# Outcomes of thermal ablation combined with u/s guided foam sclerotherapy in treatment of superficial venous reflux in patients with postphlebitic venous leg ulcer

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#### Background

Venous leg ulcers are a considerable health problem because of their high incidence, slow healing, high recurrence rate, and high cost of treatment. Minimally invasive treatments such as endovenous thermal ablation and foam sclerotherapy proved to be safe and effective. However, there is a paucity in studies focusing on the management of postphlebitic venous ulcers using endovenous thermal ablation of the superficial system in combination with foam sclerotherapy. **Objectives** 

The aim of our study was to assess the healing time, procedure-related complications and recurrence rate in patients having a postphlebitic venous leg ulcer after being treated with EVLA associated with ultrasound-guided foam sclerotherapy to incompetent perforators with compression therapy.

#### Subjects and methods

This is a prospective observational study, conducted at Ain Shams University Hospitals and Nasser institute hospital in Cairo on 30 patients presented with postphlebitic venous leg ulcers.

#### Results

After one year, 90% of cases had a totally healed ulcers, 10% with ulcer decrease in size of more than 50%, and recurrence rate 6.7%. The adverse events of this procedure were DVT (6%), hematoma (6%), ecchymosis (43%), thrombophlebitis (6%), and pain (70%). There was significant improvement of the VCSS as regard pain, edema, inflammation, ulcer size, and number. There was highly significant (P < 0.0001) improvement in the mean (SD) VCSS (preoperative 18 [2.808] vs. postoperative 6.367 [2.3449]).

#### Conclusion

Patients with totally recanalized deep venous system post deep venous thrombosis, presenting with nonhealing venous leg ulcers, may benefit from thermal ablation of superficial varicose veins combined with ultrasound-guided foam sclerotherapy. This combined approach is a feasible, safe, and effective modality in terms of improved healing rate, low recurrence rate, low complications, and significant improvement in guality of life.

#### Keywords:

compression therapy, foam sclerotherapy, postphlebitic venous ulcers, thermal ablation, venous reflux

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#### Introduction

Venous ulceration is the most severe presentation of chronic venous disease (CVD) at a prevalence of about 1% in the adult population, which increases with age and commonly affect obese patients and women [1].

Venous ulcers significantly hinder the quality of life, and their treatment represents a major financial burden upon healthcare systems [2]. Chronic venous hypertension may be countered by high elevation of the leg and multi-layered compression bandaging applied by trained staff within the setting of a specialist leg ulcer service [3,4]. Simple superficial venous surgery i.e., saphenous vein ablation theoretically removes underlying venous incompetence in legs with isolated superficial venous reflux. The ESCHAR study compared patients with isolated superficial venous reflux undergoing compression therapy alone with those having compression treatment and superficial venous surgery and concluded that surgical correction of superficial

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venous reflux in legs with chronic leg ulceration provided increased hemodynamic benefit versus compression alone and may reduce ulcer recurrence rate at 1, 2, and 3 years [5]. Consequently, surgery was frequently performed once ulcers had healed to prevent recurrence.

Moreover, the Early Venous Reflux Ablation (EVRA) ulcer trial [6] identified that patients who underwent early endovenous ablation had improved ulcer healing rates and ulcer-free time.

Chronic deep venous insufficiency has been shown to hasten the progression of venous disease leading to increasing the rate of venous ulcer formation and, when coexisting with superficial venous reflux (SVR), it has been found to be an additional factor influencing clinical status. Therefore, the resolution of deep venous reflux (DVR) along with SVR is important for preventing chronic venous insufficiency. Several authors demonstrated that closure of incompetent great saphenous vein in patients with DVT in the affected leg is feasible and could render benefit. It should be performed only after the thrombus has resolved and venous flow is restored, this is to allow for sufficient venous return through the deep system after the procedure [7,8]

The new techniques, such as laser ablation, radiofrequency and foam sclerotherapy are minimally invasive and have shown efficacy in superficial venous intervention in patients with venous leg ulcers [9].

The controversy between the effect of thermal ablation vs. traditional stripping was conducted in many studies that concluded endovenous laser ablation of superficial venous insufficiency in patients with healed or active venous ulcers confers both ulcer healing and low recurrence rates in most patients with a low rate of complications and a modest rate of re-interventions [10,11].

