

# A new device for minimally invasive mechano-chemical method of saphenous vein ablation. Report of 12 months of follow up

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## Abstract

**Introduction.** *The purpose of the study was to assess the effectiveness of endovascular mechanochemical ablation of the Great Saphenous vein and the Small Saphenous vein (GSV/SSV) using the use of Flebogrif<sup>®</sup> catheter and method, based on results obtained from the analysis of 200 patients.*

**Material and methods.** *200 patients underwent mechanochemical ablation using the Flebogrif<sup>®</sup> technique, of the 200 patients, 172 patients experienced insufficiency of the GSV and 28 experienced insufficiencies of the SSV. Follow-up assessment was established by outpatient appointments at 1, 3, 6, and 12 months postoperatively. During each subsequent visit, the result of the procedure was evaluated with the use of ultrasound. Furthermore, the intensity of clinical manifestations was assessed with the use of VCSS, CEAP, VASP scales. Any complications were also noted.*

**Results.** *During 12-month follow-up the number of participants decreased to 168 (152 female, 16 male). Complete closure of the vein was achieved in 154 patients (140 female, 14 male). According to adopted criteria, 15 cases of recanalization were detected (10 complete and 5 partial). Based on the obtained results the effectiveness of the method was assessed at 92%.*

**Conclusions.** *The statistical analysis of the 12-month follow-up data allowed us to conclude the following the procedural method had 92% of effectiveness at 12-month follow-up, vein diameter was not a significant limitation for the application of the technique, there was a low rate of serious complications, and adverse cosmetic effect was minimal. However, the method requires further long-term follow-up to allow for a complete assessment.*

**Key words:** mechanochemical ablation, endovascular procedures, Flebogrif<sup>®</sup>, varices, obliteration

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## Introduction

The significant number of patients presenting with chronic venous insufficiency remains an inspiration for further search of an effective therapeutic method associated with long-lasting effectiveness, high level of safety, and broad accessibility [1, 2]. Endovascular thermal ablation techniques introduced in the early 1990s utterly transformed vein surgery, resulting in a new minimally invasive approach [3]. The procedures gained the approval of both patients and physicians [4]. Due to their high efficacy and reproducibility of the outcome, they remain the most commonly used procedures for endovascular GSV/SSV ablation [4]. Our proposed method of endovascular mechanochemical GSV/SSV ablation with the use of Flebogrif® catheter is an effective, minimally invasive treatment of venous insufficiency [5]. The model pathological mechanism of Flebogrif® method is based on shrinking of the veins, and the resultant fibrosis due to the inflammatory process as a consequence of chemical damage to the endothelium initialized by mechanical injury of the vessel wall.

The main goal of this study was to assess: the effectiveness of mechanochemical ablation of the GSV/SSV using the Flebogrif catheter (expressed as the percentage of fully closed veins). Clinical effectiveness based on the evaluation of the intensity of clinical signs at fixed follow-up intervals, using the VCSS, CEAP, VAPS scales, and safety of the procedure, based on the analysis of the type and clinical significance of observed complications were also assessed.

## Material and methods

200 patients underwent surgical procedures from January 2013 to December 2015 due to Great Sa-

phenous Vein (GSV) and Small Saphenous Vein (SSV) insufficiency. Tables 1 and 2 present the demographic data the respective number of participants during the 12 month follow-up period.

The study was performed after obtaining approval from the Ethics Committee at the Medical University of Lublin. The analyzed patients met all the inclusion criteria, and no exclusion criteria were established. After signing the consent form, each patient underwent an ultrasound to confirm the insufficiency of the GSV/SSV. Special attention was given to such deep vein pathologies, such as post-thrombotic changes, partial obstruction, and total occlusion. The ultrasound was completed while in a standing position. Ascertaining the length of the insufficient vein helped to better determine the proper site for the puncture of the vessel. In the case of the GSV the optimal puncture site location was the lowest point in the segment of the insufficient vein, whereas the SSV was punctured maximally peripherally in relation to sapheno-popliteal junction. Table 3 shows the diameter, number and location of the operated veins.

