Color duplex ultrasound-guided foam sclerotherapy: an approach in the management of patients with superficial varicosities of the lower extremity

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Background
Duplex ultrasound-guided foam sclerotherapy (UGFS) is now considered a valuable option in varicose vein treatment; it is conducted as an outpatient procedure, and compared with surgery results in an earlier return to normal activities.

Aim
The objective of this study was to describe the efficacy, results, and safety of UGFS for treating superficial venous disease of the lower limbs.

Patients and methods
A total of 80 patients (28 males and 52 females) who were diagnosed to have clinical and radiological evidence of lower extremities venous diseases in the Department of Vascular Surgery at Qena and Assiut University Hospitals from November 2014 to November 2015 were included in the present study. Their ages ranged from 18 to 57 years. As considered suitable for UGFS, the foam was prepared by using Tessari's method. Any residual veins were treated with another session.

Results
A total of 80 patients presenting with symptomatic varicose veins of superficial system were included in the study. There were 52 (65%) female and 28 (35%) male patients, with a mean age of 55.76±9.67 years. The affected segments of the superficial system that were treated were great saphenous (70.0%), small saphenous (17.5%), great saphenous vein and varices (6.25%), and small saphenous vein and varices (6.25%). After 1 year of follow-up, by using colored duplex ultrasound, 70% patients achieved complete occlusion, 15% had partial occlusion, and 80% showed improvement in the clinical, etiological, anatomical and pathological classification.

Conclusion
UGFS is a safe and effective treatment for superficial system varicosities, and an alternative to surgical treatment. Complications are few and appear as mostly self-limiting.

Keywords:
ultrasound-guided foam sclerotherapy, varicose veins, venous diseases

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Introduction

A valuable treatment for primary varicose veins should be minimally invasive and capable of being repeated as required. Significant complications should be few and the treatment should be efficient in removing venous reflux [1]. The treatment should be cost effective and capable of achieving functional and cosmetic improvement, with the patient staying off his or her usual occupation for as little time as possible [2]. Ultrasound-guided foam sclerotherapy (UGFS) has been considered particularly promising because it avoids the need for general anesthesia, hospital admission, and long recovery time [3]. The aim of this study was to report the author's own series of patients with chronic venous disease treated through UGFS.

Patients and methods

Patients

Our group consisted of 80 patients (28 males and 52 females) who were diagnosed to have clinical and radiological evidence of venous diseases in their lower extremities in the Department of Vascular Surgery at Qena and Assiut University Hospitals from November 2014 to November 2015. Their ages ranged from 18 to 57 years. Local ethics committee granted the approval for the study, and all patients

signed written informed consent before participation. To be considered eligible for UGFS, patients had to have symptomatic (clinical, etiological, anatomical and pathological (CEAP) C2–6) venous disease (i.e. treatment was not offered for cosmetic indications) and significant reflux (>0.5 s) in a segment of the superficial system [above knee great saphenous vein (AK-GSV), below knee great saphenous vein (BK-GSV), short saphenous vein (SSV), and/or other superficial veins] on duplex ultrasound (DUS). The vein size was measured. Patients with absent pedal pulses or an ankle brachial pressure index less than 0.9 were excluded from the study, as were those with post-thrombotic deep venous disease.

Pretreatment assessment

Patients underwent history taking, clinical examination, and DUS at the initial clinic attendance so that the sites of superficial, deep, and communicating venous reflux could be identified.

Ultrasound-guided foam sclerotherapy treatment

All treatments lasted less than 30 min, and were carried out as office procedures in a duplex room. Tessari's method was used to prepare the sclerosant foam: 1 cm^3 of sclerosing agent (aethoxysklerol 2%) in one syringe and 3 cm^3 of air in the other were mixed by applying 20 alternative movements from one syringe to the other by using a stopcock to produce 4 cm^3 of foam.

