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### RESEARCH ARTICLE

## A PROSPECTIVE STUDY ON EFFECTIVENESS OF DUPLEX GUIDED FOAM SCLEROTHERAPY IN THE MANAGEMENT OF VARICOSITIES WITH ISOLATED PERFORATOR INCOMPETENCE IN OUR INSTITUTION.

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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 primary goal of this study is to study the duplex guided foam sclerotherapy in the management of leg varicosities having isolated primary perforator incompetence. Via the clinical parameters (return to normal activity, primary symptom relief), duplex parameters (recurrence in treated veins, complete occlusion of treated veins) Though there are many procedures for treating isolated Perforator IC like ambulatory phlebectomy, EPLS; Foams sclerotherapy is the one with shorter time and low cost and as a day care procedure. It is superior to other in our institutional experience. 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.

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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.

The primary goal of this study is to show the clinical, functional, and duplex outcome in the management of leg varicosities having isolated primary perforator incompetence by duplex guided foam sclerotherapy.

#### Patients and Methods:-

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This is a prospective study based on the analysis of varied cases of varicosities of the lower limbs with isolated primary perforator IC. This study was conducted between June 2017 and June 2018 at the Department of Vascular Surgery in a tertiary care teaching hospital in southern India. After obtaining approval from the ethics committee and informed consent, patients with lower limb varicosities of both genders were clinically examined and duplex

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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**

1. Varicosities in lower limbs with or without venous ulcers
2. Duplex showing only perforator incompetence with saphenofemoral junction, saphenopopliteal junction, and deep veins being normal
3. Persistent/recurrent varicosities after compression therapy for isolated perforator incompetence

#### **Exclusion Criteria**

1. Prior history of deep vein thrombosis
2. Allergic to sclerosants
3. Associated arterial and neuropathic problems
4. Pregnant and lactating women
5. Prior history of trauma
6. Lymphedema

#### **Preprocedure Workup**

The patients with leg varicosities attending Surgical and Vascular Outpatient Clinic were examined. A thorough 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 [1] was done for all the patients, and the disease severity was determined by Venous Clinical Severity Scoring (VCSS) [2]. 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.

#### **Patient Selection by Duplex Criteria and Procedure**

A total of 50 patients with varicose veins were subjected to duplex examination from 2017 - 2018. The pulsed-wave Doppler of 9–3 MHz linear array transducer (Philips IU22) was used. For deep venous examination, the patient is placed in supine posture with a slight Trendelenburg position and with external rotation of hip and slight knee flexion to avoid the venous compression by normal anatomic structures of the lower extremity. The veins are examined in 3–5-cm intervals and is started below the inguinal ligament at the common femoral vein and saphenofemoral junction (SFJ) and moved distally.

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 [3]. 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:

1. A shorter time cut point of 0.35 s was used to define the reflux.
2. Perforators with a diameter of  $>4$  mm.

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

Among the 50 patients with isolated perforator incompetence, 42 patients (64 %) are males and 8 (36 %) are females.

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

Study Group: duplex guided foam sclerotherapy (Fig. with 1 % polidocanol foam preparation with 2% topical lignocaine)

After mapping the treatment area, access to the veins to be treated was visualized and a 25–30-gauge needle was placed within the vein by duplex guidance. A small amount of foam which is prepared by Tessari's technique [4] was injected initially to confirm needle placement within the vein. The target veins which were most proximal were treated first. The amount of foam injected was determined by using ultrasound to visualize when the targeted vein was filled with foam. The deep venous system was carefully interrogated with the ultrasound probe. In case of foam migration to the deep system, vigorous ankle flexion–extension was used to dissipate the foam fragments. On completion, the needle was removed and a folded 2 × 2-in. gauze was secured over the injection site with adhesive tape. An average of 9 ml of foam was used per patient (range 6–15 ml). The amount of foam used was based on the number of perforators treated.

**The higher the number of perforators, the higher the amount of foam used.**

Procedure time was noted for each patient. Compression dressing with Elastocrepe bandage was applied after the procedure with the objective to maintain vein wall apposition, and the same was removed on day 2. Patients were observed for 6 h to watch for signs of allergy and bleeding, and they were instructed to ambulate and perform flexion–extension of ankles at frequent intervals after the procedure. Adequate analgesics were given in post-procedure period for pain control. Compression therapy was given with standard grade 2 compression stockings (Sigvaris, made of polyamide and cotton) for 3 weeks which deliver a pressure of about 20–40 mmHg [5]. The pressure girth profile (a measure of quality control) of the stockings was checked and found to be at a standard range by the manufacturer.

**Follow-up**

Patients were instructed to return for follow-up in intervals of 2 weeks, 1 month, 3 months, and 6 months, respectively. Their symptomatic and clinical improvement was documented at the end of the third and sixth months (+3 good improvement/asymptomatic, +2 moderate improvement, +1 mild improvement, 0 unchanged, –1 mild worsening, –2 moderate worsening, –3 marked worsening). Patients were termed to have Batisfactory/good response^ or Bpoor/no response^ based on the relief of primary symptoms. The duration of return to normal day activities and the perioperative complications following the procedures were also noted. At follow-ups, the patients were assessed clinically for presence of varicosities, resolution of skin changes, and healing of ulcers. The elasticity of the stockings was checked during the follow-up period, and the patients were instructed on the proper application of the stockings as well.