In a study to evaluate the clinical outcomes of superficial and perforator ablation and the effects on wound healing by adding iliac vein stenting of nonthrombotic iliac vein lesions (NIVLs) in patients presenting with active venous ulcers the results have suggested an association between improvement in the overall success of venous leg ulcer healing when including treatment of NIVLs with stents [12].

A systematic review was conducted by Goldschmidt *et al.*, to summarize the available evidence on how to treat patients with nonhealing leg ulcers after successful

elimination of superficial reflux. It concluded that additional ablative procedures to address incompetent perforating veins and persistent superficial reflux in combination with ongoing compression therapy is effective in healing persistent or recurrent venous ulcers after the elimination of superficial venous reflux [13].

In 2020 there was a study to evaluate the impact of three treatment modalities, superficial truncal vein ablation, perforator vein ablation, and deep venous stenting on venous leg ulcer (VLU) healing. The results showed that patients who underwent deep venous stenting and ablation of both incompetent truncal and perforator veins had an ulcer healing rate of 87% at 36 months and ulcer recurrence of 26% at 24 months and concluded that correction of superficial truncal vein reflux, as well as deep vein stenosis, both contribute to the healing of VLU. The authors recommended that patients who fail to heal their VLU after superficial and perforator ablation should have the iliocaval system imaged to identify hemodynamically significant stenoses or occlusions amenable to stenting, which facilitates venous ulcer healing even in patients with large ulcers [14].

Recently a study was conducted in Mansoura University to compare radiofrequency ablation of markedly incompetent perforators to conventional compression therapy regarding the time required for healing of postphlebitic venous leg ulcers. The results revealed statistically significant shorter time to healing (ulcer complete healing or satisfactory clinical improvement) and lower recurrence rate, in favor of the radiofrequency group, over the follow-up period of 24 months [15].

# Aim of the work

The aim of our study was to assess the healing time, procedure-related complications and recurrence rate in patients having a postphlebitic venous leg ulcer after being treated with EVLA associated with ultrasoundguided foam sclerotherapy to incompetent perforators with compression therapy.

# Patients and methods

This is a prospective observational study conducted at the Department of Vascular and Endovascular Surgery in Ain shams university hospitals and Nasser institute hospital in Cairo over 30 patients who have had post phlebitic venous leg ulcers that was treated by endovenous laser ablation (EVLA) of the great saphenous vein (GSV) associated with ultrasoundguided foam sclerotherapy to incompetent perforators beneath the ulcer, together with compression therapy.

We included patients who had nonhealing venous ulcer of more than two months duration and were known to have one attack of ipsilateral lower limb DVT more than 6 months before being enrolled in the study, with radiological evidence of complete recanalization with concomitant deep and superficial venous reflux. Also, patients who had iliofemoral DVT and were treated with iliac stenting were included.

We excluded patients with untreated osteomyelitis, infection, or deformity. We also excluded patients known to have diabetes mellitus to rule out the effect of microangiopathy on healing promotion. Also, patients who have had ABPI < 0.9 will be excluded due to unfeasibility of the compression therapy.

#### Preinterventional

All patients were subjected to careful history taking with special emphasis on the history of the previous attack of DVT, local examination was carried out, including assessment of the state of the deep venous system and incompetence of the superficial system with measurement of ABI to exclude patients with chronic ischemia. Also, the venous ulcer was assessed clinically. Patients were assessed according to venous clinical severity score (VCSS) [16].

The venous duplex examination was performed to determine the state of recanalization of the deep

system, and the presence of superficial and deep reflux, and incompetent perforators. CT-venography was performed to ensure patency of iliac veins and patency of previously applied stents.

#### Procedure

Under general, or spinal anesthesia, a puncture of GSV was done under ultrasound guidance with the introduction of a 6 F sheath. We used a standard laser catheter (1.8 mm diameter) that was Positioned 2 cm distal to the saphenofemoral junction. Injection of tumescent in saphenous fascia was done. Endoluminal heat generation produced by the laser device (ENDOTHERME<sup>TM</sup> 1470 on power 10 watts (Fig. 1) or BIOLITEC CERALAS E15 on power 15watts (Fig. 2) with continuous pullback. we performed ultrasound-guided foam sclerotherapy of the perforators underneath the ulcer using polidocanol 1% (Fig. 3). Curettage and debridement to the ulcer were done if needed. At the end of the procedure, we applied a four layers compression bandage.

