

*Research Article***Comparative study of ambulatory phlebectomy and foam sclerotherapy in the treatment of primary non-axial varicose veins****Amer Y. Mohammed, Mohamed A. Alhewy, and Ahmed A. Neaz Tawfik**

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**Abstract**

Perforators are those which connect the superficial and deep venous system either directly to main veins or indirectly through the muscular and soleal venous plexus. The emergence of minimally invasive techniques like ambulatory phlebectomy (AP) and foam sclerotherapy (FS) has led to increasing interest about the appropriate therapy for the treatment of isolated perforator incompetence. There have been no studies which have compared the effectiveness of these in-office procedures in isolated perforator incompetence due to the low prevalence of cases. **Aim of the work** is to compare the clinical parameters (return to normal activity, primary symptom relief), functional parameters (procedure time, change in disease severity, course of venous ulcer), and duplex parameters (recurrence in treated veins, complete occlusion of treated veins) in the management of leg varicosities having isolated primary perforator incompetence by ambulatory phlebectomy and duplex guided foam sclerotherapy. Though the procedure time was shorter with FS than AP, the other parameters of primary symptom relief such as change in disease severity, faster healing of venous ulcer, complete occlusion of treated veins in follow-up duplex examination, and lower recurrence of treated veins are better with AP than FS. **Conclusion**, the interruption of perforators is effective in decreasing the symptoms of chronic venous insufficiency and for the rapid healing of ulcers. The interruption of the incompetent perforating veins appears to be essential to decrease ambulatory venous hypertension. It is apparent from this study that ambulatory phlebectomy stands distinct with enormous benefits and serves as a superior alternative to foam sclerotherapy in treating patients with isolated perforator incompetence.

**Keywords** Isolated perforator incompetence .Ambulatory phlebectomy. Foam sclerotherapy. Compression therapy

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**Introduction**

Perforators are those which connect the superficial and deep venous system either directly to main veins or indirectly through the muscular and soleal venous plexus. The emergence of minimally invasive techniques like ambulatory phlebectomy and foam sclerotherapy has led to increasing interest about the appropriate therapy for the treatment of isolated perforator incompetence. There have been no studies which have compared the effectiveness of these in-office procedures in isolated perforator incompetence due to the low prevalence of cases. The primary goal of this study is to compare the clinical, functional, and duplex outcome in the management of leg varicosities having isolated primary perforator incompetence by ambulatory phlebectomy and duplex guided foam sclerotherapy.

**Patients and Methods**

This is a prospective study based on the analysis of varied cases of varicosities of the lower limbs with isolated primary perforator incompetence. This study was conducted between November 2017 and July 2018 at the Department of General Surgery and Vascular Surgery in Al-Azhar university hospitals. This study will include 100 patients with primary or recurrent lower limb varicose vein.

After obtaining approval from the ethics committee and informed consent, patients with lower limb varicosities of both genders were clinically examined and duplex examination was done. Those patients with isolated perforator incompetence of the lower limbs found by duplex examination (including those with venous ulcers) were enrolled for this study.

**Inclusion Criteria**

- (A) Varicosities in lower limbs with or without venous ulcers
- (B) Duplex showing only perforator incompetence with saphenofemoral junction, saphenopopliteal junction, and deep veins being normal
- (C) Persistent/recurrent varicosities after compression therapy for isolated perforator incompetence

**Exclusion Criteria**

- (A) Prior history of deep vein thrombosis
- (B) Allergic to sclerosants
- (C) Associated arterial and neuropathic problems
- (D) Pregnant and lactating women
- (E) Prior history of trauma
- (F) Lymphedema

**Preprocedure Workup**

The patients with leg varicosities attending Surgical and Vascular Outpatient Clinic were examined. Through history and clinical examination was done to assess the venous system. The presenting symptoms such as dilated veins, pain, night cramps, edema, ulcer, itching, bleeding, pigmentation of skin, eczema, activity tolerance, depression, and sleep alteration were recorded. Revised Clinical-Etiology-Anatomy-Pathophysiology (CEAP) documentation Eklöf B, Rutherford RR, Bergan JJ et al., (2004) was done for all the patients, and the disease severity was determined by Venous Clinical Severity Scoring (VCSS) Rutherford RB, Padberg FT Jr, Comerota AJ et al., (2000)