Procedure

The procedure involves the following:

(1) Mapping and drawing the venous network on the skin to choose the site(s) of injection, and to decide the section to be sclerosed.
(2) Preparing the skin.
(3) Placing a needle into the vein under duplex guidance.
(4) Checking the blood reflux in a hose, and attaching the needle to the skin with adhesive tape.
(5) Preparing the foam.
(6) Positioning the probe over the needle tip.
(7) Elevating the limb, with compression either at the saphenofemoral or the saphenopopliteal junction to avoid the entry of bubbles into the deep venous system and deep vein thrombosis (DVT) incidence.
(8) Injecting the first bubbles.
(9) Verifying the bubbles inside the vein.
(10) Injecting the sclerosing foam progressively, followed by massaging it with the probe in the varicose network, and then ensuring the foam fills all the desired veins.
(11) Checking the apparition of venous spasm.
(12) Removing the needle, and place a ball of cotton on the site of injection.
(13) Applying bandage and grade 2 medical stockings, and keeping the stockings for 24 h and then for all day long only.
(14) Giving instructions to all patients regarding walking and mobilizing early.
(15) Scheduling a follow-up after 2 weeks, either for duplex evaluation or for another injection.

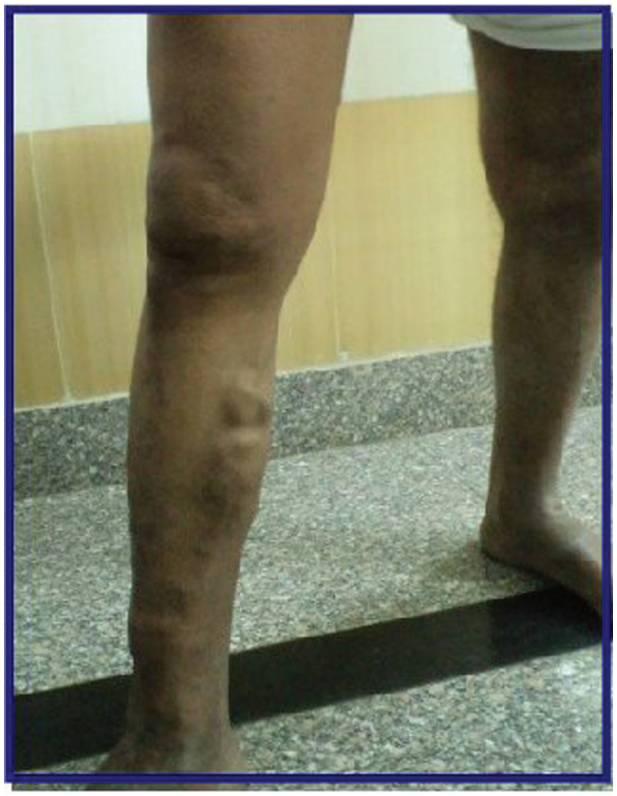
Figures 1–6 show our procedure.

Outcome measures and follow-up

The aim of the treatment was to relieve the symptoms of venous hypertension and to completely eradicate superficial venous reflux in the trunk and major tributaries of the superficial system.

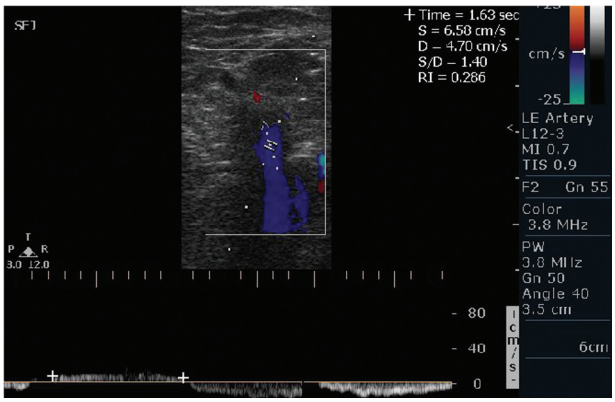
All patients were seen at 1, 6, and 12 months after undergoing treatment in the outpatient clinic. Repeated DUS were performed at each follow-up visit as the pretreatment duplex. In addition, occlusion of the treated vein was assessed by a lack of compressibility and the absence of any flow. Complete occlusion was defined

