Role of Catheter-directed Foam Sclerotherapy in Treatment of Lower Limbs Primary Varicose Vein

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Abstract

Background: Spider telangiectasias, reticular veins, and true varicosities are all common kinds of varicose veins. If spider telangiectasias and reticular veins are included, it affects 80% of men and 85% of women. Varicose veins affect 22 million women and 11 million men between the ages of 40 and 80.

Objectives: Evaluate the role of Catheter-directed Foam sclerotherapy in Treatment of Lower Limbs Primary Varicose Vein

Patients and methods: This randomized controlled clinical trial included patients from Qena University Hospital, South Valley University's vascular surgery outpatient clinics. 60 patients had catheter-directed foam sclerotherapy and were monitored clinically by CEAP classification, venous clinical severity score, and venous duplex.

Results: The study included 24 males, 36 females (average age 34.45±7.243). Most had left saphenous vein incompetence (65.0%). Preoperative GSV diameter: 4-9 (mean 6.27±1.103). After one week, 75.0% had GSV obstruction (63.3% after one year). Partial GSV recanalization without reflux: 16.7% after one year. After one week, 8.3% had partial GSV reflux recanalization, 13.3% after one year. GSV reflux recanalization: 1.7% after one week, 6.7% after one year. Technical success: 80.0% after one year (down from 90.0% after one week). Hyperpigmentation: 6.7%, thrombophlebitis: 3.3%. CEAP classification pre-treatment: C2(50.0%), C3(40.0%), C4(10.0%). After one year: C0(60.0%), C1(31.6%), C2(3.3%), C3(5.0%). Pre-procedure VCSS: 2-9 (mean 4.75±1.46), decreased to 1.39±1.41 after one year.

Conclusion: Catheter-directed Foam sclerotherapy is safe , effective available method to manage lower limbs varicose veins with the advantage of shorter time of admission with less complication than traditional method.

Keywords: Catheter-directed Foam sclerotherapy; VCSS; CEAP.

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Introduction

Venous disease, often overlooked, surpasses arterial occlusive disease in complexity, with manifestations ranging from asymptomatic telangiectasias to edema and ulceration **(Lombardi et al., 2021).** Varicose veins (VVs) represent a prevalent and impactful vascular disorder globally, affecting the subcutaneous venous system and causing dilatation to at least 3mm in diameter **(Abd Elsalam et al., 2020).** The burden of this condition extends beyond mere cosmetic concerns, encompassing painful symptoms, disability, soft tissue damage, and, in severe cases, venous ulcers. The prevalence of varicose veins has prompted a substantial healthcare burden, necessitating effective and minimally invasive treatment options **(Gao et al., 2020).**

Treatment selection considers symptoms, location, and severity, with options including lifestyle modifications, compression therapy, ablative therapies, surgical interventions, and endovenous ablative therapies **(Grill et al., 2022).**

High ligation coupled with surgical stripping has been widely accepted as the most effective method for treating insufficiency of the Great Saphenous Vein (GSV). Nevertheless, there has been a significant change in recent years with the use of minimally invasive treatments **(Whing et al., 2021).** Chemical ablation, using foam or liquid sclerotherapy, has become more popular for treating large and small veins. Endothermal catheter modalities, such as Endovenous Laser Ablation (EVLA) and Radiofrequency Ablation (RFA), are now the favored procedures because of their high success rates. This shift in approach demonstrates a growing recognition of the constraints of conventional surgical methods and a rising inclination towards less invasive and more effective treatments **(Belramman et al., 2019; Stoughton & Lee, 2023; Dekiwadia, 2023).**

Foam sclerotherapy emerges as an effective approach, with benefits such as higher efficacy when using a repeatedly perforated catheter for reticular veins **(Georgakarakos et al., 2023).** Additionally, foam sclerotherapy accelerates ulcer healing and outperforms liquid sclerosant for vascular venous malformations **(Liu et al., 2019; Zhu et al., 2023).**

Catheter-directed foam sclerotherapy (CDFS) emerges as a contemporary and promising intervention for primary lower limb varicose veins. The procedure employs a systematic approach, identifying incompetent veins through pretreatment skin marking and utilizing ultrasound guidance for the injection of polidocanol and room air foam using Tessari's method. This induces immediate histological wall damage, forming micro-thrombi and obstructing the vein lumen **(Lim et al., 2020).**