The location of varicosities, the presence or absence of skin pigmentation, edema, dermatitis, ulceration, venous eczema, and lipodermatosclerosis were documented. A duplex study of the venous system was done preoperatively to assess the extent of varicosities, the presence or absence of saphenofemoral or saphenopopliteal incompetence, perforator vein incompetence, and the status of the deep veins. For the superficial and perforator system, the veins are examined in standing position with the limb slightly flexed and externally rotated. The weight of the patient is on the contralateral limb at the time of examination. Perforators are easily distinguished from the superficial and deep veins since they are perpendicular to the course of

these veins and they pierce the deep fascia. The deep fascia is dense and echogenic and can be easily visualized on the ultrasound scan. Perforators were examined using transverse and oblique scanning since their long axis is seen well in those planes. The veins are visualized properly and evaluation of the flow, compressibility, and augmentation of flow with movements are documented. The incompetent superficial and deep veins having a shorter reflux time ( $\leq 0.5$  s) and those with signs of obstruction (thrombus) were excluded from the study Labropoulos N, Tiongson J, Pryor L et al., (2003). Eliciting venous reflux in short perforating veins is difficult, and in order to term a perforating vein to be incompetent, the following criteria were used:

- (A) A shorter time cut point of 0.35 s was used to define the reflux.
- (B) Perforators with a diameter of  $>4$  mm.

The site and the number of perforating veins is marked and noted. Those patients satisfying all the inclusion, exclusion, and duplex criteria were included in the study.

Out of 100 patients, 60 patients (60 %) were found to have isolated perforator incompetence without superficial or deep venous pathology. The rest of the patients (40/100; 40%) had either major superficial or deep venous pathology and were excluded from this study. Among the 60 patients with isolated perforator incompetence, 40 patients (66%) are males and 20/60 (34 %) are females. They are randomly allocated using randomized block design, ensuring that subjects within each block are randomly assigned to undergo either ambulatory phlebectomy (30 patients (20 males and 10 females)) or foam sclerotherapy (30 patients (20 males and 10 females)). An overview of the study group is shown in the study chart.

For patients with venous ulceration, conservative management with daily saline dressings and layered bandage application was executed until the active infection subsided. The patients were taken up for procedure once the inflammation and infection subsided, and the ulcer floor was clean and granulating. The procedure was not delayed by waiting for the complete healing of the ulcer. All target veins were traced and marked preoperatively both in supine and standing positions.

Total patients underwent ambulatory phlebectomy =30, Total patients underwent foam sclerotherapy = 30

**Group (A)** is composed of 30 patients prepared for ambulatory phlebectomy: After local anesthesia has been injected into the perivenous tissues, a micro-incision or puncture is done near the vein with the number 11 blade. Most incisions are oriented vertically, except around the knee, where stab incisions will be done along Langer's lines. Using gentle traction, successive hemostats will be applied to the varix end and longer vein segments are excised. Another incision is made at an equivalent distance, and the procedure will be repeated.

**Group (B)** is composed of 30 patients prepared for foam sclerotherapy: foam sclerotherapy which is prepared by Tessari's technique will be injected after a cannula is placed within the vein, A small amount of foam is injected initially to confirm cannula placement within the vein. The target veins which are most proximal will be treated first. On completion, the needle is removed and a folded 2 × 2-in. gauze is secured over the injection site with adhesive tape

After obtaining informed consent, patients with lower limb varicosities of both genders is clinically examined and duplex examination was done. Those patients with isolated perforator incompetence of the lower limbs found by duplex examination is enrolled for this study.

## Results

**Table 1:** Demographic data and treatment characteristics for patients with varicose veins and great saphenous vein incompetence

	<b>Plebectomy</b>	<b>Foam Sclerotherapy</b>
<b>No. of patients</b>	30	30
<b>Age (years)</b>	35 (18-45)	34 (23-50)

**Table 2:** Sex distribution among the studied patients

	<b>Plebectomy</b>	<b>Foam Sclerotherapy</b>
<b>Females</b>	10	10
<b>Males</b>	20	20

## Statistical Analysis

The collected data was revised, coded, tabulated and introduced to a PC using Statistical package for Social Science (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). Data was presented, and suitable analysis was done according to the type of data obtained for each parameter.

- Description of quantitative variables as mean, SD and range.
- Description of qualitative variables as number and percentage.
- **Chi-square test** was used to compare qualitative variables.
- **Two sample t-test** was used to compare quantitative variables between independent groups in parametric data.
- **Paired t-test** was used to assess the statistical significance of the difference between two means measured twice for the same study group
- **McNemar test** was used assess the statistical significance of the difference between a qualitative variable measured twice for the same study group.
  - P- value: level of significance
    - P > 0.05: Non-significant (NS).
    - P < 0.05: Significant (S).
    - P < 0.01: Highly significant (HS).

