ablation of superficial vein system insufficiency was Doppler ultrasound diagnosis of trunk insufficiency in one of the superficial veins system GSV/SSV. Demographic data and numerical distribution of patients treated with mechano-chemical ablation using Flebogrif® catheter are presented in Table 1.

Before the procedure, the intensity of clinical symptoms was assessed according to Venous Clinical Severity Score (VCSS), CEAP (clinical, etiology, anatomic, pathophysiologic) and visual analog pain scale in each patient. Based on ultrasound examination, the site of insufficient vein puncture was determined. For both GSV and SSV it was the lowest point of the insufficient vein segment. The numerical distribution of the puncture site is presented in Table 2.

Table 1. Demographic data of patients included in the study

Gender	n	Age			Total
Females	170	87	56	18	200
Males	30	75	46	23	

Table 2. Numerical distribution of vein puncture site

Gender / Puncture site	Aobove the knee		Knee level		Below the knee	
	n	Total	n	Total	n	Total
Female	37	44	36	42	97	115
Male	7		6		18	

The procedure was carried out in a standard operating room. The only form of analgesia used was anaesthesia of the sheath passage insertion site, which was the access point for the insertion of the Flebogrif® catheter. The ablation of insufficient veins using the Flebogrif® catheter was performed according to the IFU protocol enclosed by the manufacturer (Instruction for use). Mechanical endothelial damage was caused by the cutting elements of the catheter (five hooked bent "wires" towards the endothelial surface), while the 3% Polidocanol administered through the central channel of the catheter to the vessel lumen initiated inflammation, leading in the long term to fibrosis and permanent closure of the vein lumen. During the procedure, the great saphenous vein outlet to the femoral vein was closed by compression. The aim of this manoeuvre was to prevent inadvertent injection of a sclerosant into the deep vein system. After the procedure, each patient was provided with a compression agent in the form of a flexible stockings of pressure class II. The patients were discharged home within one hour after the procedure.

Results

VCSS, CEAP and Visual Analog Pain Scale (VAPS) were used to assess the clinical status of patients. Numerical data obtained before the procedure, i.e., on the 0-baseline day and at individual follow-up time points, were statistically analyzed using Anova Friedman test for non-parametric variables.

A statistically significant decrease in the total value was observed in individual time points in relation to day 0 — baseline, and the lowest value for the VCSS scale in 12 months was 4.40, with a standard deviation of 2.94, and $P < 0.001$. The difference in VCSS value between day, 12 and 24 months was not statistically significant (Table 3).

Graphical characteristics for the assessment of clinical condition using the VCSS scale are presented in Figure 1.

Similar variability was observed in the case of the total values of the numerical data obtained for evaluation using the CEAP scale. The decrease in the numerical value for CEAP was statistically significant at all time points in relation to the 0-baseline day, with the largest decrease

Table 3. Variability in the point value for Venous Clinical Severity Score (VCSS) scale in 24-month observation

	n	min	max	M	SD	Me	P
VCSS-B	200	3.00	21.00	10.72	3.96	9.00	**< 0.001**
VCSS-1	182	2.00	19.00	8.08	3.88	7.00	
VCSS-3	179	1.00	16.00	5.79	3.52	5.00	
VCSS-6	174	0.00	15.00	4.75	3.13	4.00	
VCSS-12	168	0.00	15.00	4.40	2.94	4.00	
VCSS-24	112	0.00	14.00	4,71	2.73	5.00	

M: mean; SD: standard deviation; Me: median

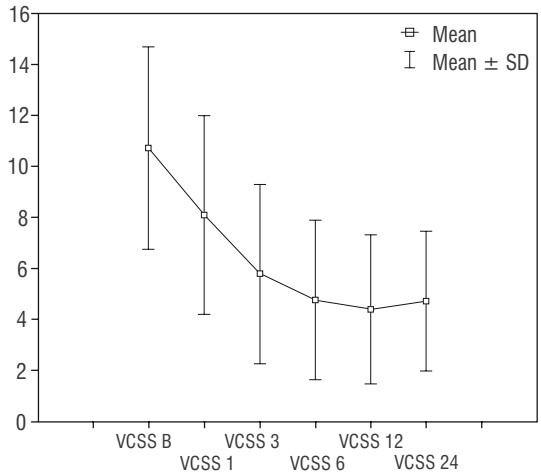

Figure 1. Variability in the point value for Venous Clinical Severity Score (VCSS) scale in a 24-month observation

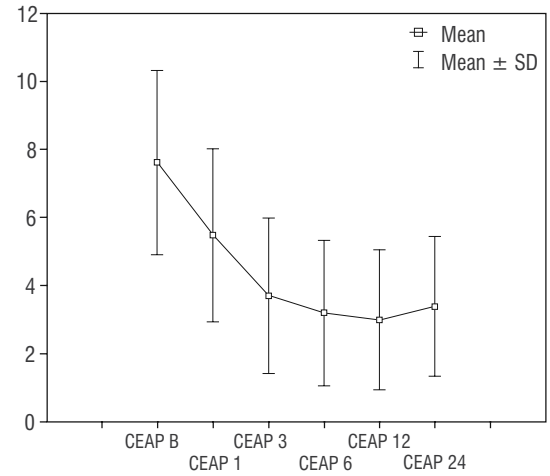

Figure 2. Graphical characteristics for the variability in the point value for CEAP (clinical, etiology, anatomic, pathophysiologic) scale in a 24-month observation

observed during the follow-up visit of 12 months: 2.99, with a standard deviation of 2.05 for $P < 0.001$ (Table 4).

