

## Value of Duplex Guided Foam Sclerotherapy in the Management of Chronic Venous Ulcers

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### Abstract

**Introduction:** Venous ulcer is one of the complications of chronic venous insufficiency and is considered the most common cause of lower extremity ulceration. Venous ulcers account for approximately 80% of all lower extremity ulcers, with an overall prevalence of 1–2%. Chronic venous insufficiency has a great impact on patients health related quality of life (HRQOL), and is associated with considerable health care costs. Surgical treatment is relatively invasive. The rate of recurrence of venous ulcer after treatment has been reported to vary from 20% to 80%.

**Objectives:** To assess the safety and efficacy of duplex guided foam sclerotherapy for treatment of chronic venous ulcers.

**Patients and Method:** This is a randomized, controlled clinical trial conducted on 50 patients who presented with lower limb chronic venous ulcer. All studied patients were assessed by a detailed duplex study prior to injection sclerotherapy. Following the technique all patients were followed up for a period of one year to report safety, efficacy and patient satisfactions after treatment.

**Results:** There were significant good results regarding ulcer healing, efficacy, patient satisfaction, low complications and recurrence rate. There were 96% of cases with complete ulcer healing with complete satisfaction and 4% recurrence rate.

**Keywords:** Foam sclerotherapy; Duplex guided; Venous ulcer

## Introduction

Venous ulcers account for approximately 80% of all lower extremity ulcers, with an overall prevalence of 1–2% [1]. Lower extremity venous insufficiency is a common medical condition. Half of the adult population has stigmata of minor venous disease and about 25% of the population has lower extremity varicose veins and 2% have skin changes which may precede venous ulceration [2, 3].

Although, there is no documented data about the venous insufficiency in Egypt, it is one of the most common medical problems. More than 25% of people with varicose veins have insufficiency of the truncal veins of the legs. Classic symptoms of venous insufficiency are aching, disfigurement and edema. Associated complications are eczema, lipodermatosclerosis, superficial thrombophlebitis, and venous ulcers. Treatment of chronic venous ulcer remains controversial with disappointing outcomes, especially in the presence of (post-thrombotic) deep venous reflux [4].

Chronic venous insufficiency has a great impact on patients' health related quality of life (HRQOL), and is associated with considerable health care costs [5]. Surgical treatment is relatively invasive [6]. The rate of recurrence of venous ulcer after treatment has been reported to vary from 20% to 80% [7]. Methods such as endovenous laser ablation; radiofrequency ablation and foam sclerotherapy have been increasingly used in these patients [8].

Duplex ultrasound guided foam sclerotherapy is minimally invasive and capable of being repeated as required. Moreover, it is less costly and capable of achieving both functional and cosmetic improvement. Duplex guided foam sclerotherapy has been considered particularly attractive because it avoids the need for general anesthesia, hospital admission and long recovery times [9].

## Patients and Methods

This prospective, randomized, controlled clinical trial was approved by the institutional ethical committee. 50 patients were selected based on clinical history, physical examination and ulcer assessment as well as duplex assessment. All patients supplied informed consent before

participating in this study according to the 1975 Helsinki Declaration.

Pre-injection assessment was performed using a color duplex scanner with a 5 - 10MHz transducer to detect venous reflux and incompetent perforators. Venous reflux was considered to be present if the duration of reflux exceeded 0.5sec. This diagnostic tool was routinely used in all cases before injection, to check, incompetent perforators as well as their relation to the ulcer.

Fifty patients were treated by Foam compression sclerotherapy and compression therapy according to the following inclusion and exclusion criteria.

### Inclusion criteria:

- Any age group.
- Venous ulcer with 1ry varicose veins +/- incompetent perforators.

### Exclusion criteria:

- Mental or psychiatric impairment, chronic liver disease, renal insufficiency, pregnancy or lactation, progressive malignant disease, cardiac or respiratory insufficiency, history of deep venous thrombosis, coagulopathy, and a known allergy to polidocanol injection.