During the preoperative assessment (baseline), the intensity of clinical signs reflecting illness severity was collected and analyzed. The procedures were performed in a conventionally equipped operating room. In cases of GSV insufficiency, the patient was placed in a supine position, whereas in SSV cases, in a prone position was preferred. The procedure was performed with a prepared set, consisting of 18G needle, 0,035 "J" angulated wire", 6 Fr vascular sheath, 2 syringes with a connector and a 6 Fr Flebogrif® catheter. Before use, all the equipment was flushed with saline. Under ultrasound guidance, the vein was punctured with 18G needle at the level determined preoperatively. The introducer was inserted through venous cannula and its

**Table 1.** Demographic data of the investigated group of patients

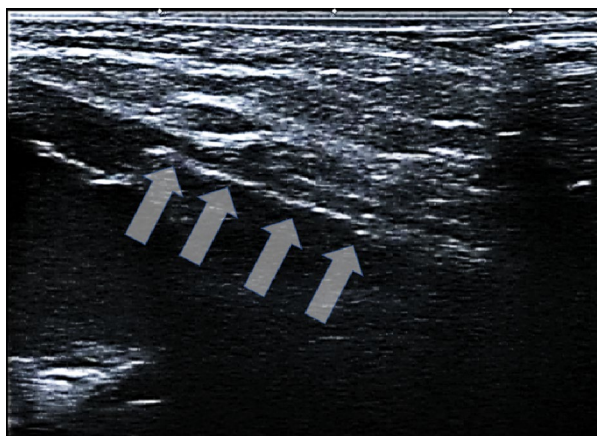
Gender	Number of patients	Age			Total number of patients
		Max	Average	Minimum	
Females	170	87	56	18	200
Males	30	75	46	23	

**Table 2.** Number of patients over 12 months of observation

Postoperative time	Baseline day „0”	1 month	3 month	6 month	12 month
Patients					
Number	200	198	182	179	174
Females	170	170	158	157	156
Males	30	28	24	22	18

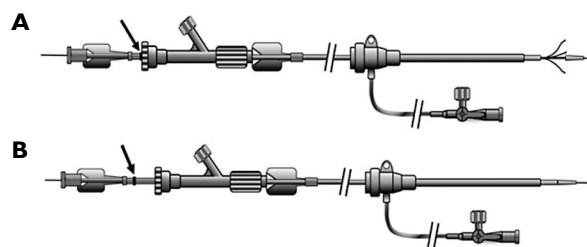
**Table 3.** Diameter, number, and the side of puncture of operated veins

The diameter of the vein (from-to/average)			Number of operated limbs				Proportion	
Below SFJ	Mid-thigh	Knee level	Females		Males		GSV	SSV
			Right	Left	Right	Left		
4,2	3,8–17,1/6,2	3,8–11,9/6,6	68	102	13	17	172 (86%)	28 (14%)

**Figure 1.** The ultrasound view of working part of the Flebogrif<sup>®</sup>

tip was advanced to the level of the Sapheno-Femoral junction in GSV cases and the Sapheno-Popliteal junction in SSV cases. Before inserting the vascular sheath, the skin was anaesthetized with 1 ml of 1% Lignocaine. A small skin incision at the puncture site facilitated its introduction. The Flebogrif<sup>®</sup> catheter was inserted on the introducer through the vascular sheath, and its tip was positioned 2 cm from Sapheno-Femoral junction. Maintaining this distance prevented the application of obliterating agent into the femoral vein. Proper position of the Flebogrif<sup>®</sup> was confirmed by ultrasound (Fig. 1). By retracting the outer sheath, five cutting elements were released. The hooked tips of these elements “bit” into the venous wall. A crucial aspect of the procedure was to withdraw the Flebogrif<sup>®</sup> catheter at a constant speed of 5 cm/s with simultaneous injection of a frothed obliterating agent, 3% Polidocanol, which was prepared according to the Tessari method (1 ml of sclerosing agent mixed with 4 ml of air). To maintain its proper consistency, the obliterating substance was prepared directly before its application. The construction of the catheter and functions of its constituent parts are presented in Figure 2.

