

Catheter-directed foam sclerotherapy: a new technique for treating varicose veins

Islam Atta^a, Amr El Abd^b, Haitham Fouda^c, Ahmed Sawaby^d

Departments of ^aVascular Surgery,

^cRadiodiagnosis, Faculty of Medicine, Kafrelsheikh University, Kafrelsheikh,

^bDepartment of Radiodiagnosis, Faculty of Medicine, Alexandria University, Alexandria,

^dDepartment of Vascular Surgery, Faculty of Medicine, Port Said University, Port Said, Egypt

Correspondence to Islam Atta, 40 Khalil Motran Street, Saba Basha, Alexandria, Egypt.
e-mail: islamatta81@gmail.com

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Objectives

This was an observational prospective study to assess the safety and efficacy of catheter-directed foam sclerotherapy (CDFS) in the treatment of axial reflux and incompetence of saphenous veins with short-term to mid-term follow-up.

Patients and methods

A total of 20 patients [11 (55%) male and nine (45%) females] with either reflux of the long saphenous vein and/or short saphenous vein were subjected to CDFS. Overall, 10 ml of foam using polidocanol 2% was injected via long catheter into the saphenous vein. Then patients were followed up on 1 day after procedure, 1 month, 3 months, 6 months, and 1 year by duplex and clinically using visual analog scale (assess satisfaction of the patients which is related to improvement of their symptoms).

Results

After 1 year, 90% of the patients were satisfied by using visual analog scale, 85% (17 patients) had total ablation of the saphenous vein and 15% (three patients) had partial recanalization, with resultant reflux in two (10%) patients and one (5%) patient had competence of the saphenous vein owing to reduction of its diameter. One patient had deep venous thrombosis (5%), one patient had superficial thrombophlebitis (5%), and one patient had hyperpigmentation of the skin (5%).

Conclusion

CDFS is a safe and cost-effective procedure for treating axial reflux and incompetence of saphenous veins in terms of clinically and duplex-based outcome at short-term and mid-term follow-up.

Keywords:

catheter directed, foam sclerotherapy, varicose vein

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Introduction

More than 20% of the population are complaining of varicose veins (swelling, heaviness, disfigurement, etc.) and its complications like superficial thrombophlebitis (STP), bleeding varicose veins, and venous ulcers [1]. Many treatment modalities have been proposed such as saphenofemoral disconnection and stripping, phlebectomy, endovenous thermal ablation using laser or radiofrequency catheters, and endovenous chemical ablation by foam sclerotherapy or cyanoacrylate embolization. Recurrence rates at 5 years were reported to be 30% by some authors [2,3].

Data from the literature showed inferiority of chemical ablation using foam sclerotherapy in comparison with thermal ablation or surgery in terms of occlusion rate [4,5]. Although foam sclerotherapy has been proved to be effective in treatment of saphenous vein, its tributaries, perforators incompetence, venous ulcers, and venous malformations, data showed increased rates of recanalization for large veins with increased diameters owing to increased volume of the blood content which deactivates liquid and foam sclerosing

agent [6,7]. The use of the catheter as a method of delivering foam sclerosant material is proposed to deliver sclerosant material with better distribution, and also the use of intrasaphenous irrigation with saline is proposed to achieve nearly blood-free saphenous vein before delivering of sclerosing material to get better results [8–19].

Foam sclerotherapy usage had increased markedly in the past decades, as it is considered the least expensive modality for treating reflux in long and short saphenous vein, and it also does not require anesthesia with an acceptable safety profile and efficacy. Sclerosing agents damage the endothelium of the vessel by disrupting its cell membrane, resulting in spasm of the vessel ending with fibrous occlusion of the vessel [20,21]. So the aim of this work was to assess the efficacy of catheter-directed foam sclerotherapy (CDFS) in treating

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varicose veins in terms of ablating of saphenous veins, degree of reflux, improvement of symptoms assessed by visual analog scale (VAS) [22,23], and treating complications, like healing of venous ulcers and cure of bleeding varicose veins.

