

Mechano-Chemical Endo-Venous Ablation of Varicose Veins with Flebogrif Occlusion Catheter

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Abstract

Background: Varicose veins may present a major health problem nowadays, as it has been detected in about 70% of population worldwide. This created a sense of urgency to develop less invasive techniques to manage such a condition.

Aim of Study: The aim of this study was to evaluate the effectiveness and safety of mechano-chemical ablation technique in management of varicose veins using the flebogrif endo-venous occlusion catheter.

Patients and Methods: A total of 30 patients (35 lower limbs) had mechano-chemical ablation for their varicose veins using the flebogrif endo-venous catheter; 22 for great saphenous vein (GSV) incompetence, 9 bilateral GSV, 3 shorts saphenous vein (SSV), one bilateral SSV and 2 combined unilateral great saphenous vein and SSV. Patients came back for follow-up one week, one month and 3 months post procedure having ultrasound duplex done. Recanalization, pigmentation, intra and post procedural pain were recorded, as post-operative complications.

Results: All 35 procedures were under local anaesthesia. Complete occlusion of the treated vein was initially achieved in all the patients, but at 3 months' follow-up, there was only partial recanalization in 2 from 35 (6%) of the veins. Those two were successfully treated with additional complementary ultrasound guided foam sclerotherapy. No significant complications were reported.

Conclusions: Flebogrif is an effective treatment for chronic venous insufficiency of the long and short saphenous veins. Bilateral procedures can be successfully performed and tolerated as can multiple veins in the same setting and same leg.

Key Words: Flebogrif – Mechano-chemical endovenous ablation – varicose veins.

Introduction

VARICOSE veins, since considered a global health condition affecting around 70% of population worldwide, has always been an area of promising research to create an easier treatment plan. Tradi-

tionally, varicose veins have been treated with surgical ligation and stripping under general anaesthesia, but, lately, minimally invasive techniques under local anaesthesia have become areas of growing interest [1]. Minimally invasive techniques like ultrasound-guided foam sclerotherapy (US-GFS), have revolutionized the management of varicose veins [2]. Radiofrequency ablation (RFA) and endovenous laser therapy (EVLT) has gone to the same result. These methods have many benefits including fewer complications, quicker return to work and improved quality of life. Fast rack recovery entails reduced need for postoperative analgesia and improved cosmetic outcome. So, the National Institute of Clinical Excellence (NICE) 2013 guidelines recommends the use of endovenous thermal ablation techniques (RFA and EVLA) as first-line treatment for truncal vein reflux [3].

Tumescent anaesthesia creates a problem for endothermal ablation techniques. As it is currently required in such procedures which carries the rare risk of thermal-related complications such as skin burn and prolonged pain. Tumescence insertion actually can also be painful and may cause complications [4,5].

The flebogrif mechano-chemical occlusion catheter system is a new minimally invasive closure technique. It works by the mechanism of endothelial mechanical damage and chemical injury with a foam sclerosant infusion. Tumescent anaesthesia is not required and no risks of heat-related injury to the surrounding tissue and structures.

Patients and Methods

The study was conducted on 30 patients and 35 lower limbs including 20 females and 10 males who came to the Radiology Department Interventional unit, Ain Shams University Hospital from

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October 2018 to May 2019 who presented with varicose veins after ethical committee approval. After taking their consent; Patients underwent examination and duplex ultrasound evaluation using a Logic P5 ultrasound machine (GE-General Electric Healthcare-USA) preoperative, intraoperative and postoperative follow-up.

We included patients who were:

- 1- Age >18 years old.
- 2- Primary GSV or SSV incompetence.
- 3- CEAP (C2-C6) varicose veins.

We excluded:

- 1- Allergic to sclerosant.
- 2- If their GSV/SSV were severely tortuous.
- 3- History of deep venous thrombosis.
- 4- Peripheral arterial disease (ABPI <0.8).
- 5- Pregnant and lactating.
- 6- Anticoagulation with warfarin.