Duplex scanning was done at the sixth month of visit to assess the status of the treated veins. The parameters used were as follows:

1. Functional outcome (return to normal activity/primary symptom relief)
2. Clinical outcome (procedure time/change in disease severity assessed by venous clinical severity scoring and change in CEAP classification/course of venous ulcer)
3. Duplex outcome (recurrence in treated veins/complete occlusion of treated veins)

**Statistical Analysis:-**

The means and Student's *t* test were used to compare continuous variables, and chi-square and Fisher's exact tests were used to compare nominal variables. The statistical comparisons were performed using SPSS 20.0. A *p* value of less than 0.05 was considered significant.

**Results:-**

Among the 50 patients, 84 % were men (42/50) and the rest were women (16 %; *n*=8/50). In both males and females, the most commonly affected age group was 31–40 years with a mean age of 36 years. The prevalence of

isolated perforator incompetence was found to be more common in males than in females in the vicinity of this study.

Among the presenting primary symptoms, dilated veins were the most common in 80 % ( $n=40/50$ ) of the patients. Other presenting symptoms were distributed in this manner: pain, 60 % ( $n= 30/50$ ); lipodermatosclerosis, 20 % ( $n= 10/50$ ); edema, 10 % ( $n= 5/50$ ); ulcer, 22 % ( $n= 17/78$ ); itching, 6 % ( $n= 3/50$ ); and bleeding, 6 % ( $n= 3/50$ ).

The major clinical manifestation according to the revised CEAP classification was dilated veins (C2) (varicose veins; 80 % ( $n=40/50$ )). The other manifestations included C1 (telangiectasia or reticular veins; 8 % ( $n=6/78$ )), C3 (edema without skin changes; 10 % ( $n= 5/50$ )), and C4 (skin changes ascribed to venous disease; 20 % ( $n= 10/50$ )). Twenty-eight percent of the patients had ulcers at presentation, of which 15 % ( $n=12/78$ ) had healed ulcers (C5) and 13 % ( $n= 10/ 78$ ) had active ulcers (C6).

The average venous reflux time used to define the incompetent perforators was 0.35 ms. An average of seven incompetent perforators was needed to produce symptoms. Most commonly, the Cockett group of paratibial perforators was found to be incompetent. The diameter of the veins range between 1 and 7 mm, and the average diameter of the veins treated with foam sclerotherapy (FS) was 3 mm. Any perforators above 3.4 mm in diameter were more likely to produce symptoms, and the perforators whose diameter was <2 mm were less likely to produce symptoms. In patients presenting with advanced disease, more incompetent perforating veins were found and their diameters were also larger.

The primary symptom of the patient for which the patient was seeking medical attention was relieved in 80 % ( $n= 40/ 50$ ) of the patients in foam sclerotherapy were relieved from their presenting symptoms. The average procedure time was 23 min in foam sclerotherapy.

In the post-procedure period, pain is the most common symptom (22 %;  $n= 11/ 50$ ). Other symptoms including transient skin pigmentation (6 %;  $n=3/50$ ) and superficial thrombophlebitis (10 %;  $n= 5/50$ ) puncture site ulcer (2%) , infection (2%), bleeding (2%) were found to be in the immediate post op period. Twenty percent ( $n=6/50$ ) of the patients received more than 12 ml foam based on the number of perforators, and the incidence of superficial thrombophlebitis and skin pigmentation was more common in these patients though no deep vein thrombosis was reported.

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Patients resumed normal day-to-day activities after 1 day following the procedure. The mean size of the ulcers of those who underwent both ambulatory phlebectomy and foam sclerotherapy was 2.9 cm (range 1.3–5.5 cm). The symptomatic improvement of active ulcer (granulation tissue, decrease in size of ulcer, decrease itching sensation in ulcer) began around the second week, and signs of satisfactory healing of ulcer took an average of 6 weeks (40 days) in foam sclerotherapy. The initial size of the ulcer did not correlate neither with the rate of ulcer healing nor with the time taken for the healing of the ulcer. All the active ulcers healed with no recurrence (0 %) in the follow-up period. VCSS improved to 60 % ( $n =30/50$ ) in patients who underwent foam sclerotherapy.

During the follow-up with duplex at 6 months, treated veins showed 64 % ( $n=32/50$ ) showed evidence of incomplete occlusion. Recurrent perforators developing leg varicosities were found in 6 % ( $n=3/50$ ) of the patients in the foam sclerotherapy group had recurrence.

### **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 [6] in the adult population and is more common in developed industrial countries than underdeveloped countries. The prevalence for varicose veins is higher and ranges from <1 to 73 % in females and from 2 to 56 % in males [6]. 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 % [7] and 8.4 % [8] 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. [9] and Guest et al. [10] 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.

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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 anatomical, 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[11], 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:

1. Negus and Friedgood et al. [12], having an ulcer healing rate of 84 % and a recurrence rate of 15 %
2. Pierik et al. [13], having a healing percentage of 90 % and a recurrence rate of 0 %
3. Sato et al. [14], having an ulcer healing rate of 100 % and a recurrence rate of 68 % Contradicting to the results of this study, Burnard et al. [15] 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 2.

The NASEPS registry [16] 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 post-operatively 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. [17] 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. [18] 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. Foam sclerotherapy is one of the best day care procedure and an effective one in treating isolated perforator IC varicose veins in our institutional experience

### **Compliance with Ethical Standards**

Conflict of Interest The authors declare that they have no conflict of interest.

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