The volume of 3% of foam applied did not exceed 10 ml (1 ampule/60 mg of pure Polidocanol frothed according to Tessari method in 1:4 ratio). Small varices were closed at the same time with 1% foam. However, the entire (main vein trunk + varices) amount

**Figure 2.** **A** – working part (cutting elements) — of the Flebogrif<sup>®</sup> is advanced forward; **B** — Working part (cutting elements) withdrawn into the catheter. The black ring at the proximal end of the catheter (see the black arrow in the Figure) indicates the position of the working part.

of obliterating agent did not exceed 1 mg/kg. Larger varicose veins requiring a larger volume of sclerosant were obliterated in the next session. The estimated volume of foamed substance administered to the vein lumen was 1 ml per 5 cm of vein. The maximum amount of Palidocanol used was 10 ml, and the minimum was 4 ml. Postoperatively, every patient was fitted with a compression stocking with a pressure of 20–30 mm Hg. The patient was advised to use the compression stocking continuously for 24 hrs after the procedure as well as during the daytime for 4 weeks following the intervention. Each patient returned to normal physical activity immediately after the procedure and was discharged home within the following hour. Follow-up appointments were planned for 1, 3, 6, 12, 24, and 36 months postoperatively.

### Obtained data analysis

During arranged follow-up visits, evaluation of each patient clinical condition was performed with the use of the VCSS, CEAP scales, in combination with the visual analogue pain scale. Obtained data from the VCSS, CEAP and VAP scale underwent statistical analysis using the Friedman ANOVA test. Regarding the VCSS scale, a statistically significant decrease in clinical signs was observed in comparison to day “0” (baseline) ( $p < 0,001$ ). No statistically significant differences were observed between the evaluation at 6 and 12 months. Table 4 presents the statistical characteristics of the obtained data.

**Table 4.** Statistical analysis for the assessment using the VCSS scale

	n	Min	Max	M	SD	Me	p
VCSS — B	200	3.00	21.00	10.72	3.96	9.00	<b>&lt; 0.001</b>
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	

n: number; min: minimum; max: maximum; M: mean; SD: standard deviation; Me: median

**Table 5.** Statistical analysis for the assessment using the CEAP scale

	n	min	max	M	SD	Me	p
CEAP — b	200	2.00	14.00	7.62	2.71	7.00	<b>&lt; 0.001</b>
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	

n: number; min: minimum; max: maximum; M: mean; SD: standard deviation; Me: median

**Table 6.** Statistical analysis for the assessment of using the VAPS scale within 12 months follow-up

	n	min	max	M	SD	Me	p
VAPS — b	200	0.00	8.00	3.23	1.75	3.00	<b>&lt; 0.001</b>
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	

n: number; min: minimum; max: maximum; M: mean; SD: standard deviation; Me: median

**Table 7.** The correlations between the diameter, length of the vein, the amount of foam and the full recanalization in the rang Spearman table

Feature	Diameter SFJ	Diameter GSV	V foam	L vein
Diameter SFJ	—	<b>0.6608</b>	0.4200	-0.0389
Diameter GSV	<b>0.6608</b>		<b>0.8002</b>	-0.0548
V foam	0.4200	<b>0.8002</b>		0.2643
L vein	-0.0389	-0.0548	0.2643	—

Similarly, data from the evaluation of clinical state with the CEAP scale was statistically analyzed. A statistically significant decrease in clinical sign intensity was observed at follow-up points in relation to point “0” (baseline) ( $p < 0.001$ ). No statistically significant differences were found between 6<sup>th</sup> and 12<sup>th</sup> month follow-up. Table 5 shows the statistical analysis of the CEAP scale.

Data obtained from the visual analogue pain scale show a statistically significant drop at follow-up time points in comparison to the initial point “0”, with a

significance level of  $p < 0.001$ . The difference between 6<sup>th</sup> and 12<sup>th</sup> month follow-up points was not statistically significant (Table 6, Fig. 5.)

The impact of the diameter of the closed vein with the Flebogrif<sup>®</sup> catheter was also analyzed. The type of recanalization is not differentiated statistically significantly age, diameter, Sapheno-Femoral junction as well as the diameter of the trunk of Great Saphenous Vein, volume of the foam, and the length of the vein. Correlations were evaluated using rang Spearman table (Tables 6, 7).