Flebogrif technique:

All the patients were positioned supine with the leg slightly flexed abducted and externally rotated leg to make both the GSV and the SSV more accessible. This represented an advantage for combined GSV/SSV procedures. No tumescent anaesthesia, sedation or antibiotics were required. All procedures were performed under ultrasound guidance with local anaesthesia (10ml, bupivacaine and Xylocaine mixture) injected at the site of puncture.

We introduce a short micropuncture 5Fr introducer sheath below knee, via Seldinger technique into either the GSV or SSV ultrasound guided and flushed with saline. The flebogrif catheter tip was inserted through the sheath and the tip of the dispersion wire positioned 5cm distal to the Sapheno-femoral junction or Sapheno-popliteal junction. Then the catheter was advanced on the wire to that point, the wire then removed, the five arms of the working part with sharp hooks on the ends were released and directed toward the wall of the vein and scarification of the vein was performed by withdrawing the system with continuous movement to the site of the puncture. The withdrawal speed is approximately 5cm/s and the volume of the injected foam amounted to 1mL/5cm of vein. For veins with a diameter of 15mm, 2% polidocanol was used, and for veins of larger diameter 3% polidocanol.

Post-operative, the patients were advised to wear compression stockings second grade for minimum of ten days.

The assessment included evaluation of GSV/SSV reflux, (clinical, aetiological, anatomical and pathophysiological elements) (CEAP) classification and its follow-up during each follow-up visit.

As for pain, intra and post procedure pain were assessed using visual analog pain scale, which is a straight line with one end meaning no pain and the other end meaning the worst pain imaginable. The patient marked a point on the line that matches the amount of pain he or she feels. Numerical interpretation was done where zero was the least point and 10 was the maximum pain available.

Follow-up visits were scheduled at one week, one, three and six months after procedure.

Statistical analysis:

The analysis of data was done using IBM SPSS statistics (V. 24.0, IBM Corp., USA, 2016). Quantitative and qualitative data are expressed as mean \pm SD, frequencies, and percentages.

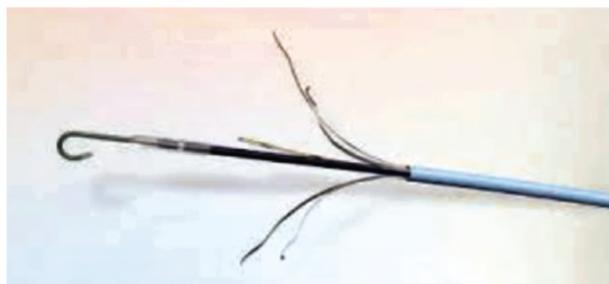


Fig. (1): The tip and distal end of the flebogrif catheter while it opened and hooks are seen with a wire in its center.



Fig. (2): Preparation of foam sclerotherapy by mixing 1ml sclerosant with 4ml of air by Tessari method.



Fig. (3): Site of introduction of short micro-puncture 5Fr introducer sheath below knee using Seldinger technique.



Fig. (4): Mechanism of mixing and injection the foam sclerotherapy.

Results

The study was conducted on 30 patients and 35 lower limbs operated upon including 20 females and 10 males diagnosed by means of Doppler ultrasound with great saphenous vein or small saphenous vein insufficiency or both. All patients qualified for mechano-chemical ablation of the saphenous vein using the Flebogrif system.

Among our patients; 19 patients suffered from unilateral great saphenous vein insufficiency, 2 of them were right sided and 17 were left sided. 2 patients had short saphenous vein insufficiency both on the left side.

4 patients had both great and short saphenous veins insufficiency, all on left side, and 5 patients had bilateral great saphenous insufficiency.

Table (1): Showing the distribution of number of patients according to affected vein.

	Unilateral	Bilateral
GSV	19	5
SSV	2	
Both GSV and SSV	4	—

Mean diameter for great saphenous incompetent vein was 6.5mm.

CEAP score improved markedly starting intra procedural and declining through the follow-up visits.