Figure 1



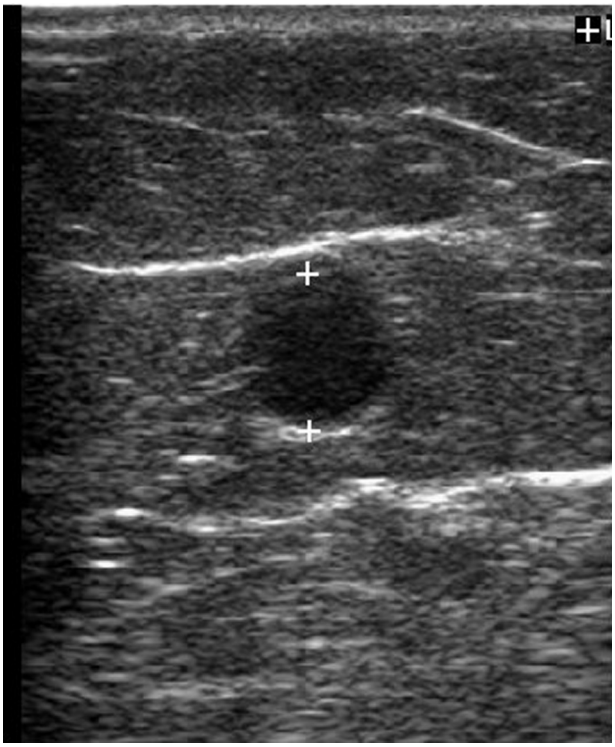
Right primary varicose veins (VV) of long saphenous vein.

Figure 2



Reflux at saphenofemoral junction (SFJ) by duplex.

Figure 3



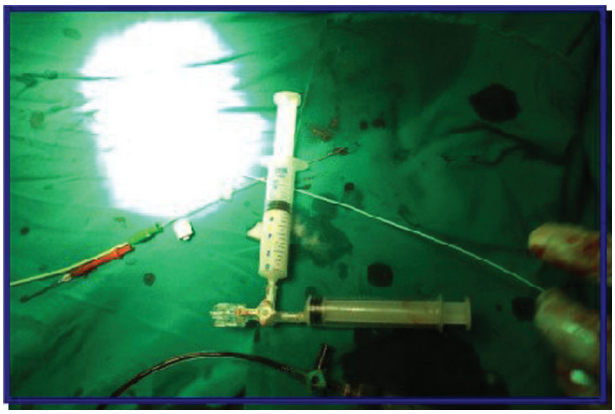
Diameter of the right saphenous vein.

as occlusion over the entire length of the treated vein. Recanalization was defined as the presence of flow in either an antegrade or a retrograde direction in a previously occluded vein. Wherever recanalization was detected, the presence or absence of recurrent reflux was determined. Patients with residual reflux or recanalization at any follow-up appointment were offered further treatment by repeating foam sclerotherapy.

Results

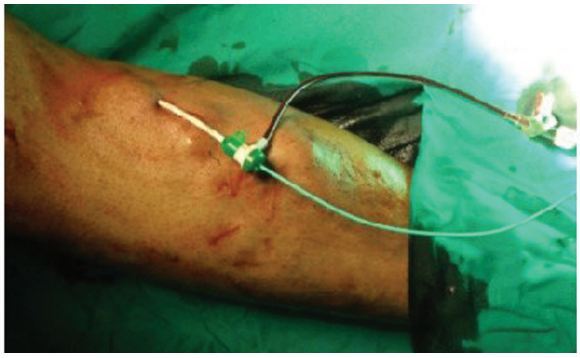
In total, 80 patients presenting with symptomatic varicose veins of the superficial system were included

Figure 4



Foam formation.

Figure 5



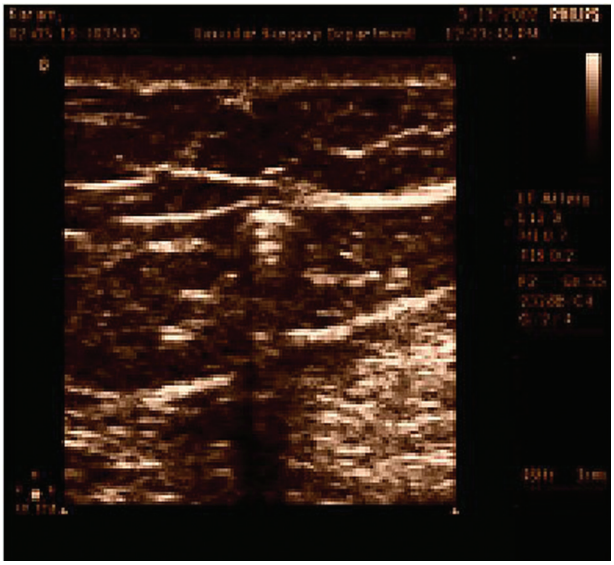
Sheath within the vein.