Recurrences post-foam sclerotherapy are successfully eliminated with repeated sessions, and long-term observations show minimal new recurrences. Subsequent compression therapy with medical elastic socks enhances the end result and reduces hyperpigmentation **(Hoss et al., 2020).**

Patients and methods

This investigation was conducted among individuals seeking medical attention at outpatient clinics within the vascular surgery department of Qena University Hospital, affiliated with South Valley University under ethical code: **SVU-MED-VSS015-2-21-7-214.** The study employed a randomized controlled clinical framework. 60 patients were included to be managed by catheter directed foam sclerotherapy and followed up clinically by CEAP classification and venous clinical severity score nad radiologically by venous duplex.

Sample size : The sample size was obtained using the equation of Steven K. Thompson. **(Gelman, 2017)**

$n = Nxp\ (1-p)\ [[N-1x\ (d2\div z\ 2)] + p\ (1-p)]$

The variables used in this context are as follows: n represents the sample size, N represents the population size, Z represents the confidence level at 95% which is equal to 1.96, d represents the absolute error or precision which is set at 0.05, and p represents the probability which is 50%. There were a total of 60 patients.

Inclusion criteria

- Patients with primary lower limb varicose vein with CEAP class from C2 to C4 .

- Duplex scan showing great saphenous vein incompetence .

Exclusion criteria

- Patients with ankle brachial pressure index less than 0.9 , coagulopathies or diabetic patients .
- Patients with a history of superficial thrombophlebitisin the great saphenous vein , patent foramen ovale ,or deep vein thrombosis

Before being allocated to the experiment, all patients obtained informed consent, as approved by the ethical committee of Qena Faculty of Medicine, South Valley University.

All patients were subjected to the following :

- Full complete medical history : Diabetes, Hypertension or tobacco use
- History of medications and anti-coagulants .
- General examination: general condition ,vital signs
- Local examination: lower limb examination , pre-intervention venous clinical severity score will be applied , pre-intervention CEAP classification will be determinded.
- Investigations : pre-intervention venous duplex scan will be done , full routine laboratory tests

All the patients were subjected to the following after taking informed written consent.

Catheter directed foam sclerotherapy procedure: In the preprocedure phase, identification of incompetent veins was accomplished through meticulous skin marking. Subsequently, under ultrasound guidance using the GE LOGIC S8 xDClear 2.0(R4) system, cannulation below the knee to great saphenous vein with an 18 or 21 gauge needle was performed, followed by the insertion of a 0.038 or 0.035 wire upwards. The next step involved the placement of a 6f, 11 cm sheath, with patients positioned in the Trendelenburg position to facilitate the emptying of leg veins for foam injection. To minimize column of blood , the sheath was flushed with normal saline. Introduction of a wire (standard , 0.035) then 4f, 100 cm angiographic catheter (Bern) . The protocol included the administration of a maximum quantity of 10 ml of polidocanol foam (docavarico) via Tessari's method by injection. A foam was generated by mixing polidocanol 2% with room air in a 1:4 ratio. Upon completion of the injections, the foam was seen to almost reach the saphenofemoral junction. Patients were instructed to do ankle dorsiflexions to facilitate the elimination of foam from the deep veins. The saphenofemoral junction (SFJ) was squeezed manually with the aid of the hand for a period of 10-15 minutes. After applying continuous pressure to the finger joint for 15 minutes, the limb was tightly bound with a 12 cm-wide elastic bandage for a period of 5 days. Afterwards, below-knee elastic stockings with a pressure of 30-40 mmHg were worn for a duration of 3 months (**Fig.1A-C**).