Patients and methods

After taking a written consent from patients and approval from the ethical committee of Aswan University Hospital, 20 patients were included in this study (11 males and nine females). This study was approved by the ethical committee of Aswan University Hospital. It was performed on 20 patients (11 males & 9 females) each patient signed his consent. These patients were admitted in Aswan University Hospital and other vascular centers in Egypt in the period between January 2018 and March 2019.

Inclusion criteria

The following were the inclusion criteria:

- (1) Any patient with primary varicose vein (C2), and edema (C3), lipodermatosclerosis (C4), and healed and active ulcers (C5 and C6, respectively).
- (2) Refluxing saphenofemoral junction (SFJ) and/or refluxing saphenopopliteal junction by colored duplex.
- (3) Patients with bleeding varicose veins.

Exclusion criteria

The following were the exclusion criteria:

- (1) Any patient with secondary varicose veins [deep venous thrombosis (DVT)], acute STP, thrombophilic patients, patients with cancer, and pregnant patients.
- (2) Markedly dilated varicosities with excessive tortuosity.
- (3) Patients with pulmonary hypertension, history of previous pulmonary embolism, symptomatic patent foramen ovale, renal or cardiac disease, or critical lower limb ischemia.
- (4) Patient with allergy to the sclerosant material (polidocanol).

Methods

All patients were subjected to detailed history taking regarding symptoms (pain, heaviness, swelling) and its duration, and occurrence of complications, followed by full body examination, and then detailed vascular examination for the lower limbs, such as examination of the pulses and site of varicosities. Laboratory investigations were done, such as complete blood picture, prothrombin time, and

international normalized ratio. Radiological investigations were done in the form of colored duplex examination to detect any reflux either at SFJ, saphenopopliteal junction, and/or perforators and also to exclude recent or old DVT.

Technique

Local anesthesia was applied at puncture site (mostly few centimeters below the knee) using 2 ml xylocaine 2%. Leg was positioned in dependent position. Ultrasound-guided puncture for the long saphenous vein at below-knee level was done using Seldinger technique. A standard guide wire 0.035 was introduced through the vein followed by insertion of 6-Fr long sheath reaching about 4 cm distal to SFJ. Elevation of legs was done followed by frequent irrigation with 0.9% normal saline through the side port of the sheath to wash most of the blood inside the vein. Overall, 10 cm of foam sclerotherapy using polidocanol 2% as sclerosant material was prepared for injection in a ratio of 4 : 1 (4 cm air to 1 cm liquid). Compression at SFJ was applied without occluding deep vein to allow wash of sclerosant material if some of it escaped into deep vein. Foam was injected gradually while slowly removing of the sheath. Gauze application was done at the puncture site followed by compression using class II elastic stocking for one week (Figs 1 and 2).

Follow-up of the patients by duplex was done to detect occlusion, partial occlusion, or recanalization of the saphenous vein and the degree of reflux, and also change in the diameter of the vein was measured. Improvement of symptoms was assessed by VAS. A VAS is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. It is often used in epidemiologic and clinical research to measure the intensity or frequency of various symptoms. For example, the amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain. From the patient's perspective, this spectrum appears continuous±their pain does not take discrete jumps, as a categorization of none, mild, moderate, and severe would suggest. The simplest VAS is a straight horizontal line of fixed length, usually 100 mm. The ends are defined as the extreme limits of the parameter to be measured (symptom, pain, and health) orientated from the left (worst) to the right (best). In some studies, horizontal scales are orientated from right to left, and many investigators use vertical VAS [22,23]. Moreover, occurrence of complications was detected such as STP, DVT, pulmonary embolism, tissue

Figure 1



Technique of insertion of the catheter inside the long saphenous vein to deliver the foam using Seldinger technique.

necrosis, and hyperpigmentation. Clinical follow-up of the patients was done, as well as assessment by the VAS at one day after procedure, 1 month, 3 months, 6 months, and 1 year later. Follow-up by duplex was done on one day and at 1 year after the procedure.

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package, version 20.0. (IBM Corp., Armonk, New York, USA). The Kolmogorov–Smirnov test was used to verify the normality of distribution of variables. Comparisons between the different stages for categorical variables were assessed using McNemar–Bowker, whereas Friedman test was assessed for comparison between different periods for abnormally distributed quantitative variables and followed by post-hoc test (Dunn's) for pairwise comparison. Significance of the obtained results was judged at the 5% level.