in the present study. There were 52 (65%) females and 28 (35%) males, with a mean age of 55.76 ± 9.67 years. CEAP clinical grade showed C2 in 60.0%, C3 in 10.0%, C4 in 21.25%, C5 in 2.5%, and C6 in 6.25% of the patients (Table 1).

Etiology in our group was primary in 75.0% and secondary in 25.0% of the patients. Anatomical patterns of venous reflux were superficial and deep in 70.0% and superficial only in 30.0% of the patients. Pathophysiological classification in our group was reflux for all patients (100.0%). Intervention was opted only for the superficial system and not for secondary varicose veins (VV) as it is well known that treatment of secondary VV is mainly conservative.

Different segments of the superficial system were treated with duplex-guided foam sclerotherapy: great saphenous (70.0%), small saphenous (17.5%), great saphenous vein (GSV) and varices (6.25%), and small saphenous vein and varices (6.25%) (Table 2).

Figure 6



Diffusion of foam inside the vein.

Table 1 CEAP clinical grade in the foam sclerotherapy group

CEAP clinical grade	Descriptive [*n* (%)]
C2	48 (60.0)
C3	8 (10.0)
C4	17 (21.25)
C5	2 (2.5)
C6	5 (6.25)

Table 2 Veins treated in the foam sclerotherapy group

Items	Descriptive [*n* (%)]
Great saphenous	56 (70.0)
Small saphenous	14 (17.5)
Great saphenous vein and varices	5 (6.25)
Small saphenous vein and varices	5 (6.25)

Table 3 Number of foam sclerotherapy sessions

Number of sclerotherapy settings	Descriptive [*n* (%)]
One	56 (70)
Two	15 (18.75)
More than two	9 (11.25)

Regarding the number of sclerotherapy sessions, there were no visible VV in 56 (70%) legs after one and in 15 (18.75%) legs after two treatment sessions, resulting in the eradication of the reflux and disappearance of VV.

Table 4 Complications in the foam sclerotherapy group

Items	Descriptive [*n* (%)]
Superficial thrombophlebitis	16 (20)
Pain	12 (15.0)
Skin staining	24 (30)
Deep vein thrombosis	0.0
Allergic reaction	2 (2.5)
Skin blistering	4 (5.0)
Visual disturbance	0.0

Table 5 Follow-up in the foam sclerotherapy group

Items	Descriptive [*n* (%)]
Resolved complete occlusion	56 (70.0)
Resolved partial occlusion	12 (15.0)
CEAP declined	64 (80.0)

Nine legs had residual VV after two sessions. Out of them, five showed satisfactory results and were did not need further treatment. For the remaining four legs, a further single session of foam injections directly into the visible varicosities successfully treated the residual VV (Table 3).

Reported complications with foam were as follows: superficial thrombophlebitis in 16%, pain in 15%, and allergy in 2.5% of the patients (Table 4).

As regards follow-up with colored DUS, by 12 months, 56 (70%) patients still had no visible VV or reflux after their primary course of treatment, nine legs had recurrent VV in addition to recanalization at 6 months, and another three had recurrent VV in addition to recanalization at 12 months. Twelve patients were lost to follow-up (Table 5).

Discussion

Varicose veins represent a chronic, frequently relapsing condition that develops secondary to valvular failure. It is, therefore, unrealistic to expect the complete and permanent eradication of superficial reflux in all patients following a single treatment whether that be surgical, UGFS, or another minimally invasive alternative [4].

