

## OUTCOME OF SCLEROTHERAPY IN THE TREATMENT OF NON-HEALING VARICOSE ULCERS UNDER ULTRASOUND CONTROL

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### ABSTRACT:

**BACKGROUND & OBJECTIVE:** Varicose veins are the commonest vascular problem both in men and women worldwide. Lack of timely management, inadequate treatment, and maltreatment of varicose veins can lead to the development of nonhealing ulcers and affects the quality of life in terms of health. Surgery, heat therapy, chemical therapy, and endoscopic treatment are the options of treatment. Foam sclerotherapy is relatively a new technique being practiced all over the world and has promising results. The objective was to determine the outcomes of foam sclerotherapy in the treatment of non-healing varicose ulcers.

**METHODOLOGY:** In this descriptive study, 240 patients with chronic leg ulcers with varicose veins had been managed with foam sclerotherapy under ultrasound and compression bandage. All patients were reviewed at 7 days, 1 month, 3 months, 6 months, 1 year, and 18 months both clinically and radiologically with a doppler ultrasound to assess the ulcer healing rates.

**RESULTS:** The overall healing after 04 weeks of foam sclerotherapy was 83%. Two hundred and twenty-nine patients (95.4%) with ulcers healed within 02 months of the start of ultrasound-guided foam sclerotherapy. Delayed healing occurred after four months in 11 cases. All those cases had either previous varicose veins surgery or deep vein thrombosis, or extensive perforator disease. During 18 months of follow-up, seven patients showed recurrence with a mean symptom-free period of 07 months.

**CONCLUSION:** Chronic venous ulcers treated with foam sclerotherapy under ultrasound guidance are associated with a high healing rate and low recurrence rate.

**KEYWORDS:** Chronic, Foam sclerotherapy, Treatment, Venous ulcer.

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## INTRODUCTION:

The varicose veins are common worldwide both in men (5-15%) and women (3-29%) and can lead to venous insufficiency<sup>[1]</sup> and venous ulceration<sup>[2]</sup> if they remain untreated. The venous insufficiency leads to ambulatory venous pressure in the affected limb, which affects the microcirculation of the skin and hence causes venous ulceration<sup>[3]</sup>. One percent of the adult European population is affected with chronic venous ulcers, and 0.1% of people have active venous ulcers at any one time<sup>[4]</sup> and adversely affects the living style<sup>[5]</sup>. Traditionally varicose veins are managed by surgery (flush ligation, multiple phlebectomies, stab avulsions, and stripping) and stockings. Radiofrequency ablation (RFA), endovenous laser ablation (EVLA), and ultrasound-guided foam sclerotherapy (UGFS) currently very popular in the treatment of varicose veins and its complications.

Ultrasound-guided foam sclerotherapy is relatively safer, highly attractive, and efficient among all the interventions, especially in patients not fit for anesthesia<sup>[6]</sup>. Our study assessed the healing and recurrence rate in nonhealing varicose ulcers treated by UGFS.

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## METHODOLOGY:

An ethical approval letter (Ser. No. 68/14/05/20) was taken from the ethical review committee of Combined Military Hospital Rawalpindi for this prospective observational study prior to the study. A total of 240 consecutive patients with non-purposive sampling technique, having nonhealing ulcers and managed by foam sclerotherapy under ultrasound control and compression between September 01, 2018, and 29 February 2020, were included. The Statistical analysis was done with SPSS Version 17.0 (SPSS© Inc., IL, USA). The numerical variables were expressed as Means and Standard Deviations