Figure 2 presents a graphical characteristic for the discussed variability in the point value for CEAP scale in a 24-month observation.

Numerical values for VAPS in 24-month observation showed a statistically significant decrease in individual time points of observation, whereas between 12 months and 24 months there were no statistically significant differences. The maximum decrease was observed during the 12-month visit: 0.60 with standard deviation of 0.86 for $P < 0.001$ (Table 5).

The graphical illustration for the discussed variability of the VAPS scale is shown in Figure 3.

Initial success was achieved in all patients. However, in the 24-month observation, cases of recanalization were observed, which were divided into two groups: partial and total recanalization. Table 6 shows the numerical distribution of cases of recanalized veins taking into account sex, age, length of vein segment subjected

Table 4. Variability in the point value for CEAP (clinical, etiology, anatomic, pathophysiologic) scale in a 24-month observation

	n	min	max	M	SD	Me	P
CEAP-B	200	2.00	14.00	7.62	2.71	7.00	**< 0.001**
CEAP-1	182	1.00	12.00	5.48	2.54	5.00	
CEAP-3	179	0.00	10.00	3.70	2.28	3.00	
CEAP-6	174	0.00	10.00	3.20	2.13	3.00	
CEAP-12	168	0.00	10.00	2.99	2.05	3.00	
CEAP-24	113	0.00	10.00	3.39	2.04	4.00	

M: mean; SD: standard deviation; Me: median

Table 5. Variability in the point value for Visual Analog Pain Scale (VAPS) scale in a 24-month observation

	n	min	max	M	SD	Me	P
VAPS-B	200	0.00	8.00	3.23	1.75	3.00	**< 0.001**
VAPS-1	182	0.00	7.00	1.88	1.43	1.00	
VAPS-3	179	0.00	6.00	0.92	1.22	1.00	
VAPS-6	174	0.00	6.00	0.72	1.06	0.00	
VAPS-12	167	0.00	4.00	0.60	0.86	0.00	
VAPS-24	112	0.00	4.00	0.64	0.89	0.00	

M: mean; SD: standard deviation; Me: median

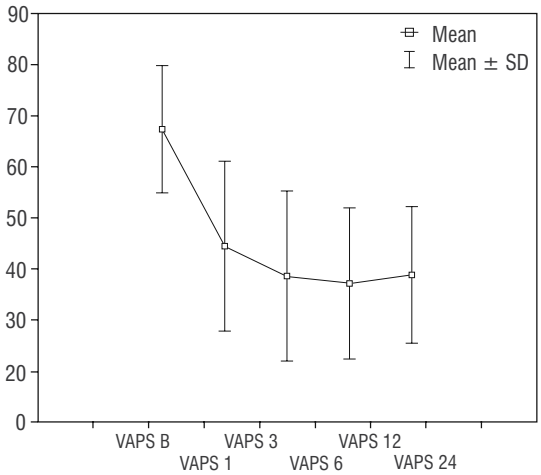

Figure 3. Graphical characteristics for the variability in the point value for Visual Analog Pain Scale (VAPS) scale in a 24-month observation

to mechano-chemical ablation, amount of obliterating agent used and its concentration.

Based on the classification of the European Consensus on Sclerotherapy (Tagernsee 2006), the cases of recanalization are divided into two groups: the total and partial one [7]. Table 7 shows their numerical distribution by vein type and sex.

No statistically significant correlation was found between the amount of obliterating agent, its concentration, vein length, diameter and number of recanalization at particular time points.

In the observation between the visit of 12 months and 24 months, there were no further cases of complications.