## Technique

- Body position: supine with the leg elevated.
- Sclerosing agents: Aethoxysclerol (polidocanol).
- Preparation of sclerosing agent: In the current study, we adopted the use of sclerosant (polidocanol), air ratio 1:4, to avoid the severe pain associated with trials of 1:3 ratios and the inefficiency of diluted 1:5 ratio.
- Volumes of agents: No more than 4 ml were injected per session; max volume of foam is 20 mm. according to the sclerosant/air ratio (usually 1:4).
- Concentration: 1% or 2%.
- Post-injection bandaging and walking after putting saline soaked dressing over the ulcer.

All patients were followed up for a period of one year. Duplex assessment was done post injection at intervals of one week then one, three, six months and 12 months after treatment

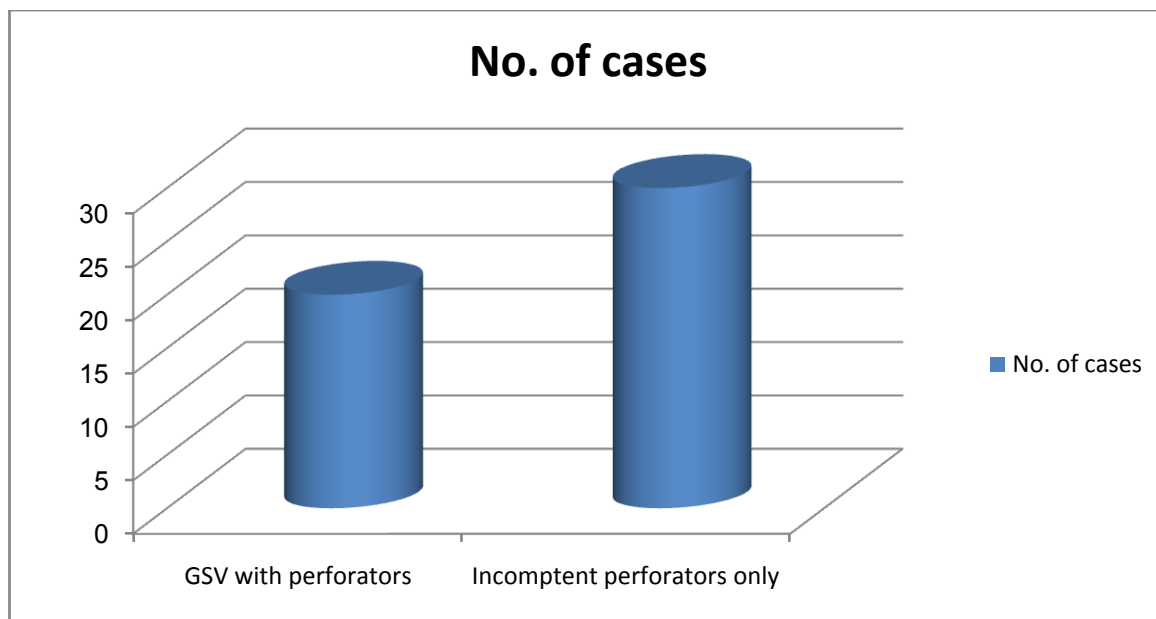
Patient satisfaction was evaluated using a grading scale that deals with symptom changes (1-5) [10];

- 1 = worse than before treatment (failure)
- 2 = no change (failure)
- 3 = minimal disappearance (partial satisfaction)
- 4 = moderate disappearance (partial satisfaction)
- 5 = complete disappearance (complete satisfaction)

## Results

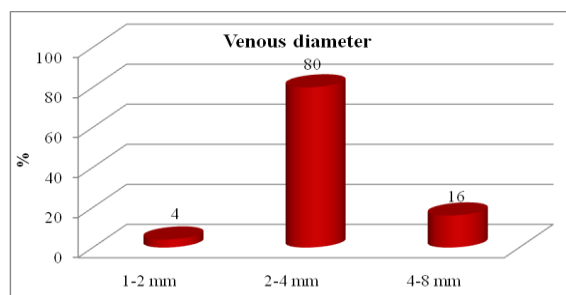
The age of studied patients ranged from 20-55 years. They were 40 males and 10 females. Pain and ulcer resistant to healing are the most common complaint.