(SD), and categorical data were expressed as Frequency and Percentage. Patients were divided into two groups, and the characteristics such as demographics, ulcer healing, and sclerotherapy sessions were compared. Groups were compared using the students' T-test, and the p-value was considered statistically significant if  $p < 0.05$ . Patients diagnosed with deep vein thrombosis and chronic arterial limb ischemia were excluded. The foam was made by mixing sodium tetradecylsulphate (3% for truncal veins and 1% for smaller veins) with air as one ml of sclerosant and four ml of air. The foam was then injected into the affected vein under ultrasound control, followed by a compression bandage. Post-procedure Inj. Heparin was given subcutaneously (5000 I.U.) for 03 days along with Tab. Augmentin 625 mg thrice a day and Diclofenac potassium 50mg twice a day for 05 days. First follow-up was done after 7 days in the clinic and the leg was assessed both clinically and with Duplex Ultrasound for occlusion of varicosities and presence of any complication. Second, third and fourth sessions were performed for residual or new varicosities. The primary endpoint of the study was healing of the ulcer and compression was continued for 3 months after healing was complete. Secondary endpoints were the requirement of subsequent sessions of sclerotherapy.

## RESULTS:

Demographic data of 240 patients with active chronic venous ulcers were recorded (Table-I). Mean age was 34 years. There were 48.3% (n=116) males with a male to female ratio of 1:1.06. Duplex findings before the start of treatment are given in table-II. A total of 74.5% (n=179) patients had primary varicose veins, 17% (n=41) had recurrent varicosities after previous surgery. Deep vein reflex was present in 8.3% (n=20) patients with patent deep veins. ABPIs was  $> 0.8$  in all cases. Mean Ulcer healing time was 4.5 months (Range 3-24 months). The percentage of ulcer healing after each session of sclerotherapy is given in table-III.

The overall ulcer healing at 04 weeks was 83% and 95.4% after 08 weeks of the start of treatment with foam sclerotherapy. In 168 cases, all superficial reflex was successfully abolished after only one course of UGFS and remained so

till the end of the study period. Seventeen patients had another treatment session. Rest required another one or two treatment sessions for residual/recurrent (recanalisation) or new varicosities during follow-up.

Incomplete healing occurred after four months, in 11 patients having a previous history of venous surgery/deep vein thrombosis/extensive perforator disease/poor compliance to compression stockings. There was recurrence of the ulcer in 2.9% (n=7) patients treated with foam sclerotherapy and had their ulcers healed initially. The mean recurrent ulcer-free period was 24 weeks. In the author's opinion, this recurrence was due to the discontinuation of compression stockings or the formation of new incompetent perforators. No immediate or delayed deep vein thrombosis, pulmonary embolism, or visual disturbance occurred in our patients.

**Table-I: Demographic data.**

Characteristics		n (%)
Gender	Male	116 (48.3%)
	Female	124 (51.7%)
Ratio (Male: Female)		1: 1.06
Age (Mean±SD)		34± 08
Previous DVT with recanalized veins		20(8.3%)
Limb involved	Right	110(45.83%)
	Left	130(54.16%)

There was no statistical difference in ulcer healing rate at 4 and 8 weeks in comparing the two groups. However, it is worth noting that statistically significant female patients healed with one and two sclerotherapy sessions. Male patients required more than 2 sessions, which was also significant compared to the female group (Table -IV).

**Table-II: Pretreatment duplex findings n(%).**

Characteristics	n (%)
Primary varicose veins	179 (74.58%)
Recurrent varicose veins	41(17.08%)
Secondary varicose veins	20 (8.33%)
<b>Veins involved in duplex</b>	
Great saphenous vein primary	106 (44.16%)
Great saphenous vein recurrent	16 (6.66%)
Small saphenous vein primary	47 (19.58%)
Small saphenous vein recurrent	19 (7.91%)
Perforator veins primary	25 (10.41%)
Perforator veins recurrent	6 (2.5%)

**Table-III: Ulcer healing rates and sclerotherapy sessions.**

Results n (%)	
The ulcer healed within 04 weeks of the start of treatment	199 (83%)
Total Ulcers healed within 08 weeks of the start of treatment	227 (95.4%)
Ulcers healed after the first session of ultrasound-guided foam sclerotherapy	168 (70%)
Ulcers needed a 2nd session of ultrasound-guided foam sclerotherapy	17 (7.08%)
Ulcers needed 3rd and 4th session of ultrasound-guided foam sclerotherapy	44 (18.33%)
Non healed ulcers after 4 months of treatment	11 (4.58%)
Recurrent ulcers which remained healed for 02 weeks then recur	07(2.92%)