Table 6. Summary of recanalization cases including diameter, puncture site, amount of obliterating agent, vein length, age and sex

Age	Leg		Puncture site			Vein		Diameter		v-foam (mL)	Lenght (cm)	Sex		Recanalisation	
	R	L	–	knee	+	GSV	SSV	SFJ	VEIN			F	M	F	P
46		X			X	X		8.4	7.0	7.0	44	X		X	
48		X			X	X		7.2	5.9	6.0	43		X		X
63	X		X				X	5.7	5.4	5.0	28	X		X	
47		X		X		X		9.0	7.2	6.0	31		X	X	
60		X			X		X	6.1	5.1	5.0	21		X	X	
56		X			X	X		8.4	8.0	8.0	41	X		X	
70		X			X	X		10.2	9.4	6.5	38	X			X
74	X			X		X		7.7	5.8	5.0	29	X		X	
63	X				X	X		6.4	5.0	7.0	41	X		X	
63	X				X		X	7.6	7.4	5.0	24	X			X
42		X			X	X		8.0	7.1	6.0	39	X		X	
61		X			X	X		8.1	7.3	7.0	41	X		X	
76		X		X		X		8.2	7.1	6.0	29	X			X
39		X	X				X	9.6	8.3	5.0	23	X		X	
56		X			X	X		11.1	11.4	10	47		X	X	

R: right; L: left; GSV: great saphenous vein; SSV: short saphenous vein; SFJ: sapheno-phemoral junkction; VEIN: vein; F: female; M: male; F: full; P: partial

Table 7. Numerical distribution by vein, type and sex of racanalisation cases

Females				Males			
GSV		SSV		GSV		SSV	
P	F	P	F	P	F	P	F
1	9	1	2	2	0	0	0

P: partial; F: full; GSV: great saphenous vein; SSV: short saphenous vein

Discussion

The treatment of superficial venous insufficiencies with Flebogrif catheter is the youngest representative of mechano-chemical ablation procedures. Due to its low invasiveness, it can certainly be classified as a minimally invasive procedure. This position is supported by the opinion of patients undergoing the Flebogrif treatment, as well as physicians — Phlebologists performing the surgery [6, 8]. This is certainly not the final solution to the problem of venous insufficiency, but it should be stated that it broadens the possibilities of the treatment and is an interesting option especially in the context of the results obtained during the two-year observation. Thermal treatments developed in the early eighties of the last century like EVLT, RFA, have proven their effectiveness over the years, gaining in the opinion of experts the name of procedures recommended in the treatment of varicose veins of lower limbs caused by GSV/SSV insufficiency [3]. The later variant of thermal ablation with steam (STIM) also successfully applied to this group. Although the "STIM" method is not the most recommended treatment, it still finds a certain number of supporters [9–11]. An alternative to thermal treatments is certainly the adhesive technique. The experience so far looks promising, but the scarce number of publications relating to its effectiveness and in particular the complications in long-term observation leaves some important questions unanswered. An interesting proposal is an obliteration by catheter (using a long and short catheter). Obtained indices of total effectiveness encourage its use. Especially the short catheter technique seems to be a good tool in case of curvilinear venous insufficiency, which is a problem and sometimes a disqualification criterion for other endovascular procedures (EVLT, RFA, STIM) [12, 13]. It can be stated that the technique of catheter obliteration fits perfectly into the gap between classical intravenous procedures dedicated to trunk insufficiency with unfavourable anatomy (winding course). Another positive feature of this technique is the possibility of its use in the obliteration of inefficient collateral and perforator veins. In this context, Flebogrif® is the only unique combination of both catheter ablation and mechanical endothelial surface destruction techniques typical of MOCA treatments (Clarivein) [14–17]. The versatility of the Flebogrif® catheter technique in both trunk and collateral insufficiency makes it an interesting and multi-purpose tool [6, 18]. This thesis is supported by the results of the method's effectiveness in 24-month observation reaching 92%. By analyzing demographic data with particular regard to the increasing number of patients suffering from superficial venous insufficiency with regard to the efficacy, availability and acceptance by patients, we can conclude that we have a number of effective treatments, the combination of which allows us to solve the problem of venous insufficiency almost completely. However, none of the currently used surgical methods solves the pathology of trunk insufficiency (GSV, SSV) on its own, which leaves the issue of lower limb varicose veins still open. On the other hand, we can consider whether, with such a variety of treatments with the possibilities defined only by the invention of the doctors performing the procedure, do we need one universal method, combining the advantages of the methods currently used, or does it really exist [19]? Reviewing literature reports on the effectiveness of individual types of procedures over a shorter or longer period of observation, we conclude that the percentages given allow us to formulate a list of the most recommended ones, among which Flebogrif® is in the upper range. Assessing the availability of individual treatments, which is primarily determined by economic relations, i.e., the patient's purchasing power in correlation with the proposed price indices, we can conclude that Flebogrif® occupies a leading position. In conclusion, we would like to emphasize once again that the Flebogrif® catheter technique proposed by us is not in competition with other methods, if only because of fundamental methodological differences.

Acceptance of patients and growing interest in the method motivates us to continue using it.

Conclusions

1. Effectiveness of the method on a level of 92% in 24-month observation.
2. Good cosmetic effect.
3. Statistically significant decrease in the intensity of clinical symptoms in 24-month observation.
4. Low incidence of complications allows to consider the method safe.
5. The method of treatment allows to perform the procedure in ambulatory conditions.

Conflict of interest

None.

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