

Safety and efficacy of venous mechano-chemical ablation of the great saphenous vein

Ahmed A. Shaker, Ahmed Maged Farghaly, Ahmed Mohsen Hafez, Mohamed Fawzy Khattab, Marwan Yousry

Department of Vascular and Endovascular Surgery, Faculty of Medicine, Cairo University, Egypt

Abstract

Introduction: Endovenous mechano-chemical ablation of the incompetent great saphenous vein (MOCA) is a new technique that combines mechanical endothelial injury and infusion of a sclerosant agent.

Material and methods: This is a prospective study was conducted on 40 patients who presented with the chronic venous disease at Kasr Al Ainy outpatient vascular surgery clinic with CEAP classification namely C2–C6.

Results: A total of 40 patients were presented with great saphenous vein incompetency, the mean age was (30), 23 patients were male and 17 were female. The vein occlusion rate at one month was 93 percent and at six months was 87 percent respectively.

Conclusions: Endovenous mechanochemical ablation is a safe and effective method for the management of incompetent great saphenous veins compared to open surgery.

Key words: ablation; mechanocheical; incomptent; endovenous

Acta Angiol 2023; 29, 1: 10–14

Introduction

During the last decade, there have been many types of minimally invasive procedures used for the management of great saphenous vein incompetency as endovenous laser ablation and radiofrequency ablation [1].

These techniques have a higher success rate of up to 95% at 5 years follow-up compared to surgical methods [2].

However, these techniques depend on the delivery of a high dose of thermal energy to the walls of the veins under tumescent anesthesia guided by ultrasound which is time-consuming, painful, and have many complications such as skin burns and thrombosis [3].

Recently a new technique was used using the device ClariVein™ by a combination of mechanical injury of the vein walls together with an infusion of a sclerosant agent [4].

Material and methods

Study method and population

This is a prospective study that included 40 patients who presented with chronic venous disease. At Kasr Al Ainy outpatient vascular surgery clinic. 40 patients underwent endovenous ablation by Flebogrif™.

All patients willingly consented after explaining to them the points aforementioned in the study protocol.

Address for correspondence: Ahmed A. Shaker MD, Department of Vascular and Endovascular Surgery, Faculty of Medicine, Cairo University, Egypt, phone: 01063539447, e-mail: ahmed.alaaeldin@kasralainy.edu.eg

Received: 28.05.2022

Accepted: 16.05.2023

Early publication date: 27.06.2023

This article is available in open access under Creative Common Attribution-Non-Commercial-No Derivatives 4.0 International (CC BY-NC-ND 4.0) license, allowing to download articles and share them with others as long as they credit the authors and the publisher, but without permission to change them in any way or use them commercially.

Table 1. CEAP CLASSIFICATION (Clinical classification)

CEAP CLASSIFICATION (Clinical classification)
C0: no visible or palpable signs of venous disease
C1: telangiectasia or reticular veins
C2: varicose veins
C3: edema
C4a: pigmentation or eczema
C4b: lipodermatosclerosis or atrophic blanche
C5: healed venous ulcer
C6: active venous ulcer

Inclusion criteria

Patients with chronic venous insufficiency according to the CEAP classification namely C2–C6 (Table 1). Patients with refluxing great saphenous vein.

Exclusion criteria

- Patients with a history of stripping of the great saphenous vein.
- Obstruction or incompetence of the deep venous system.
- Peripheral arterial disease (ABI < 0.9).
- Superficial thrombophlebitis of a great saphenous vein.

Preoperative preparation

All patients did preoperative: (Complete blood count, Coagulation profile, Kidney function, Liver function).

Preoperative duplex

Duplex Ultrasound scanning was done to document the patency of the deep venous system and to evaluate the extent and severity of the reflux of the superficial veins (GSV, small saphenous vein, and perforators) and measuring the dimensions of the veins of patients in standing position.

Mechano chemical ablation procedure

In this study, we used the Flebogrif© device (Balton, Warsaw, Poland). We used the 90 cm catheter.

This catheter was designed as a typical diagnostic catheter. This catheter has a metal shank, attached to 5 thin, curved, springy wires with sharpened ends. After being pushed out of the catheter, these wires deployed into a cat's claw pattern. When the whole device (catheter and shank with open claws) is being pulled out, sclerosing foam is injected.

The patient is laid supine and is prepped first using povidone iodine. After applying sterile surgical drapes. The GSV is located below the knee under ultrasound guidance. Local anesthesia of xylocaine 1% is injected

at the desired point of puncture. The GSV access is established below the knee joint using a 6 French sheath.