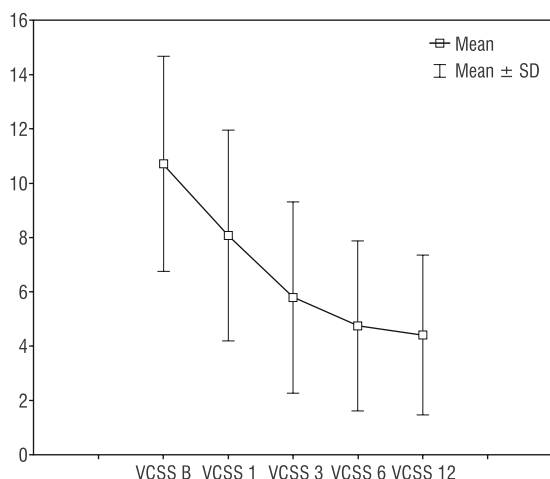


Figure 3. The time after surgery and VCSS values

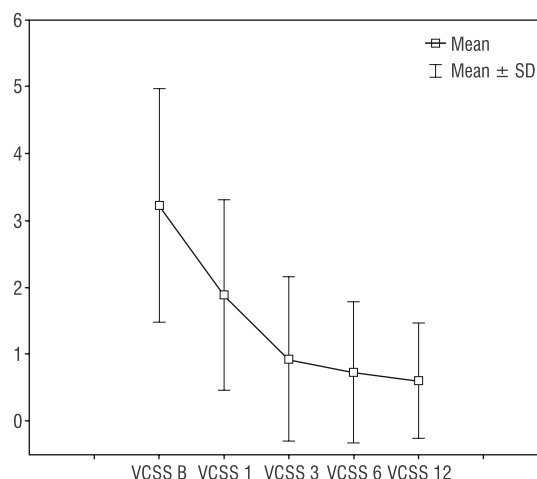


Figure 5. The time after surgery and values VAPS scale within 12 months follow-up

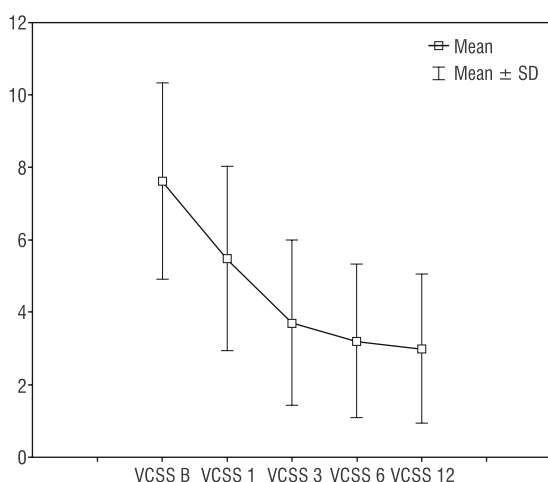


Figure 4. Postoperative time and the values of CEAP scale

During the follow-up period, 15 cases of recanalization were observed. According to the European Consensus for Sclerotherapy, the following criteria were adopted for complete recanalization: no change in the ablated vein's diameter, full patency of the vessel, reflux over 0.5 s. Whereas partial recanalization was defined as a reduction in vein diameter, and reflux below 0.5 s. The analysis of observed cases enabled classification of 10 cases as complete recanalization and 5 as partial recanalization. Table 7 shows the distribution of recanalized veins. Based on 12-month follow-up analysis, method efficacy was evaluated to be at 92%.