The effectiveness of the Flebogrif TM catheter was estimated based on the ratio of the number of total venous closure to the number of venous recanalization.

Complications:

During the 3-month follow-up, three cases developed recanalization, all were cases of short segment partial recanalization. Two cases were partial recanalization of great saphenous vein and one case was recanalization of the small saphenous vein.

Four of our patients presented in the follow-up visit with venous phlebitis which only resolved in one week, requiring only anti-inflammatory & corticosteroids cream.

At the one week follow-up visit, one case showed pigmentation along the course of the treated vein.

As for pain during the procedure and on assessment during follow-up visits, intra and post procedure pain was assessed using visual analog pain scale. Mean measurement of VAS scale intra procedural was 6. One week follow-up visit the average pain scale measurement for patients was 3.2; which decreased to 1.2 at one month visit, and at 3 months visit, patients reported no pain at all.

Table (2): Showing of frequency of occurrence of complications.

Complication	Number of patients(n)	Frequency (%)
Recanalization	3	12
Phlebitis	4	16
Pigmentation	1	4

Complementary foam sclerotherapy was performed in 16 patients (10 women, 6 men) during the 4 weeks follow-up visit after treatment. The volume of sclerosant foam ranged from 5 to 10mL and the polidocanol concentration was 2% during follow-up.

Fig. (5 A,B): Male patient 42 years old, picture (a): Showing varicose veins along the medial & posteromedial left leg along the great saphenous vein course with underlying tagged perforators. (b): Showing marked improvement and disappearance of varicosities post mechanic-chemical Flibogrif™ ablation & adjuvant foam sclerotherapy for the perforators.



Fig. (6 A,B): Male patient 44 years old, (a): Showing tortuous GSV varicosities along the thigh region. (b): Showing the patient after 1 month follow-up visit post mechanic-chemical Flibogrif™ ablation with disappearance of the varicose veins yet with pigmentation effect which improved latter on follow-up visits after anti-inflammatory topical application.

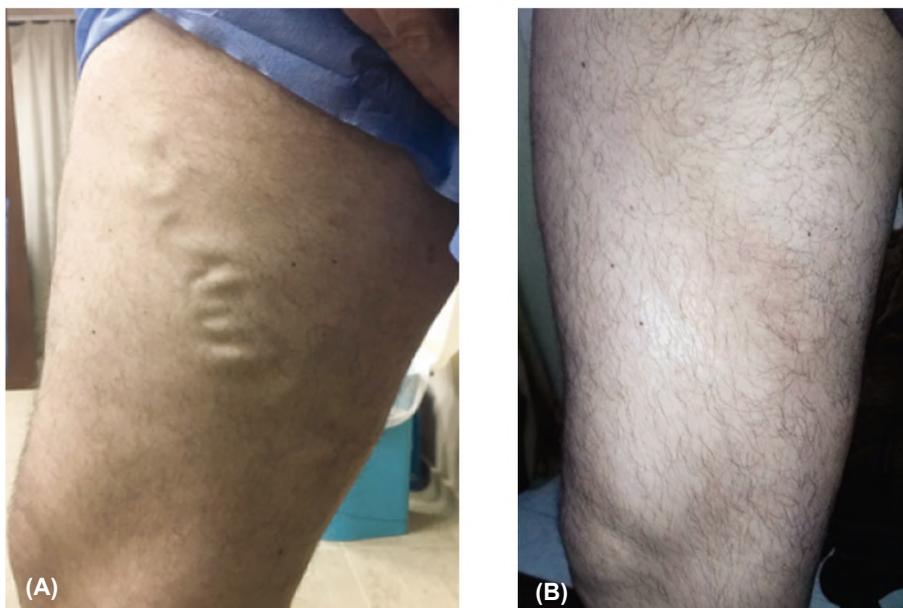
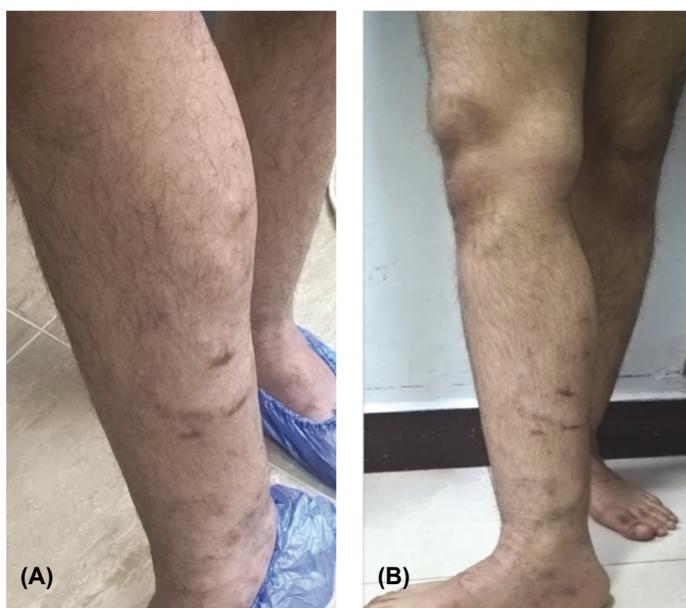