Following placement of the starter wire, the Flebogrif© device is deployed up to a point 3 cm before the saphenofemoral junction. The chemical sclerosant agent used was aethoxysclerol 3% with a ratio of 1 cm sclerosant for every 5 cm of the vein. Foam preparation of the aethoxysclerol was done using a ratio of 1 cm foam to 4 cm of air using the Tessari technique.

The device's abrasive metal nails are deployed and the device is withdrawn backward with simultaneous injection of the sclerosant agent, inducing mechano-chemical ablation.

Postoperative

Patients were observed for any hematoma formation or any intolerable pain. Patients are prescribed class II thigh-high elastic stockings to be worn for three months. They were discharged the same day home. Follow-up duplex was done immediately post-operative, 1 month and 3 months, and 6 months.

Results

A prospective study was conducted on 40 patients presented with great saphenous vein incompetency, the mean age was (30.73 ± 6.96) years, 23 patients were male (57.5%) and 17 were female (42.5%).

9 of our patients were complaining of active ulcers (C6) and 31 patients presented with visible varicose veins, edema, lipodermatosclerosis, and healed ulcers (C2–C5).

All of our patients complained of unilateral lower limb affection except for one patient; a young gentleman who had bilateral lower limb affection but the more severe left lower limb for which he was operated upon.

Diameter of GSV

Diameter comparison of upper thigh great saphenous vein dimension at the time of presentation, 3 days postoperative and one month postoperative, initially the mean diameter of GSV was 9 mm, immediately postoperative was 5 mm, and one month postoperative the mean diameter was 3 mm (Table 2).

Table 3 shows the P-value with a significant reduction in GSV diameters postoperatively and at one month.

Table 2. Comparison of GSV diameters pre and post-operative

	Age	GSV diameter initially	GSV post-op	GSV 1 month post-op
Mean	31	9	5	3
Standard deviation	6.96	0.61	0.22	0.19
Minimum	21	8	4	2
Maximum	44	10	5	3
Median	30.00	8.50	4.50	2.80

Table 3. P-value of GSV pre and post-operative

	Mean	Standard deviation	P value compared to initial
GSV diameter initial [mm]	8.51	0.61	–
GSV diameter post op [mm]	4.53	0.22	< 0.001
GSV diameter 1 month [mm]	2.71	0.19	< 0.001

Three-month and six-month follow-up duplex results

The courses of the treated GSV, deep veins, and axial veins were investigated by Duplex ultrasound for visibility, compressibility, blood flow, and reflux. A re-canalization of GSV or failure of intervention was defined as a patent segment of the treated vein more than 5 cm in length. The criterion for a varicose vein was a visible or palpable varicosity with a diameter of more than 3 mm.

At 3 months post-operative two of the cases had a recanalized Great saphenous vein while At 6 months four of the patients had a visual recanalized GSV.

Improvement in symptoms

Comparison between the pre-operative and post-operative serial measurements revealed a significant decrease in pain on the stand ($p < 0.0001$) and a non-significant difference regarding wound healing ($p > 0.05$) (Fig. 1).

Post-operative complications

We had no complications in the form of hematoma bruising or severe pain or deep venous thrombosis in the follow-up window of 6 months interval.

Discussion

Mechanochemical ablation of a great saphenous vein considered a new management strategy that is very promising and competes with surgical and non-surgical treatments that are adopted for venous disease of lower limbs. Previous studies to assess the success of using mechanochemical ablation to treat the chronic venous disease of the great saphenous vein were done using the ClariVein™, Flebogrif™ devices. Despite that, the results were very hopeful [5].

A Polish study (2021) performed on nine Merino sheep aimed to assess the effectiveness of mechanochemical sclerotherapy of venous veins with a new device — Flebogrif® — based on an animal model. They concluded that the simultaneous use of Flebogrif® and a sclerosant (lauromacrogol) yielded better results of vein lumen reduction than the use of Flebogrif® alone. The preliminary study showed no direct damage done to the vein wall by Flebogrif and a slight increase in wall diameter. In combination, Flebogrif® + sclerosant was observed to increase the connective tissue of the intima [6].

Previous studies on the efficacy of the Flebogrif device show very promising results. The study included 200 patients, 170 females and 30 males treated with ablation with Flebogrif™ to treat varicose veins, initial technical success of the surgery was achieved in all cases. During the first 3-month follow-up, recanalization of the vein occurred in 8 patients. Results showed a statistically significant decrease in the severity of clinical symptoms in comparison to ones before the intervention and between particular days of the observation during the 3-month follow-up. In comparison to our results, we had successful venous occlusion rates where at three months intervals only one patient had a recanalized GSV and at 6 months two patients had a recanalized GSV. Also out of the 40 patients studied 9 had active venous ulcers and 5 completely healed and 4 had partially improved [7].

