A systematic review and meta-analysis of mechanochemical endovenous ablation using Flebogrif® for varicose veins: A summary of evidence.

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PMID: 34091106

Published Online: **6 June 2021** | **DOI: 10.1016/j.jvsv.2021.05.010**

Objective

To review and analyse the currently available literature on Flebogrif® and define its role in the global varicose vein treatment devices market.

Methods

A systematic literature search was performed in MEDLINE, Embase, and the Cochrane Library. Studies were eligible if they included patients treated with Flebogrif for saphenous vein incompetence, were published in English, and had full text available. Methodologic quality of the articles was assessed using the Methodological Index for Non-Randomized Studies (MINORS) score. **A random-effects model was used to estimate the primary outcome of anatomical success, defined as occlusion rate of the treated vein.** The estimate is reported with the 95% confidence interval (CI). **Secondary outcomes were clinical success, complication rate, pain during and after the procedure, and time to return to work.**

Results

Five articles met the inclusion criteria, reporting 348 procedures in 392 patients. Four studies reported the 3-month anatomical success and three studies reported the 12-month anatomical success. The pooled 3-month anatomical success rate was 95.6% (95% CI, 93.2%-98.0%). **The 12-month anatomical success rate was 93.2% (95% CI, 90.3%-96.1%).**

The only major complication reported within 3 months was deep venous thrombosis, which was seen in 0.3% of the patients. The minor complications thrombophlebitis and hyperpigmentation were seen in 13.3% to 14.5% and in 3.3% to 10.0%, respectively, within 3 months. The methodological quality of the studies included was moderate.

MOCA using the Flebogrif device is a safe and well-tolerated procedure for the treatment of saphenous vein insufficiency.

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Characteristics of included studies

Investigator	Design	Period	Aim	Inclusion criteria	Exclusion criteria
Ammollo et al,[12] 2020	Prospective comparative	1/2019-5/2019	To assess efficacy of Flebogrif® by varying POL foam concentrations	Chronic venous disease symptoms; reflux at SFJ; linear GSV without large, tortuous truncular collaterals; GSV diameter at SFJ level of #60 mm	NR
Ciostek et al,[9] 2015	Prospective case series	2011-2013	To assess efficacy and safety of Flebogrif®	Primary GSV or SSV incompetence; CEAP C2-C6	NR
Iłżecki et al,[10] 2019	Prospective case series	2013-2015	To assess efficacy and safety of Flebogrif®	Primary GSV or SSV incompetence	NR
Soliman et al,[11] 2019	Prospective case series	10/2018-5/2019	To assess efficacy and safety of Flebogrif®	Age $18 years; primary GSV or SSV incompetence; CEAP C2-C6	Allergy to sclerosant; severely tortuous GSV or SSV; history of deep venous thrombosis, peripheral arterial disease (ABPI <0,8); pregnancy or lactating; anticoagulation with warfarin
Tawfik et al,[13] 2020	Randomized trial	1/2017-10/2018	To compare Flebogrif® and EVLA	Primary GSV incompetence with or without incompetent perforators based on DUS; CEAP C2-C4	Pregnancy; history of superficial thrombophlebitis, deep vein thrombosis, pulmonary embolism; venous ulcers (healed or active); severe medical illness (cardiac, hepatic, renal, cancer, bleeding disorders); recurrent VV; anticoagulant therapy; peripheral arterial disease; vasculitis; internal pacemaker

ABPI, Ankle brachial pressure index; *CEAP*, clinical, etiology, anatomy, pathophysiologic; *DUS*, duplex ultrasound; *EVLA*, endovenous laser ablation; *GSV*, great saphenous vein; *POL*, polidocanol; *SFJ*, saphenofemoral junction; *SSV*, small saphenous vein; *VV*, varicose veins.

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Baseline data of included studies

Characteristic	Ammollo et al, 2020	Ciostek et al, 2015	Investigator Iłżecki et al, 2019	Soliman et al, 2019	Tawfik et al, 2020
Patients, No.	23 (100)	39 (100)	200 (100)	30 (100)	50 (100)
Male sex	4 (17)	6 (15)	30 (15)	10 (33)	17 (34)
Legs, No.	24	39	200	35	50
Age, years	NR	52 ± 16	51	NR	34 ± 10
CEAP	NR		NR	NR	
C2		5			0
C3		9			16
C4		12			34
C5		7			0
C6		6			0
Mean total score	NR	NR	7.6	NR	NR
Mean total VCSS	NR	5.9	10.7	NR	11
Treated vein					
GSV	24	NR	172	33[a]	50[b]
SSV	0	NR	28	6[a]	5[b]
GSV diameter, mm	4.6 ± 0.5	6.2 ± 2.0	6.2 (3.8-17.1)	6.2	11.3 ± 3.9
SSV diameter, mm	NR	5.6 ± 2.7	6.2 (3.8-17.1)	NR	NR
Polidocanol concentration, %				NR[c]	
1.5	12	0	0		0
2.0	12	39	0		50
3.0	0	0	200		0
Post-treatment compression, days	NR	21-24	28	10	NR
Ultrasound surveillance	3	1, 3, 6, and 12 months	1 week; 1, 3, 6, 12, and 24 months	1 and 3 months	1 week; 1, 6, and 12 months

CEAP, Clinical, etiology, anatomy, pathophysiologic; *GSV,* great saphenous vein; *NR,* not reported; *SSV,* small saphenous vein; *VCSS,* venous clinical severity score.
Data presented as number (%) or mean ± standard deviation, unless stated otherwise.
[a] Nineteen unilateral GSV, five bilateral GSV, two unilateral SSV, four unilateral GSV and SSV.
[b] Forty-five unilateral GSV and five unilateral GSV and SSV.
[c] Soliman et al reported the use of polidocanol 2% for veins with a diameter of 15 mm and polidocanol 3% for veins of a larger diameter; the specific number of patients in each group was not reported.

Conclusion

MOCA using the Flebogrif device is a safe and well-tolerated procedure for the treatment of saphenous vein insufficiency. However, well-designed studies of sufficient sample size and follow-up are required to compare the effectiveness with other endovenous treatment modalities and define the definitive role of the Flebogrif device.