**Table 3** Patients was categorized according to CEAP

	<b>Plebectomy</b>	<b>Foam Sclerotherapy</b>
<b>CEAP C2–C3 (legs)</b>	28	25
<b>CEAP C4–C6 (legs)</b>	2	5

**Table 4** diameter of great saphenous vein in both groups of this study.

	<b>Foam Sclerotherapy</b>	<b>Plebectomy</b>
<b>GSV diameter (mm)*</b>	8.7 (3–20)	7.8 (3–14)

**Table 5** : presenting primary symptoms

	<b>Number of patients</b>	<b>Percent</b>
<b>Dilated veins</b>	36	60 %
<b>Pain</b>	5	8.3 %
<b>night cramps</b>	3	5 %
<b>edema</b>	4	6.67 %
<b>Ulcer</b>	13	22 %
<b>itching</b>	1	2 %
<b>Bleeding</b>	1	2 %

**Table 6:** Major clinical manifestation according to the revised CEAP classification

	<b>Number of patients</b>	<b>Percent</b>
<b>C 1</b>	4	6.67 %
<b>C 2</b>	27	45 %
<b>C 3</b>	7	11.67 %
<b>C4</b>	6	10 %
<b>C 5</b>	9	15 %
<b>C 6</b>	7	11.66 %

**Table 7:** Operation time

<b>Average</b>	<b>Plebectomy</b>	<b>Foam Sclerotherapy</b>
<b>Procedure time (min)*</b>	40	23

**Table 8:** Grading of primary symptom relief

	<b>Grading</b>	<b>Ambulatory phlebectomy</b>	<b>Foam sclerotherapy</b>
<b>+3</b>	<b>good improvement/asymptomatic</b>	80 % (n = 24/30)	53.33 % (n=16/30)
<b>+2</b>	<b>moderate improvement</b>	13.33% (n=4/30)	13.33 % (n=4/30)
<b>+1</b>	<b>mild improvement</b>	6.67 % (n=2/30)	20 % (n=6/30)
<b>0</b>	<b>unchanged</b>	Nil	6.67 % (n = 2/30)
<b>-1</b>	<b>mild worsening</b>	Nil	6.67 % (n = 2/30)
<b>-2</b>	<b>moderate worsening</b>	Nil	Nil
<b>-3</b>	<b>marked worsening</b>	Nil	Nil

**Table 9:** post-procedure symptoms

	Number	percent
<b>Transient skin pigmentation</b>	9	30 %
<b>Superficial thrombophlebitis</b>	6	20 %
<b>Small ulcers</b>	2	6.67 %
<b>Transient loss of sensation</b>	1	3.33 %
<b>Bleeding</b>	1	3.33 %

**Table 10:** Change in disease severity

	Phlebectomy	Foam Sclerotherapy
<b>Improvement of VCSS</b>	26 (86.67%)	22 (73.33%)

## Discussion

The most common manifestation of chronic venous insufficiency (CVI) worldwide is varicose veins. The prevalence of CVI varies from <1 to 40% in females and from <1 to 17% in males Beebe-Dimmer JL, (2005) in the adult population and is more common in developed industrial countries than under-developed countries.

The prevalence for varicose veins is higher and ranges from <1 to 73 % in females and from 2 to 56 % in males Beebe-Dimmer JL, (2005). CVI reduces an individual's ability to engage in social and occupational activities and, in turn, reduces the quality of life.

Isolated perforator incompetence as an independent factor for varicosities has been rarely studied, though it has been reported in various literatures to range between 2 % Lees TA, (2014) and 8.4 % Bergan JJ, (2012) of limbs with skin changes. Isolated perforator incompetence is seldom taken into consideration when managing disorders of chronic venous insufficiency. Nevertheless, it plays a significant role in determining the severity of CVI. Recently, Ambulatory Phlebectomy and Foam Sclerotherapy are being routinely performed because of its minimally invasive nature.

Compression therapy is usually the first-line treatment for CVI and venous ulcers with perforator incompetence. In the recent years, compression therapy has transitioned from primarily undergoing evaluation to comparison of compression therapy alone versus other modalities of treatment.

Zamboni et al., (2003) and Guest et al., (2003) showed that the effectiveness of compression therapy is 96 and 68%, respectively, in patients with venous ulcers due to major superficial venous incompetence, and their results are comparable to minimal invasive procedures.

But compression therapy alone ironically did not produce satisfactory results in most of the patients with isolated perforator incompetence though it had been proven to be good in major venous incompetence. Around 30 % of the patients in this study group with isolated perforator incompetence tried compression stockings before without any improvement. Hence, the interruption of these isolated incompetent perforating veins without major venous incompetence appears to be mandatory to decrease ambulatory venous hypertension.