In a different study also using the Flebogrif device conducted by Piotr Ciostek Et al in 2015 to treat GSV disease and assess the efficacy and safety of this device in such disease, 40 cases were treated with mechanochemical ablation using the Flebogrif device. Efficacy of the procedure at follow-up was 97.4%, 94.9%, 89.7%, and 89.7% at 1, 3, 6, and 12 months respectively [8].

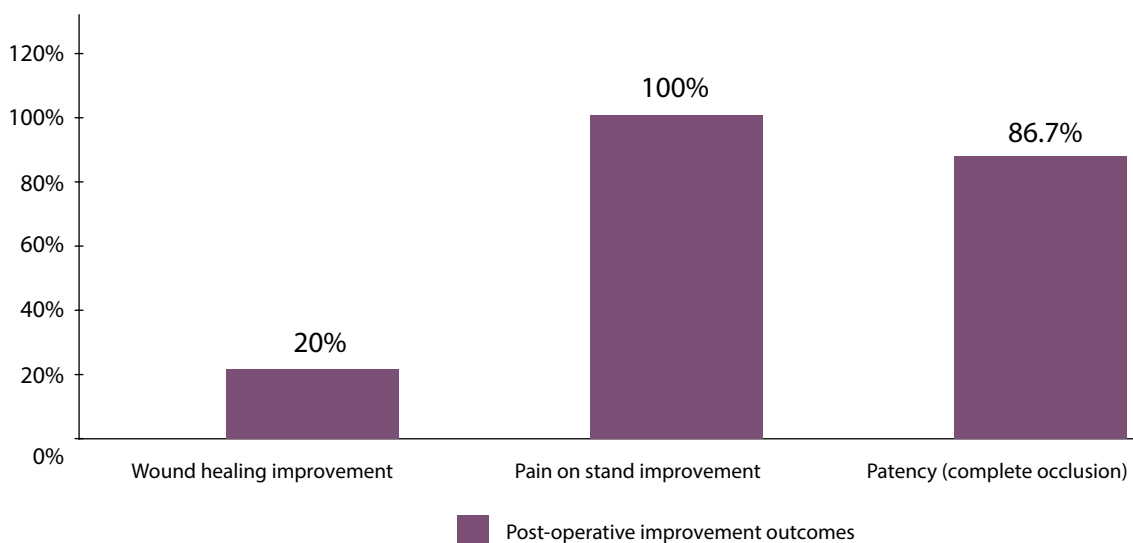


Figure 1. Postoperative outcome

Another randomized trial was done to compare the intra-procedural pain using the ClariVein device and RFA using the visual analog score. Pain values were also recorded at 3- and 6-month follow-ups. About 170 cases were followed over a 21-month period from 240 screened. Patients in ClariVein group experienced less maximum pain significantly during the procedure by Visual Analogue Scale versus RFA 34 mm, $p < 0.003$) and number scale versus RFA $p < 0.002$). 'Average' pain scores were also significantly less in the first group. Results of our trial show significant improvement in the pain score p -value < 0.001 [5].

A study using the ClariVein device was done on patients for the management of symptomatic varicose veins at the Charring Cross NHS Hospital in London. 119 patients have been randomized, with 60 patients using ClariVein and 59 to RFA. Results show that 66% of patients were at one-month follow-up, and the complete or proximal occlusion rates were 92% for both groups. At one month follow-up, the clinical and the quality of life scores for both groups had similar improvements. Compared to our study the vein occlusion rate at one month was 93 percent and at six months was 87 percent respectively [7].

In the meantime, there is no randomized control trial to compare the results of mechanochemical ablation versus endovenous laser ablation.

From our study, we have also come to find that there are fewer complications as regards complications of mechanochemical ablation compared to other interventions. A total of 808 cases were managed with RFA and EVLA (2057 procedures). The success rate of RFA was 98.4%, that equivalent to EVLA at 98.1%.

The success rates of thermal ablation for each vein were: GSV, 98.5%; SSV, 98.2%; ASV, 97.2%; and PVs, 82.4%. The overall thrombotic complication rate was 10.5%. The thrombotic complications include endovenous heat-induced thrombosis (EHIT; 5.9%) and acute superficial venous thrombosis (4.6%). The rate of a thrombotic complication after the procedures for each vein was: GSV, 11.8%; SSV, 5.5%; ASV, 6.5%; and PVs, 2.4%. The thrombotic complication rate was 7.7% for RFA and 11.4% for EVLA ($P < 0.007$) [9].