#### Postprocedural care and follow up

All patients were examined for signs of DVT, and other complications related to procedure as thrombophlebitis, cellulitis, skin gangrene, lower limb edema, neuropathy, and postoperative pain. Prophylactic anticoagulation was used for one month. All patients used below-knee class II compression graduated elastic stockings. Pentoxifylline was given 3 times daily till ulcer healing.

All patients were followed up at 1, 3, 6, and 12 months. During follow-up visits: Ulcers were examined and



a: ENDOTHERME<sup>™</sup> 1470 on power 10 watts. b: laser fiber catheter.

# Figure 1

compared regarding shape, size, and progression of healing. Patients were examined and venous clinical severity score was recorded as well as a follow-up duplex was performed.

All procedures were done by skilled vascular surgeons with endovascular capabilities and experience.

### Figure 2



BIOLITEC CERALAS E15 on power 15 watts.

#### Endpoints

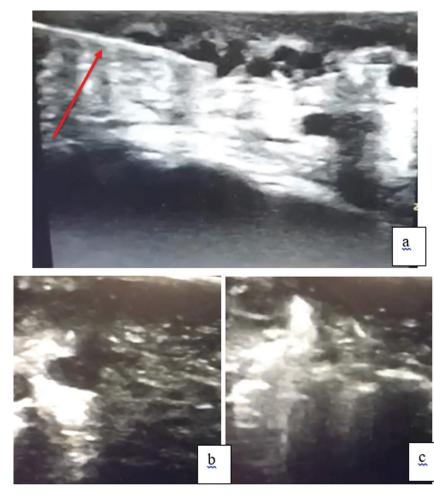
Our primary endpoints were ulcer healing rate, and related intervention complications. Secondary endpoints included ulcer recurrence and the need for further intervention.

#### Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The T-test was used to verify the normality of distribution. Quantitative data were described mean standard deviation, median and interquartile range (IQR). The significance of the obtained results was judged at the 5% level.

# Results

This was a prospective observational study with data obtained from 30 patients with demographics shown in Table 1, from the period of January 2022 till March 2023. Patients with post phlebitic venous leg ulcers with complete recanalization of the deep system proved by duplex ultrasound and CT venography underwent



Injection of foam sclerotherapy to incompetent perforators under ultrasound guidance. a: needle cannulation of the perforator (arrow: needle). b: before injection. c: after injection of foam.

#### Figure 3

endovenous laser ablation of the GSV together with the injection of foam sclerosants to incompetent perforators.

All included patients had a prior single attack of ipsilateral DVT with a mean time since diagnosis of 17.6±5.36 months. Twenty-four patients representing 80% of our cohort had DVT of the femoropopliteal segment, while only six patients (20%) had previous iliofemoral DVT for which stenting of the iliac veins were mandatory to regain luminal patency.

All patients had reflux of the saphenofemoral junction with incompetent ankle perforators underneath the ulcer site. The mean diameter of the great saphenous vein was  $8.3\pm1.52$  mm. All patients underwent EVLA of the GSV associated with foam sclerotherapy injection to the incompetent perforators related to the venous ulcer.

All patients were assessed according to venous clinical severity score before and after the procedure and at every follow-up visit. Table 2 shows VCSS before the procedure and after 12 months.

Postoperatively patients were followed up for the occurrence of adverse events, (Table 3).

The procedure was done as a day case procedure and the patients were discharged at the day of the procedure or the day after.

Only two patients (6%) needed further admission, a patient who developed severe swelling of the lower limb and was diagnosed to have iliofemoral DVT and had catheter-directed thrombolysis, the other patient

#### **Table 1 Patient demographics**

	Total no. = 30		
Sex			
Male	21 (70%)		
Female	9 (30%)		
Age (mean±SD)	37.1±10.16 years		
Hypertension			
Yes	6 (20%)		
No	24 (80%)		
Smoking			
Yes	13 (43%)		
No	17 (57%)		
BMI			
Underweight	3 (10%)		
Normal	19 (63%)		
Overweight	5 (17%)		
Obese	3 (10%)		

developed severe pain with redness along the course of the GSV and was diagnosed with thrombophlebitis for which the patient was hospitalized and received nonsteroidal anti-inflammatory drugs and parenteral prophylactic anticoagulation.