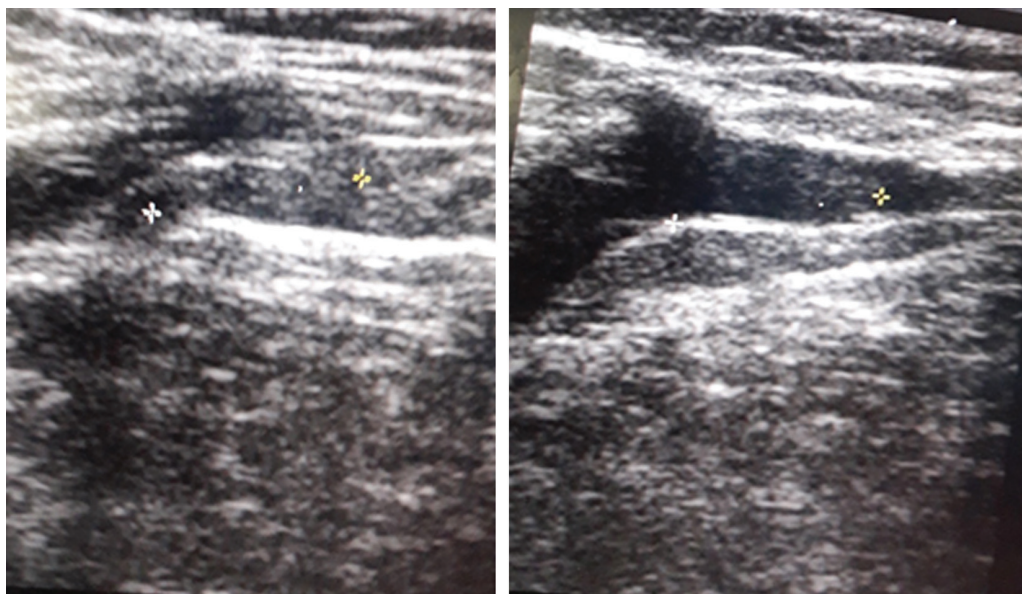
Results

This study included 20 patients, comprising 11 (55%) males and nine (45%) females. Their demographic data, clinical examination, duplex results, incidence of complications, and their clinical staging are summarized in Table 1.

By comparing the results of duplex for the 20 patients who underwent this study, there was a statistically significant difference ($P < 0.001$) between the reflux before and following CDFS (Table 2).

There was a statistically significant difference regarding patients' symptoms (pain, heaviness, and swelling) before and after serial times of follow-up, which was assessed by the VAS, denoting marked improvement of patients' symptoms (Table 3 and Fig. 3).

Figure 2



Tip of the catheter about 4 cm away from SFJ (ultrasound guided). SFJ, saphenofemoral junction.

Discussion

Recent therapy for sclerotherapy depends on the ultrasound device, probes, and the sclerosing agent, which damages the intima of vein wall and subsequently changing the vein wall and replacing its lumen by collagen fibers. The usual procedure used is by injection of the foam using peripheral intravenous cannula or butterfly needle. Tessari described the CDFS, and also Parsi discussed its various types because using these catheters gives better results in ablation of the veins. Usage of CDFS for treatment of varicose vein and injection with low pressure while withdrawing the catheter reduces the amounts of foam going into the deep veins, which passes mainly via thigh perforators into the deep veins [19,24–28]. Therefore, the aim of this study was to assess the efficacy of this method in treating varicose vein and comparing our results with previous studies results.