**Figure 1:** Incidence of GSP reflux with incomplete perforator.



Great saphenous vein (GSV) reflux with incompetent perforators was observed in 40% of cases. Incompetent perforators around ulcer were detected in 60% of the cases

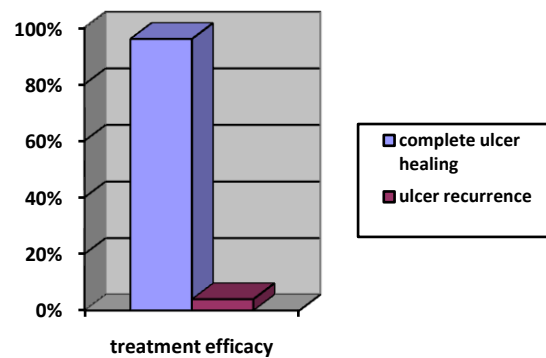
**Figure 2:** Great saphenous vein diameter in the studied patients



In cases of GSV affection, venous diameter of 2-4 mm was the most frequent finding (80%).

Regarding treatment with foam sclerotherapy, the numbers of sessions were usually two (48% of cases). The numbers of ampoules consumed in each case were usually was 3 (44% of cases). The concentration of ampoules consumed was mainly 1% concentration (60% of cases) which was used in cases of incompetent perforators only.

**Figure 3: Outcome**



Complete ulcer healing occurred in 48 cases (96%) with no recurrence with complete satisfaction and only 2 cases (4%) had recurrence after 4 months during follow up and re-injected with foam again with good results. Post sclerotherapy complications included pigmentation, gastrocnemius vein thrombosis in 1 case which completely resolved after 1 month and recurrence which was present in 2 cases (4%) after a follow up period of 6 months after treatment. There was no Phlebitis, DVT, drug reaction, skin necrosis, extravasation, pulmonary embolism or sensation of chest tightness. It is important to note that patient satisfaction was excellent (complete satisfaction in 96% of cases).

## Discussion

In this study, an attempt was made to evaluate the efficacy of foam sclerotherapy in treatment of venous ulcers associated with incompetent perforators and/or long saphenous veins pathology. The random nature of distribution of cases in both groups has ensured a non specific selection of patients, whereas the sex prevalence was in favor of males (80% of cases) which were not coincident with the normal prevalence of worldwide female incidence ranging between 35% and 55% [11].

Nowadays, duplex study is the gold standard in confirming reflux and demonstrating anatomy in cases of lower limb venous disease and to certify the patency of the deep system before injection [12-14]. Polidocanol was used in the current study in injection group as it is now the most commonly used agents worldwide, with a well-documented safety and efficacy spanning 40-50 years. It is also well tolerated and effective in both solution and foam formulation [15, 16]. The European Consensus Meeting on foam sclerotherapy at Tegernsee Germany on 2004 recommended using (sclerosant: air) by the ratio either 1:3 or 1:4 [17].

Sclerotherapy for varicose veins proved to be safe and efficient method of management with minimal complications. The introduction of duplex guided foam sclerotherapy has further reduced the incidence of complications with good results [18, 19]. In the current study, only one patient (0.5%) developed gastrocnemius vein thrombosis which completely resolved after 1 month. Two cases (4%) had ulcer recurrence within 6 months after

treatment. Serious complications as femoral vein thrombosis [20], perforating venous thrombosis and popliteal vein thrombosis [21] were not reported in our study. Moreover, no pulmonary embolism was reported post foam injection.

Guex et al., Varcoe and Barrett et al. [22-24] in their different studies reported many other transient benign side effects as vasovagal, headache, visual disturbances, paresthesia, nausea, vomiting and cramps. All these complications did not occur in our study.

Based on symptoms, a suggested scale was used to assess patients' satisfaction after intervention. The application of this scale on the included patient revealed high patient satisfaction (96%). All the patients considered sclerotherapy to be a successful modality for treatment of venous ulcers followed by compression. Similar observations coinciding with these results were published in many other studies [24-28].

In conclusion, the ideal treatment for lower extremities venous ulcers with GSV and or incompetent perforators should be relatively noninvasive, repeatable if necessary, cost effective and cosmetically acceptable. Duplex ultrasound guided foam sclerotherapy is an efficient, relatively cheap, and a safe modality in the treatment of great saphenous vein reflux and incompetent perforators in management of venous ulcers. Cases of resistant venous ulcers due to venous reflux have impressive good prognosis after combined foam injection and compression. Duplex assistance during foam injection gives more accuracy and less complications and better follow up during and after the procedure.

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