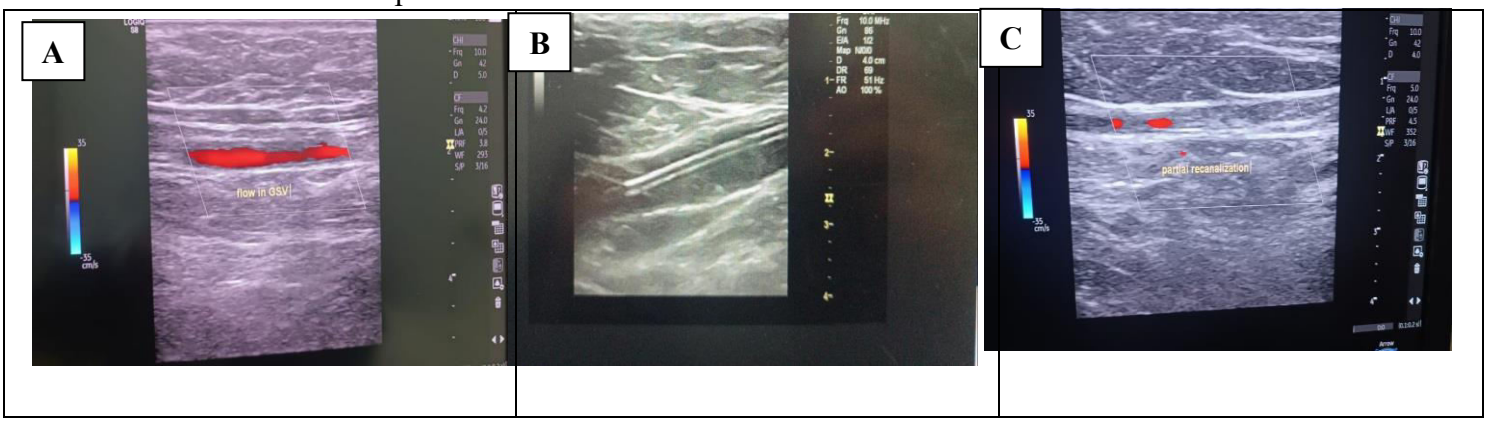

Fig.1.A. Color flow inside Great saphenous vein (patent vein).**B)** During intervention shows insertion of catheter inside Great saphenous vein near junction before foam injection. **C)** One month post intervention picture at : shows partial occlusion occlusion of great saphenous vein

Follow up

1- CEAP at one week and 1 , 3 ,6 , 12 months .

2- VCSS at one week and 1 , 3 ,6 , 12 months .

3- Dplex ultrasound examination at one week and 1 , 3 ,6 , 12 months .

Outcome

The main outcome was the achievement of technical success, which was determined by ultrasound examination showing full closure of the incompetent vein and partial restoration of blood flow without any backward flow. The secondary outcome measured the incidence of complications during follow-up, specifically focusing on thrombophlebitis, hyperpigmentation, and recurrence.

Statistical analysis

The data was analyzed using IBM SPSS software package version 26v.0, developed by IBM Corporation and released in 2017. Quantitative data were represented using numerical values and percentages. The quantitative data were characterized using several statistical measures including the range (minimum and maximum values), mean, standard deviation, median, and interquartile range (IQR). The used statistical tests included the Chi-square test, Mann Whitney test, and The Kruskal-Wallis test.

Results

Male participants constituted 24 individuals (40.0%), whereas female participants accounted for 36 individuals (60.0%).The age distribution spanned from 22 to 50 years, exhibiting a mean of 34.45±7.243 years. Among the patients, a majority, specifically 39 individuals (65.0%), manifested great saphenous vein incompetence on the left side, while the remaining 21 individuals (35.0%) exhibited great saphenous vein incompetence on the right side (**Table.1**).

Table 1. Distribution of studied sample according to demographic data

Variables	Number	Percent
Age (years)		
Range	22 – 50	
Mean±S.D.	34.45±7.243	
Sex		
Male	24	40.0
Female	36	60.0
Side		
Left	39	65.0
Right	21	35.0

The preoperative great saphenous vein (GSV) diameters, ranging from 4 to 9, with a mean value of 6.27±1.103. post operative follow up shows total occlusion of the GSV in 45 individuals (75.0%). This proportion decreased to be 43 (71.7%), 40 (66.7%), 38 (63.3%), and 38 (63.3%) at 1, 3, 6, and 12 months, respectively. Partial recanalization of the GSV without reflux occurred in 9 patients (15.0%) at one week and persisted in 9 (15.0%), 10 (16.7%), 11 (18.3%), and 10 (16.71%) at 1, 3, 6, and 12 months, respectively. Cases of partial recanalization with reflux, initially observed in 5 patients (8.3%) after one week, increased to 6 (10.0%), 7 (11.7%), 7 (11.7%), and 8 (13.3%) at 1, 3, 6, and 12 months, respectively. Total recanalization of the GSV with reflux, noted in 1 patient (1.7%) at one week, demonstrated an increase to 2 (3.3%), 3 (5.0%), 4 (6.7%), and 4 (6.7%) at 1, 3, 6, and 12 months, respectively (**Table.2**).