Camillo had performed CDFS for 46 patients with median follow-up of 54 months. Of the 46 patients, 34 (73.9%) had complete occlusion rate, and then after 1–2 years, four (11.7%) patients presented with very small great saphenous vein (GSVs), with diameters of less than 2 mm, and fibrotic saphenous veins. Partial occlusion occurred in 10 (21.7%) of 46 patients, and complete failures were seen in two (4.3%) of 46 patients. In all these patients, except patients with complete failure, there was reduction of symptoms and varicose veins and decreased CEAP. There was no recurrence of varicose veins in the groin in any patient. Regarding complications of the procedure, DVT was

reported in 1.5%, STP less than 0.5 mm from femoral vein without DVT in 3%, and phlebitis in 3.1% of the patients. In the current study, complete occlusion of the vein was revealed in 17 (85%) of 20 patients and partial occlusion was revealed in three (15%) of 20 patients, with resultant reflux in two (10%) patients, which was considered as a failure of the procedure, and in one (5%) patient although he had partial occlusion, there was no reflux owing to reduction of the vein diameter to 2.5 mm. Regarding complications, we had one (5%) patient who developed DVT, one (5%) patient had STP, and one (5%) patient had hyperpigmentation. This small difference between the current study and the study by Camillo [29] may be owing to shorter time of follow-up in this study, which is 12 months, and also smaller number of cases.

Devereux and colleagues had performed CDFS on 20 patients. After 12-month follow-up, they revealed in 15 (75%) of 20 patients, their targeted GSVs were fully occluded, four (20%) of 20 patients had partial occlusion of GSV, and one (5%) patient of 20 patients was classified as treatment failure. The overall satisfaction rate for the procedure was 92%. Regarding complications, no patients had DVT, 10% of patients had STP, persistent hyperpigmentation in 15% of patients, and matting in 25% of patients. In the current study, complete occlusion of the vein was revealed in 17 (85%) of 20 patients and partial occlusion was revealed in three patients of 20 (15%) patients, with resultant reflux in two (10%) patients, which was considered as a failure of the

Table 1 Distribution of the studied cases according to different parameters (N=20)

	n (%)
Sex	
Male	11 (55)
Female	9 (45)
Age	
<40	11 (55)
≥40	9 (45)
Mean±SD	39.5±9.1
Median (minimum–maximum)	38.5 (22–55)
Clinical staging	
C2	4 (20)
C3	5 (25)
C4	5 (25)
C5	1 (5)
C6	5 (25)
Bleeding varicose veins	
No	17 (85)
Yes	3 (15)
Duration of symptoms (years)	
Mean±SD	7.2±4.3
Median (minimum–maximum)	7.5 (1–14)
Complications of the procedure	
None	17 (85)
STP	1 (5)
DVT	1 (5)
Hyperpigmentation	1 (5)
CBC	
Normal	20 (100)
INR	
Normal	20 (100)
Arterial examination	
Mean±SD	1±0.1
Median (minimum–maximum)	1 (0.8–1.1)
Healing of venous ulcer after 1 year	
No healing	2 (40)
Complete healing	3 (60)
Patient satisfaction according to VAS	
Not satisfied	2 (10)
Satisfied	18 (90)
Diameter of the vein	
Pre	
Mean±SD	6.3±1.3
Median (minimum–maximum)	6.5 (4–8)
Post	
Totally ablated	17 (85.0)
Partial recanalization	3 (15.0)
Reflux by duplex (pre)	
SFJ	16 (80)
SPJ	4 (20)
Both	0

CBC, complete blood count; DVT, deep venous thrombosis; INR, international normalized ratio; SFJ, saphenofemoral junction; SPJ, saphenopopliteal junction; STP, superficial thrombophlebitis; VAS, visual analog scale.

procedure, and one (5%) patient, although he had partial occlusion there was no reflux owing to reduction of the vein diameter into 2.5 mm. The

Table 2 Comparison between the saphenous vein reflux before and after treatment by using duplex

	Reflux by duplex		McN _P
	Pre	1 year	
Incompetent	20 (0)	2 (10)	<0.001*
Competent	0 (100)	18 (90)	

McN_P, *P* value for McNemar test for comparing between the two studied periods. *Statistically significant at *P* value less than or equal to 0.05.