Fig. (7 A,B): 36 male patient with leg scars of previous surgical phlebectomies presented with recurrent GSV distribution varicose veins with images showing pre & post mechano-chemical ablation with flebogrif catheter



Discussion

Percutaneous intravascular ablation methods for insufficient superficial veins like thermal ablation techniques included Radiofrequency ablation (RF) and Endovenous Laser Treatment (EVLT) were associated with side effects including pain, paresthesia, hematoma, and transient skin discoloration, which occur in a relatively small percentage of patients. Other serious complications, such as injury of the deep veins, iatrogenic arteriovenous fistula were reported to occur [6-11].

Other promising treatment options include non-thermal methods based on mechano-chemical venous ablation (MOCA), cyanoacrylate adhesives, or microfoam obliteration. All these methods, which are free of thermal effects, cause less trauma and fewer local complications and provide a valid alternative to thermal methods [12].

On the other hand, scaling back on the anaesthesia (no tumescence) introduces a risk to the heart of minimally invasive treatment namely periprocedural or postoperative pain [12].

The new, alternative system of mechano-chemical ablation presented in this study, Flebogrif, is significantly a simple system, Flebogrif which does not require an expensive starting system. When performing operations on a small diameter vein (<4mm) the risk of vessel perforation in the Flebogrif system appears to be minimal. The system also allows effective operation on veins with a diameter exceeding 20mm, our results reached 92 % after 3 months of follow-up [13].

Limitations:

Complete evaluation of the quality of the mechano-chemical occlusion method for treatment of chronic venous insufficiency with the Flebogrif catheter needs longer period of follow-up post-procedural.

Conclusions:

The Flebogrif system is a safe and highly efficient with high occlusion rate after three months of follow-up reaching 92%. The procedure showed good cosmetic results and low complications. Treating venous insufficiency with the Flebogrif catheter seems to improve patients' quality of life and reduce post-procedural period complications.

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الإستئصال الآلى الكيمايى لأوردة الدوالى عن طريق قسطرة إنسداد الفليبوغريف

القصور الوريدى المزمن هو مشكلة صحية كبيرة فى جميع أنحاء العالم. تشير التقارير إلى أن ٧٠٪ من السكان قد يعانون من الدوالى مرة واحدة فى حياتهم. هذا خلق شعور بالإلحاح لتطوير تقنيات أبسط لعلاج مثل هذه الحالات.

يمكن إستخدام الفليبوغريف لتقليص الدوالى من الصافن الطويل والقصير. يمكن تنفيذ الإجراءات الثنائىة بنجاح، ويمكن تحملها جيداً مثل الأوردة المتعددة فى نفس المكان ونفس الساق. النتائج المبكرة واعدة ولكن هناك حاجة إلى مزيد من المتابعة على المدى الطويل.