**Table-IV: Comparison between Male and female groups in terms of risk factors, ulcer healing, and sclerotherapy sessions.**

Results n (%)			
Variables	Male	Female	p-value
Age	36	29	0.07
Previous DVT	15	5	0.001
Primary varicose veins	79	100	0.08
Recurrent veins	31	10	0.02
Secondary Varicose veins	6	14	0.058
Ulcer healing rates:			
Within 4 weeks	94	105	0.091
Within 8 weeks	103	124	0.061
Sclerotherapy sessions required for complete ulcer healing:			
One session only	68	100	0.002
Two sessions	2	15	0.001
More than 2 sessions	35	9	0.0039
Non healed ulcer	10	1	0.0053

**DISCUSSION:**

Superficial and deepvenous reflux leads to venous insufficiency and venous hypertension in chronically affected limbs, leadingto chronic venous ulceration. Traditional treatment of varicose veins is surgery. Most patients with chronic venous ulcers are frail and old, so not fit for surgery. New techniques (RFA,EVLA, and UGFS) are now under practice to treatthis condition<sup>[7]</sup>. Wehad treated 240 patients having active chronic venous ulcers in our study with UGFS and compression for eradication of superficial venous reflex. Our healing rate at 18 monthsis comparable with the results of the ESCHAR trial (40%)<sup>[8]</sup>. Most of the studies reported are of short duration<sup>[9,10]</sup>. Theulcer healing was 96% at 24 weeks, and recurrence (7.1%) at 1 year has been reported in a study of twenty-seven patients treated with UGFS<sup>[9]</sup> by Cabrera et al. showed83% healing rate in 151 casesat 24 weeks and recurrence rate of 6.3% at 24 weeks in his study<sup>[11]</sup>.

Bergan et al. demonstrated that only46%of

ulcerswere healed in patients where the only compression was applied compared to 100% healing where compression and sclerotherapy were performed <sup>[12]</sup>. In another study, where Hertzman used UGFS to treat 13 cases of non-healing venous ulcers, healing took place in 11 cases after 14 days<sup>[13]</sup>. Similarly, O' Hare and Earnshaw showed healing in 77.2% of patients treated with compression alone compared to 94% healing with compression combined with sclerotherapy<sup>[10]</sup>.

Ulcers healing did not occur in eighteen cases in our study. Seven had a recurrence and 11 never healed.Deep venous insufficiencyon doppler ultrasound and longer duration of ulcers before UGFS, poor compliance to pressure bandage/ stockings and development of new superficial venous reflex, previous venous surgery, and extensive perforator diseasewere thefactors associated with nonhealing / recurrence<sup>[11,14]</sup>. All of our patients were advised to use compressionbandages/stockings during the treatment period. The healing rate in our study

was highest in main superficial veins, high in main veins with perforator disease, and patients with previous venous surgery. It was relatively low in patients with only perforator disease. A randomized control study is needed to document whether UGFS with compression is better than compression alone. We have started such a study in our department from April 2020 onward.

UGFS can abolish superficial venous reflux in 90% of patients with only one session. This technique is safe, clinically effective, inexpensive, and a good alternative to varicose vein surgery<sup>[15]</sup>.

Chronic venous insufficiency with active chronic venous ulcers needs compression stockings and intervention with regular follow-up both clinically and radiologically to allow re-treatment of recurrence<sup>[15]</sup>.

### CONCLUSION:

UGFS combined with compression bandages/stockings probably offers the best treatment option to eradicate all superficial venous reflux and chronic venous ulcers. It promises the highest healing and low recurrence rates. It is simple, safe, and effective in recurrent or new superficial venous reflux.

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#### Author's Contribution:

**Muhammad Jamil:** Data collection, article writing, data organization and data analysis.

**Rashid Usman:** Correction and revision.

**Kishwar Ali:** Correction and revision.

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**Rai Ahmad Khan Kharl:** Reference collection.

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