In a systematic review and meta-analysis conducted by (Alozai et al 2022), five articles met the inclusion criteria, reporting 348 procedures in 392 patients. 4 studies reported the 3-month anatomic success, and 3 studies reported 12-month anatomic success. The 3-month anatomic success rate was 95.6% (95% CI, 93.2–98.0%). The 12-month anatomic success rate was 93.2% (95% CI, 90.3–96.1%). Major complication reported within 3 months was deep vein thrombosis (0.3%) while thrombophlebitis and hyperpigmentation had occurred in 13.3% to 14.5% and 3.3% to 10.0% of patients, respectively, within 3 months. [10].

Conclusions

Mechanochemical ablation is a minimally invasive day-case treatment solution for cases with chronic venous disease. It is an emerging treatment for the management of chronic venous disease that avoids the complications of surgery ranging from anesthetic problems to other complications.

Conflict of interest

None.

References

- Elias S, Raines JK. Mechanochemical tumescentless endovenous ablation: final results of the initial clinical trial. *Phlebology*. 2012; 27(2): 67–72, doi: [10.1258/phleb.2011.010100](https://doi.org/10.1258/phleb.2011.010100), indexed in Pubmed: [21803800](https://pubmed.ncbi.nlm.nih.gov/21803800/).
- Proebstle TM, Vago B, Alm J, et al. Treatment of the incompetent great saphenous vein by endovenous radiofrequency powered segmental thermal ablation: first clinical experience. *J Vasc Surg*. 2008; 47(1): 151–156, doi: [10.1016/j.jvs.2007.08.056](https://doi.org/10.1016/j.jvs.2007.08.056), indexed in Pubmed: [18178468](https://pubmed.ncbi.nlm.nih.gov/18178468/).
- Bos R, Arends L, Kockaert M, et al. Endovenous therapies of lower extremity varicosities: A meta-analysis. *J Vasc Surg*. 2009; 49(1): 230–239, doi: [10.1016/j.jvs.2008.06.030](https://doi.org/10.1016/j.jvs.2008.06.030), indexed in Pubmed: [18692348](https://pubmed.ncbi.nlm.nih.gov/18692348/).
- Boersma D, van Eekeren RR, Werson DAB, et al. Mechanochemical endovenous ablation of small saphenous vein insufficiency using the ClariVein® device: one-year results of a prospective series. *Eur J Vasc Endovasc Surg*. 2013; 45(3): 299–303, doi: [10.1016/j.ejvs.2012.12.004](https://doi.org/10.1016/j.ejvs.2012.12.004), indexed in Pubmed: [23312507](https://pubmed.ncbi.nlm.nih.gov/23312507/).
- Lane T, Bootun R, Dharmarajah B, et al. A multi-centre randomised controlled trial comparing radiofrequency and mechanical occlusion chemically assisted ablation of varicose veins - Final results of the Venefit versus Clarivein for varicose veins trial. *Phlebology*. 2017; 32(2): 89–98, doi: [10.1177/0268355516651026](https://doi.org/10.1177/0268355516651026), indexed in Pubmed: [27221810](https://pubmed.ncbi.nlm.nih.gov/27221810/).
- Rybak Z, Janeczek M, Dobrzynski M, et al. Study of Flebogrif-A New Tool for Mechanical Sclerotherapy-Effectiveness Assessment Based on Animal Model. *Nanomaterials (Basel)*. 2021; 11(2), doi: [10.3390/nano11020544](https://doi.org/10.3390/nano11020544), indexed in Pubmed: [33669987](https://pubmed.ncbi.nlm.nih.gov/33669987/).
- Tomasz Zubilewicz., (2016) "Application of Endovenous Mechanochemical Ablation (MOCA) with Flebogrif TM to Treat Varicose Veins of the Lower Extremities: A Single Center Experience over 3 Months of Observation," *Acta Angiologica*.
- Ciostek P, Kowalski M, Woźniak W, et al. Phlebogriffe – a new device for mechanochemical ablation of incompetent saphenous veins: a pilot study. *Phlebological Review*. 2015; 3: 72–77, doi: [10.5114/pr.2015.57466](https://doi.org/10.5114/pr.2015.57466).
- Rutherford RB. (2014) Chronic venous disorders: non operative treatment. In: Rutherford RB, editor. *Vascular surgery*. 8th ed. Philadelphia: WB Saunders;. p. 858–67.
- Alozai T, Huizing E, Schreve M, et al. A systematic review and meta-analysis of mechanochemical endovenous ablation using Flebogrif for varicose veins. *J Vasc Surg Venous Lymphat Disord*. 2022; 10(1): 248–257.e2, doi: [10.1016/j.jvsv.2021.05.010](https://doi.org/10.1016/j.jvsv.2021.05.010), indexed in Pubmed: [34091106](https://pubmed.ncbi.nlm.nih.gov/34091106/).