Although still considered by many surgeons as the 'gold standard', the effectiveness of GSV surgery is limited by the reluctance, based on fear of damaging the saphenous nerve, to strip the BK-GSV – a common cause of residual and recurrent disease. Furthermore, a

redo surgery for residual or recurrent reflux is usually difficult, often morbid, and frequently associated with suboptimal patient outcomes [5]. In contrast, as clearly demonstrated here, patients can be offered a primary course of UGFS treatments until all reflux is eradicated. In most cases this requires only one treatment session using a modest volume of foam and is associated with a very low incidence of side effects and complications, and rapid return to work and other activities. Furthermore, as also shown here, if recurrent reflux develops as a result of recanalization, the disease can be very simply and effectively treated, usually by a further single injection of foam. In our study, according to CEAP clinical stages, 48 (60%) patients belonged to C2, eight (10%) to C3, 17 (21.25%) to C4, two (2.5%) to C5, and five (6.25%) to C6. The etiology in our study was primary (Ep) in 75.0% and secondary (Es) in 25.0% of the patients. In contrast, Winterborn *et al.* [6] found that etiology was primary (Ep) in 100.0% of the patients.

In present study, anatomical patterns of venous reflux were superficial and deep in 70.0% and superficial only in 30.0% of the patients. As regards pathophysiological classification in the current study, 100.0% of the patients had reflux and none had obstruction. In a study by Darvall *et al.* [7], conducted on 91 legs, 59% patients belonged to C2 clinical stage, 4.5% to C3, 23% to C4, 9% to C5, and 4.5% to C6. Overall, 100% patients were primary in etiology and pathophysiology. Superficial and deep reflux accounted for 94.5% and superficial only was 5.5%; GSV intervention was carried out in 84.5% and of SSV in 15.5% of the patients.

In a study by Gonzalez-Zeh *et al.* [8], CEAP classification of 53 patients was as follows: 30.2% belonged to C2, 30.2% to C3, 18.9% to C4, 11.3% to C5, and 9.4% to C6. Anatomical pattern was superficial in 100% patients; moreover, etiology was primary in 100% patients. GSV was used to treat these patients.

In the study by Wright *et al.* [9] on 259 patients, 27% belonged to C2, 46.33% to C3, 5.01% to C4, 8.88% to C5, and 12.74% to C6; overall, 100% were primary in etiology and pathophysiology. Superficial and deep reflux accounted for 92.66% and superficial only for 7.34% patients. GSV intervention was carried out in 81.47% and SSV in 18.53% of the patients.

The treated veins in our group were great saphenous (70.0%), small saphenous (17.5%), GSV and varices (6.25%), and small saphenous vein and varices (6.25%). This was in agreement with the findings of a study by Thomasset *et al.* [10], who documented that 75.0% of treated veins were great saphenous, 13.0% were small saphenous, 8.0% were GSV and varices, and 9.0% were small saphenous vein and varices.

As regards efficacy, foam sclerotherapy appeared to be an efficacious treatment both for main trunk and minor vein disease. The results from our study revealed no visible VV in 56 (70%) legs after one treatment session and in 15 (18.75%) legs after two treatment sessions, resulting in the eradication of the reflux and disappearance of their VV. Nine legs had residual VV after two sessions; out of them five were satisfied with the results and did not want further treatment, and for the remaining four (5%) legs a further single session of foam injections directly into the visible varicosities successfully treated the residual VV. These results were comparable to that of other studies, such as that of Darke *et al.* [11], who treated 18 legs with UGFS: 10 (55.55%) legs had complete occlusion after one treatment, five (27.77%) had complete occlusion after two treatments, and the three remaining legs had partial occlusion (either GSV still open but varicosities all closed or less than complete GSV occlusion but with patient satisfied) after one, two, or three treatments.

In a study by O'Hare *et al.* [12], 165 consecutive patients underwent foam sclerotherapy for truncal venous incompetence: 91% of the patients needed a single treatment session, 9.09% a second session, and 1.21% patients needed three sessions to achieve target vein occlusion.

Out of 27 patients who underwent foam sclerotherapy in the study by Figueiredo *et al.*[13], three (11.11%) patients required one session, 19 (70.37%) required two sessions, and five (18.5%) patients required three sclerotherapy sessions. The average number of sessions per patient was 2.1.

In a study by Darvall *et al.*[7], complete eradication of the reflux in the entire (AK and BK) GSV was achieved in 84/91 (92%) legs after one session, and in 4/91 (4.5%) legs after two treatment sessions (course of primary treatment). In three (3.5%) legs, complete eradication of GSV reflux was not achieved after one treatment session, but these patients, despite residual GSV reflux, were content with the clinical result and declined further treatment sessions.