The exact local, physiologic, and biochemical mechanisms by which compression therapy works in CVI are uncertain.

The mechanisms of the benefit of compression therapy will likely remain unknown until the underlying pathophysiology of CVI in perforator incompetence is fully studied in anatomic, physiologic, micro-circulatory, and biochemical (VEGF/THF-alpha) levels.

The probable reason for the poor response to compression therapy could have been the failure of improvement in micro-circulation. This may be due to high pressure levels of venous hypertension in patients with varicosities Burnand KG, Wadoodi A (2009), hence hindering the response to conventional grade 2 compression stockings. The thickened

skin in long-standing varicosities may deter the diffusion of oxygen and other nutrients to the cellular elements of skin and subcutaneous tissues.

To begin with, patients who underwent ambulatory phlebectomy had faster relief of symptoms than those who underwent foam sclerotherapy. Venous ulcers in the male population are more common and have a significant impact on the quality of life. Moreover, it was evident that venous ulcers healed faster with ambulatory phlebectomy than with foam sclerotherapy in this study. This study correlates with respect to the results of the following studies in open perforator interruption:

(a) Negus and Friedgood et al., (1983), having an ulcer healing rate of 84% and a recurrence rate of 15%

(b) Pierik et al., (1997), having a healing percentage of 90% and a recurrence rate of 0%

(c) Sato et al., (1999), having an ulcer healing rate of 100% and a recurrence rate of 68

Contradicting to the results of this study, Burnard et al., (1976) found satisfactory healing of ulcers but the ulcer recurrence rate was 55 % in the study of perforator interruption. The reason for the high recurrence rates in the studies by Burnard et al., was due to the fact that only class 5 ulcers were admitted in the study. A comparative view of all the studies in venous ulcer along with this study is shown in Table below.

**Table 2:** Comparative study of venous ulcers in perforator incompetence

Study	Ulcer healing rates (%)	Ulcer recurrence (%)
<b>Negus and Friedgood et al.</b>	84	15
<b>Pierik et al.,</b>	90	0
<b>Burnard et al.,</b>	Satisfactory	55
<b>Sato et al.,</b>	100	68

The NASEPS registry **Gloviczki P, (1999)** reported that the median time taken for ulcer healing was 54 days after subfascial endoscopic perforator surgery (SEPS), which was relatively longer when compared to the results of this study. The probable reason for this relative decrease in the results of this study was due to inclusion of a small group of patients with venous ulcers.

These studies also identified that the presence of a large ulcer (>2 cm), the secondary etiology of the venous disease (Es), and the presence of persistent incompetent perforating veins postoperatively were all risk factors for non-healing of the ulcers.

The severity of CVI (assessed by VCSS) was improved with ambulatory phlebectomy when compared to foam sclerotherapy. This correlates with the reports of Masuda et al., (2006) with their clinical results of foam sclerotherapy with predominantly perforator incompetence alone. After treatment, there was a significant improvement in the Venous Clinical Severity Score of 75 % in the foam sclerotherapy group.

Furthermore, 6 months postoperative, there was a higher percentage of occlusion of the treated veins in patients who were subjected to ambulatory phlebectomy than those to foam sclerotherapy.

Albeit only 6 months of follow-up for all patients was insufficient, this duration was adequate enough to determine that the incidence of recurrence was less in patients who were dealt with ambulatory phlebectomy than with foam sclerotherapy Whether (a) these perforators are retained (missed) during previous duplex examination/procedure or (b) true recurrent perforators are unknown, Pierik et al., (1997) had found a clear association between missed or recurrent perforators and ulcer recurrence.

Both foam sclerotherapy and ambulatory phlebectomy not only revealed minimal time taken for return to normal activity but also proved to be safer with regard to complications. However, the duration for performing foam sclerotherapy was shorter.

Nevertheless, surgeons treating incompetent perforator veins (IPVs) need to accept the reality that recurrent/new IPVs will develop in patients over time. This does not mean that treating IPVs is a futile pursuit. It is merely a fact that, despite our best efforts, the present technique, technology, and knowledge cannot completely halt progression of all venous diseases. Long-term follow-up is needed to study the clinical outcome and late complications.

### Conclusion

In conclusion, the interruption of perforators is effective in decreasing the symptoms of chronic venous insufficiency and for the rapid healing of ulcers. The interruption of the incompetent perforating veins appears to be essential to decrease ambulatory venous hypertension. It is apparent from this study that ambulatory phlebectomy stands distinct with enormous benefits and serves as a superior alternative to foam sclerotherapy in treating patients with isolated perforator incompetence.

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