

# INJECTION FOAM SCLEROTHERAPY OF PERI ULCER VEINS FOR TREATMENT OF CHRONIC VENOUS LEG ULCERATION - A COMPARATIVE STUDY

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## INTRODUCTION

Venous diseases broadly fall into two categories: chronic venous insufficiency and veno-occlusive disease, including superficial thrombophlebitis, and deep venous thrombosis

Untreated venous insufficiency in the deep or superficial system causes progressive manifestations as venous ulcers which are distressing for patients, expensive to manage, and challenging to treat.

The gold standard for venous ulcer treatment is compression therapy, which heals a high proportion of cases within 6 months; however, the problem is the high recurrence of the condition

Sclerotherapy has been advocated extensively to improve cosmetic appearance and to reduce the associated symptoms such as pain and burning

This study aimed to compare the efficacy and safety of foam sclerotherapy injection into peri ulcer veins added to the conservative compression therapy versus the adoption of compression therapy alone in healing chronic active venous leg ulcers.

## AIM OF THE WORK

The aim of this study was to compare the efficacy and safety of foam sclerotherapy injection into periulcer veins added to conservative treatment with compression therapy versus the adoption of conservative treatment with compression therapy only in healing chronic active venous leg ulcers.

## PATIENTS AND METHODS

The study was a prospective, single-center, randomized, placebo-controlled, single-blinded study performed on venous leg ulcer patients. The study was conducted at Alexandria University Main Hospital, Alexandria, Egypt. Institutional ethical approval of the study protocol was obtained. Written informed consent was obtained from the patients or their legally authorized representatives before enrollment. Randomization was performed using block randomization, where participants were randomized in blocks with equal numbers.

**Inclusion Criteria:**

- Patients having chronic active or recurrent VLU(s), C6 on revised CEAP classification (Clinical, Etiological, Anatomical, and Pathological).

- Age more than 18 years.
  - Maximum size of ulcer less than or equal to 12cm.
  - Competent or disconnected sapheno-femoral junction.
  - Normal or stripped great saphenous vein.
  - Patent deep venous system.
- Exclusion Criteria:**
1. Infected ulcers.
  2. Acute deep vein thrombosis (DVT).
  3. Hypercoagulable states.
  4. Peripheral arterial disease with an Ankle-Brachial Index <0.9.
  5. Pregnancy.
  6. Allergy to the sclerosant material.
  7. Malignancy.
  8. Ulcer size more than 12 cm.
  9. Primary venous insufficiency.
  10. Ulcers involving the whole circumference of the leg.
- The Results were Assessed According to:**
- Ulcer healing time at 3, 6, 9, and 12 months, measuring its size using a ruler in 2 dimensions.
  - Rate of healing.
  - Ulcer-free time (Time between the healing of ulcer and recurrence).
  - Recurrence.

## RESULTS

Table1: Comparison between the two studied groups according to demographic data

| Demographic data        | Cases (n=20)       |      | Control (n=20)     |      | Test of Sig.       | p-value |
|-------------------------|--------------------|------|--------------------|------|--------------------|---------|
|                         | No.                | %    | No.                | %    |                    |         |
| Gender                  |                    |      |                    |      |                    |         |
| Male                    | 12                 | 60   | 10                 | 50.0 | $\chi^2=$<br>0.404 | 0.525   |
| Female                  | 8                  | 40   | 10                 | 50.0 |                    |         |
| Age (years)             |                    |      |                    |      |                    |         |
| Min. – Max.             | 30.0 – 69.0        |      | 36.0 – 57.0        |      | t=<br>1.046        | 0.304   |
| Mean ± SD.              | 47.20 ± 9.68       |      | 49.75 ± 5.01       |      |                    |         |
| Median (IQR)            | 46.0 (42.0 – 55.0) |      | 50.0(46.50 – 54.0) |      |                    |         |
| Comorbidities           |                    |      |                    |      |                    |         |
| Diabetes                | 7                  | 35   | 5                  | 25   | 0.476              | 0.49    |
| Obesity                 | 6                  | 30   | 7                  | 35   | 0.114              | 0.736   |
| Smoking                 | 8                  | 40   | 6                  | 30   | 0.44               | 0.507   |
| Hypertension            | 4                  | 20   | 7                  | 35   | 1.129              | 0.288   |
| Previous Treatment      |                    |      |                    |      |                    |         |
| None                    | 5                  | 25.0 | 6                  | 30.0 | 0.694              | 0.834   |
| Compression             | 10                 | 50.0 | 11                 | 55.0 |                    |         |
| Compression + stripping | 5                  | 25.0 | 3                  | 15.0 |                    |         |

Table2: Comparison between the two studied groups according to ulcer size

| Ulcer Size (cm <sup>2</sup> ) | Cases (n = 20)     | Control (n = 20)  | t      | p-value |
|-------------------------------|--------------------|-------------------|--------|---------|
| Initial                       |                    |                   |        |         |
| Min. – Max.                   | 3.50 – 6.70        | 4.70 – 6.70       | 3.133* | 0.003*  |
| Mean ± SD.                    | 5.01 ± 0.88        | 5.73 ± 0.55       |        |         |
| Median (IQR)                  | 4.95(4.30 – 5.65)  | 5.75(5.25 – 6.15) |        |         |
| At 12 Months                  |                    |                   |        |         |
| Min. – Max.                   | 0.0 – 6.10         | 0.00 – 6.70       | 2.687* | 0.011*  |
| Mean ± SD.                    | 1.67 ± 1.56        | 3.35 ± 2.31       |        |         |
| Median (IQR)                  | 1.50(0.35 – 2.30)  | 3.0 (1.10 – 5.75) |        |         |
| Reduction                     |                    |                   |        |         |
| Min. – Max.                   | 0.0 – 6.0          | 0.0 – 6.0         | 1.651  | 0.107   |
| Mean ± SD.                    | 3.34 ± 1.58        | 2.39 ± 2.03       |        |         |
| Median (IQR)                  | 3.60 (2.80 – 4.25) | 2.80 (0.0 – 4.15) |        |         |

IQR: Inter quartile range; SD: Standard deviation; t: Student t-test;\*: Statistically significant at p  $\leq$  0.05

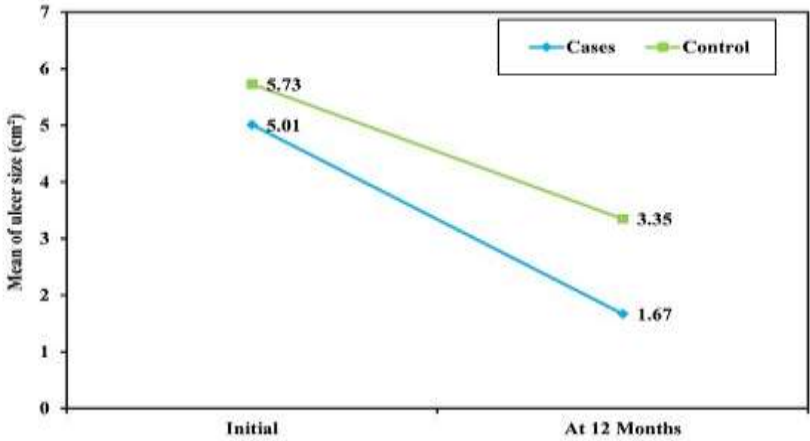


Figure 1: Comparison between the two studied groups according to ulcer size

## CONCLUSION

Foam sclerotherapy injection added to compression therapy was safe and effective in treating chronic active venous leg ulcers as it is associated with a high healing rate and low recurrence.