There was one patient who developed postoperative popliteal DVT and was treated with Direct oral anticoagulants, another patient developed thrombophlebitis in some tributaries of GSV, and improved on non-steroidal anti-inflammatory drugs.

There was transient paraesthesia over the distribution of saphenous nerve in 5 patients, while one patient had permanent numbress over medial aspect of foot.

Follow-up was done at 1, 3, 6, and 12 months, with emphasis on ulcer healing, Table 4 shows the improvement of the ulcer over this period of follow-up (Fig. 4).

During the follow-up period, duplex ultrasound was done, recurrence of incompetent perforators underneath the ulcer was note in 4 (13.3%) patients at one month, which was believed to be the cause of delay of ulcer healing, for which another session of ultrasound guided injection of foam sclerosants was given to the patients. But during the rest of follow-up period, duplex ultrasound did not show any recurrent perforators.

During the follow-up of 3 months two patients (6.7%) showed recurrence of the ulcer, and they continued to show no improvement of the ulcer size up to one year of follow-up.

## Discussion

The occurrence of a venous leg ulcer represents a severely morbid condition, which interferes with the quality of life of patients. In our study, patients having post-phlebitic venous leg ulcers associated with superficial vein incompetence with totally recanalized deep venous system were treated by EVLA with the injection of foam sclerotherapy to incompetent perforators underneath the ulcer.

After one year 90% of cases had a totally healed ulcers, 10% with ulcer decrease in size of more than 50%. The adverse events of this procedure were DVT (6%), hematoma (6%), ecchymosis (43%), thrombophilibits (6%), and pain (70%). Recurrence of venous ulcer occurred in 6.7% of cases.

	Pre	After 12 months	T-test	P value	Sig
Pain					
None	0 (0%)	29 (97%)	13.200*	0.000	HS
Occasionally	4 (13%)	1 (3%)			
Daily not limiting	12 (40%)	0 (0%)			
Daily limiting	14 (47%)	0 (0%)			
Venous edema					
None	0 (0%)	26 (87%)	17.40*	0.000	HS
Foot and ankle	10 (33%)	4(13%)			
Below knee	20 (67%)	0 (0%)			
knee and above	0 (0%)	0 (0%)			
Pigmentation					
None	0 (0%)	0 (0%)	2.313	0.121	NS
Perimalleolar	5 (17%)	12 (40%)			
Lower 2/3 calf	18 (60%)	18 (60%)			
Above lower 2/3 calf	7 (23%)	0 (0%)			
Inflammation					
None	8 (27%)	27 (90%)	15.421*	0.000	HS
Perimalleolar	9 (30%)	3 (10%)			
Lower 2/3 calf	10 (33%)	0 (0%)			
Above lower 2/3 calf	3 (10%)	0 (0%)			
Induration					
None	8 (27%)	13 (43%)	1.751	0.452	NS
Perimalleolar	17 (57%)	9 (30%)			
Lower 2/3 calf	5 (16%)	8 (27%)			
Above lower 2/3 calf	0 (0%)	0 (0%)			
Ulcer number					
None	0 (0%)	27 (90%)	16.752*	0.000	HS
One ulcer	17 (57%)	3 (10%)			
2 ulcers	12 (40%)	0 (0%)			
3 ulcers or more	1 (3%)	0 (0%)			
Ulcer size					
None	0 (0%)	27 (90%)	14.241*	0.000	HS
<2 cm	8 (27%)	2 (6%)			
2-6 cm	15 (50%)	1(3%)			
>6 cm	7 (23%)	0 (0%)			
Compression		( ),			
None	0 (0%)	0 (0%)	1.771	0.125	NS
Intermittent	4 (13%)	3 (10%)			
Most days	4 (13%)	5 (17%)			
Fully comply	22 (74%)	22 (73%)			
Mean VCSS±SD	18±2.808	6.367±2.3449		< 0.0001	HS

P-value > 0.05: Nonsignificant (NS); P-value < 0.05: Significant (S); P-value < 0.01: Highly significant (HS). \*Chi-square test.