### Discussion

The method of endovascular ablation using the Flebogrif® catheter is another effective way of solving

Table 8. The correlations between the diameter, length of the vein, the amount of foam and the full occlusion in the rang Spearman table

Feature	Diameter SFJ	Diameter GSV	V foam	L vein
Diameter SFJ		<b>0.7800</b>	<b>0.3126</b>	0.0823
Diameter GSV	<b>0.7800</b>		<b>0.3011</b>	0.0428
V foam	<b>0.3126</b>	<b>0.3011</b>		<b>0.8366</b>
L vein	0.0823	0.0428	<b>0.8366</b>	

Table 9. The cases of recanalized veins in relation to diameter of the vein, puncture site and amount of given foam

Feature Gender	Recanalization GSV		Recanalization SSV		V. Diameter		Puncture site			Volume of sclerosing agent (ml)	
	L	R	L	R	Form — to (mm)	Average	Above	Knee	Belove	GSV	SSV
Females	7	1	4	—	5.8–20.1	13.1	2	4	7	4–8	2–5
Male	2	1	—	—	6.8–10.0	11.4	0	0	2	5–8	—

the problem of chronic vein insufficiency [6]. During the last quarter of a century, several new methods (EVL, RFA, among others) were introduced. These procedures effectively drew the attention of both the medical community and patients as an endovascular, minimally-invasive way of treating superficial venous drainage insufficiency (GSV/SSV) [4, 6–8]. This procedure became a valuable alternative to the classical Babcock method of vein stripping, combined with mini-phlebectomy, which has been the dominating method in the treatment of various until the end of the 1980's. In establishing the necessity of procedures we adopt the following criteria low cost, and thus better accessibility; short hospitalization with the possibility of outpatient intervention; and most importantly, safety as well as the permanence of therapeutic effect [2]. Certainly, both thermal methods and the recently introduced superheat approach fulfil these requirements [9]. Their undoubted advantage is short patient recovery time, very good cosmetic effect and, a relatively low number of complications, therefore results in a high quality of life index [10]. They are, however, a source of new types of complications such as neuralgia, hematomas, thermal injury of the skin. Additionally, this method requires tumescence which further complicates and prolongs the procedure [6]. At present, procedures with the use of a thermal factor (EVL, RFA, STEAM) remain the most commonly performed procedures in cases of superficial venous trunk insufficiency [2, 3]. Another minimally-invasive procedure is foam obliteration, either through a catheter or with direct vein puncture under ultrasound guidance [8, 11]. Although effectiveness assessed in randomized control trials is lower when compared to surgical treatment, its low level of invasiveness combined with low complication rate encourage its supporters to apply it in treatment [12]. The introduction of Flebogri<sup>®</sup> to the European market opened a new chapter in the history of minimally-invasive procedures, especially since the procedure completely eliminates the need for tumescence manoeuvre as well as anaesthesia during the procedure [5, 13, 14]. At this point, it should be emphasized that Clarivein was historically the first procedure creating the mechanochemical group of procedures, which effectiveness and safety were confirmed in several studies [15–18]. Overall patients tolerated all the steps of the Flebogri<sup>®</sup> procedure very well, and self-assessment of pain perception using a visual analogue scale allows as to generalize that the procedure is not painful. Another additional advantage of this method is quick return to the previous physical activity. In practice, patients who undergo the procedure Flebogri<sup>®</sup> are able to walk directly afterwards and are discharged home in the course of 1 hour. When starting the procedure, we have

a prepackage set at our disposal which consists of all the necessary devices. Performing an analysis of the cost of this approach, revealed to be relatively low, thus making it more accessible for the larger cohort of patients relatively low, it more accessible for a large cohort of patients suffering from varices. Results obtained from 12-month follow-up demonstrated the highly efficacious nature of the procedure reaching 92%. Although 15 of 200 patients experienced recanalization, some of them did not require reintervention- partial recanalization, whereas remaining 10 cases had their vein successfully closed with a second procedure. The low number of complications and a cosmetic effect widely accepted by patients allowed us to add this method to the list of minimally-invasive procedures and should be seriously considered by medical professionals treating superficial vein insufficiencies [14, 19, 20].

## Conclusions

Based on obtained results we were to summarize the following conclusions:

- high 12-month follow-up effectiveness reaching 92% of closed/ablated veins;
- vein diameter is not a limitation for this method;
- the low rate of serious complications;
- good cosmetic effect;
- the method requires further long-term follow-up to fully determine the actual effectiveness of the mechanochemical technique using Flebogri<sup>®</sup>, therefore obtained findings should be treated as preliminary.

## Conflict of interest

None.

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