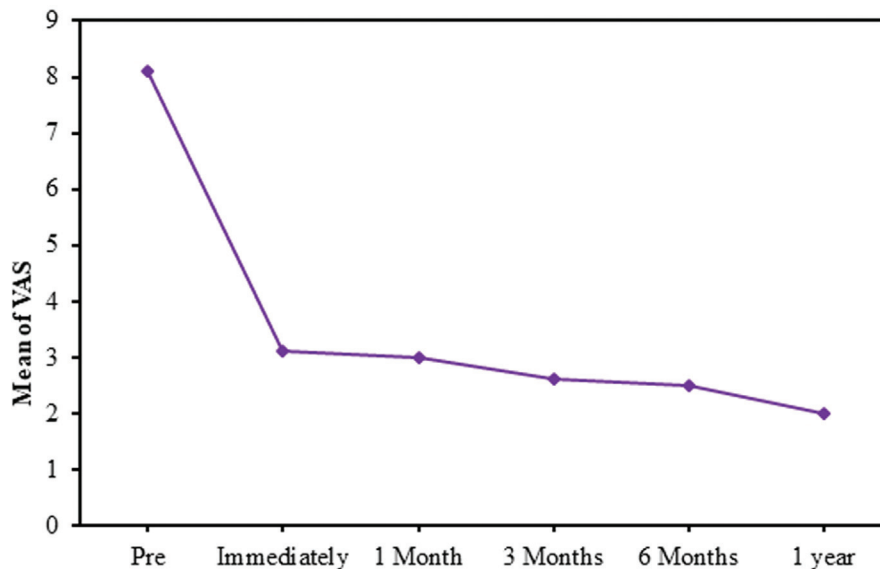
satisfaction rate in the current study was 90%. So the current study results and those of Devereux and colleagues are comparable. Devereux *et al.* [30] also performed CDFS plus using tumescent anesthesia on another group of patients, and their 12-month duplex ultrasound showed full occlusion of GSV in 17 patients of 23 (73.9%) patients, partial occlusion in two (8.7%) patients out of 23, and treatment failure in four (17.4%) patients out of 23. So they revealed no significant differences between both of their groups.

Lindblad and Kölbel had performed CDFS for 243 patients owing to superficial venous insufficiency and with documented axial reflux either in the GSV (*n*=207) or the lesser saphenous vein (*n*=36). Their median age was 59 years (22–94, 95 years) and 55% were females. After 1 year, complete occlusion of GSV was revealed in 72% of patients, partial occlusion in 17% of patients, and complete failure with recanalization and reflux in 11% of patients. Complete occlusion of short saphenous vein was revealed in 87% of patients, partial occlusion in 4% of patients, and complete failure with recanalization and reflux in 9% of patients. About patient satisfaction which depends on the decrease of patient symptoms (pain, heaviness, and swelling), 92% of patients were satisfied. In 33 (70%) patients of 47 patients who had venous ulcer (C6), their ulcers were healed, eight patients their ulcers were under healing, four patients had combined venous and arterial ulcers, one patient had an ulcer which was not healed despite treatment, and one patient was diagnosed later to have squamous cell carcinoma of the skin. Only two (0.8%) patients of 243 had thromboembolism [31]. In the current study, satisfaction rate was 90%. Three (60%) patients with venous ulcer out of five patients (C6) had healing of their ulcers, and in the other two patients, their ulcers were under the state of healing. So the current study results and those of Lindblad and Kölbel are comparable.

Table 3 Comparison between the different periods according to visual analog scale

VAS	Pre	1 day	1 month	3 months	6 months	1 year	Fr	P
Mean±SD	8.1±0.8	3.1±1	3±0.9	2.6±1.2	2.5±1.8	2±2.2	69.874*	<0.001*
Median (minimum–maximum)	8 (6–9)	3 (2–6)	3 (2–6)	2 (2–6)	2 (1–8)	1 (1–9)		
Significance between periods		<0.001*	<0.001*	<0.001*	<0.001*	<0.001*		

Fr, Friedman test, significance between periods was done using post-hoc test (Dunn's); VAS, visual analog scale. P, P value for comparing between the studied groups. P, P value for comparing between pre and each periods. *Statistically significant at P value less than equal to 0.05.

Figure 3

Different periods at the follow-up of the patients.

Conclusion

CDFS is a safe and cost-effective procedure for treating axial reflux and incompetence of saphenous veins in terms of clinical-based and duplex-based outcome at short-term and mid-term follow-up.

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Conflicts of interest

There are no conflicts of interest.

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