As regards safety, serious adverse events including arterial events, pulmonary embolism, DVT,

cutaneous necrosis, and ulceration were statistically absent. The most common adverse events associated with foam sclerotherapy in our study were skin discoloration in 30% patients, superficial thrombophlebitis in 16%, and an allergy to the foam sclerosant in 2.5%. Other studies document various complications – for example, in a study by Thomasset *et al.*[10] complications of UGFS were superficial thrombophlebitis (18% of procedures), pain (14% of procedures), skin staining (28% of procedures), DVT (1% of procedures), allergic reaction (1% of procedures), and skin blistering (1% of procedures). A total of 48 patients experienced one, or more, of these complications. No patient experienced visual disturbance, headache, or other neurological symptoms.

In a study by Myers *et al.* [14], the only complication observed was DVT, which occurred in 3.2% of the patients. This is somewhat higher than what has been reported in other studies. In a study by Coleridge [15], the reported complications were as follow. Thrombophlebitis occurred in a small number of patients (5%), and was managed by using analgesia, compression, and aspiration of the thrombus. Calf vein thrombosis was confined to isolated gastrocnemius veins or to part of the posterior tibial vein (1.23%), which was resolved with compression by stocking or bandage and exercise without using anticoagulants. No major systemic complication such as anaphylaxis, stroke, or transient ischemic attack occurred in this study. A number of patients (14.2% of all patients treated) reported visual disturbance following treatment.

In the present study, the follow-up with colored DUS was scheduled at 6 and 12 months. By 12 months, 56 (70%) patients still had no visible VV or reflux after their primary course of treatment. Nine legs had recurrent VV in association with recanalization at 6 months, and another three had recurrent VV in association with recanalization at 12 months (12 were lost to follow-up). This was in agreement with the findings of a study by Thomasset *et al.*[10], who found that the median timing of follow-up was 3 months (range: 1.5–14 months) following treatment. Duplex scans at follow-up revealed complete occlusion of the target vein following 79% of the procedures ($n=100$). Partial occlusion of the target vein was evident following 14% of the procedures ($n=18$) and a patent target vein was seen after 6% of the procedures ($n=8$). CEAP severity score declined in 123 patients following foam sclerotherapy and remained static in three patients.

Darvall *et al.*[3] in their study found that by 12 months, 273/311 (87.8%) patients still had no visible VV after their primary course of treatment (33 were lost to follow-up or had residual untreated VV). Six legs had recurrent VV in association with recanalization at 6 months, and 19 had recurrent VV in association with recanalization at 12 months. Fifteen of these 25 had further successful UGFS treatment resulting in the eradication of the reflux and disappearance of their recurrent VV. Ten legs had a few recurrent VV at 12 months but no recanalization or reflux and only two of these needed further treatment; three had VV secondary to new reflux in the SSV. Moreover, in their study, O'Hare *et al.*[12] found that the treated vein was totally occluded in 68 (74%) legs, partially occluded in nine (10%), and patent in 15 (16%). There was no significant difference in the occlusion rates in the different truncal veins.

In a study by Coleridge [15], 459 limbs were reviewed at 6 months or more following the treatment (average: 11 months and range: 6–46 months). This included 363/886 GSVs and 141/263 SSVs. Duplex examinations of the GSVs showed that occlusion had been obtained in 318/363 (88%). In the SSVs, occlusion was present in 116 of 141 (83%). In their study, Darvall *et al.*[7] found that, of the 88 legs in whom the primary course of UGFS achieved complete eradication of GSV reflux, recanalization was observed in 1/79 (1.5%) leg at 6 months and 9/77 (12%) legs at 12 months. Nine and 11 legs were not scanned at 6 and 12 months, respectively.

Conclusion

Because surgery does not provide a definitive treatment, UGFS is widely accepted as a treatment for primary venous incompetence (long and short saphenous), isolated incompetent saphenous tributaries, recurrent VV after surgery, and patients with venous leg ulcers. UGFS has the advantages of being minimally invasive, can be repeated, and following it patients return to work earlier and with fewer complications.

Conflicts of interest

There are no conflicts of interest.

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