Table 3	Major	adverse	events

DVT Infection Hematoma Ecchymosis Thrombophlebitis Pain (paresthesia)

# Table 4 Distribution of the studied cases according to ulcer improvement

No. = 30	improvement				
2 (6%)	Ulcer improvement	1 month	3months	6 months	12 months
0 (0%) 2 (6%)	<50% >50%	3 (10%) 4 (13%)	1 (3%) 1 (3%)	0 (0%) 3 (10%)	0 (0%) 3 (10%)
13 (43%) 2 (6%)	Totally healed	4 (13%) 23 (77%)	28 (94%)	3 (10%) 27 (90%)	3 (10%) 27 (90%)

We reviewed the literature looking for this combined approach for treating postphlebitic venous leg ulcers, but we were unable to find a similar study. Sinabulya *et al.*, conducted a study to assess the midterm ulcer recurrence rate in patients with healed or active venous ulcers treated with endovenous laser

#### Figure 4



Ulcer improvement during follow up visits (a) preoperative (b) more than 50% improvement after one month (c) totally healed after three months.

ablation (EVLA) for incompetent superficial axial veins and to search for possible risk factors for nonhealing and recurrence. However, only 16% of his cohort had history of old DVT. All 86 legs operated on for an active ulcer had this ulcer healed sometime between the operation and the study examination, but thereafter it recurred in 14 patients (16%) [17].

As regards ulcer healing, Sinabulya *et al.* achieved complete healing in 100% of ulcers with 16% recurrence rate within 41 months. In our study, complete healing was achieved in 94% of ulcers with 6.7% recurrence rate with 12 months.

As regards improvement in clinical picture, our study showed significant improvement in the VCSS as regard pain, edema, inflammation, ulcer size, and number. There was highly significant (P < 0.0001) improvement in the mean (SD) VCSS (preoperative 18 [2.808] vs. postoperative 6.367 [2.3449]). In the study by Sinabulya *et al.*, the preoperative mean (SD) VCSS in C6 group was (6.19 [3.9]), which is much lower than our study. At 41 months follow-up, the VCSS was 9.29 (4.4) in patients with recurrent ulcers, and 4.89 (3.3) who had no recurrence.

As regards procedure-related complications, Sinabulya *et al.*, reported a permanent sensory loss in 8% of patients, compared to 3% in our study.

16% of patients recruited by Sinabulya *et al.* had a history of DVT, and the incidence of postoperative DVT was 1%. In our study, all patients had a history of ipsilateral DVT, and the incidence of postoperative DVT was 6%.

Kamhawy *et al.*, recruited 20 patients with venous leg ulcers. Fifteen patients had peri-ulcer foam sclerotherapy associated with GSV high ligation and stripping, while 5 patients had peri-ulcer foam sclerotherapy only. 40% of patients had a history of DVT. At 12 months follow-up, total healing was achieved in 90% of ulcers, no healing in 5%, and 5% recurrence rate. There were no major complications, 15% of patients had minor skin ulcerations postinjection, that resolved within 2-4 weeks. 5% of patients had temporary amaurosis fugax [18]. These complications were not seen in our cohort.

A study with ultrasound foam injection showed an Ulcer healing rate was 100%, and 1-year recurrence rate was 2.9% [19].

Another study about endovenous ablation of refluxing superficial venous system in patients with active venous ulcer showed 100% ulcer healing with no recurrence and to reach this result this was combined with adequate phlebectomy (stab avulsion [maximum number of sites in 1 patient, 43]), compression therapy, moist wound healing, and skin care [20].

From the above discussion, it is obvious that using EVLA, or injection of foam sclerotherapy to perforators, either alone enhance the healing of venous ulcer. And from our results combining both in postphlebitic venous ulcer appears to be a safe and effective method.

#### Limitations

(1) There is a paucity in studies focusing on the management of postphlebitic venous ulcers using

endovenous thermal ablation of the superficial system in combination with foam sclerotherapy.

- (2) Follow up period was short.
- (3) Small sample size.
- (4) No unified scoring system across research articles.

#### Conclusion

Patients with totally recanalized deep venous system post deep venous thrombosis, presenting with nonhealing venous leg ulcers, may benefit from thermal ablation of superficial varicose veins combined with ultrasound-guided foam sclerotherapy. This combined approach is a feasible, safe and effective modality in terms of improved healing rate, low recurrence rate, low complications, and significant improvement in quality of life.

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#### **Conflicts of interest**

No conflict of interest.

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