Table 2. Distribution of studied sample through follow up regarding **GSV**.

Variables	Follow-up									
	1 week		1 month		3 months		6 months		1 year	
	No.	%	No.	%	No.	%	No.	%	No.	%
Preoperative GSV diameter										
Range	4 – 9									
Mean±S.D.	6.27±1.103									
Total occlusion of GSV	45	75.0	43	71.7	40	66.7	38	63.3	38	63.3
Partial recanalization of GSV without reflux	9	15.0	9	15.0	10	16.7	11	18.3	10	16.7
Partial recanalization of GSV with reflux	5	8.3	6	10.0	7	11.7	7	11.7	8	13.3
Total recanalization of GSV with reflux	1	1.7	2	3.3	3	5.0	4	6.7	4	6.7

The predominant outcome observed among the patient cohort one week postoperatively was technical success, with a prevalence of 90.0%. However, this proportion decreased to 80.0% after one year of follow-up, specifically in 48 individuals.

The analysis of complications within the studied group revealed that 4 individuals (6.7%) experienced hyperpigmentation, while 2 individuals (3.3%) developed thrombophlebitis (**Figs.2,3**).

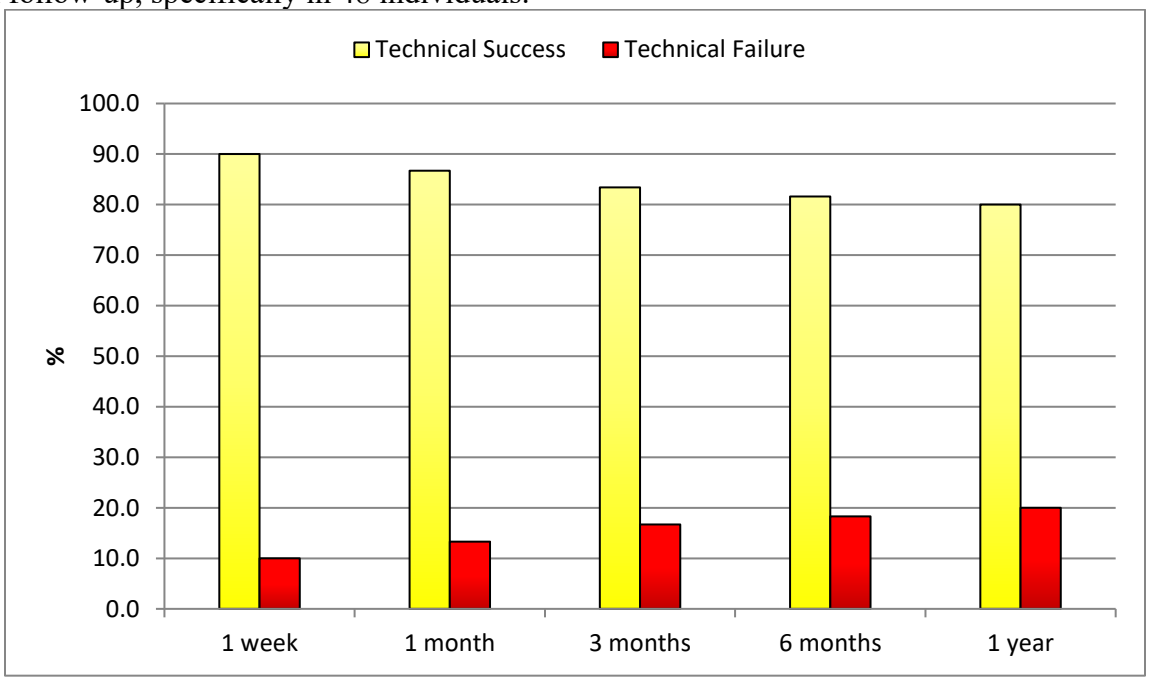

Fig.2. Distribution of studied sample according to Technical Success.

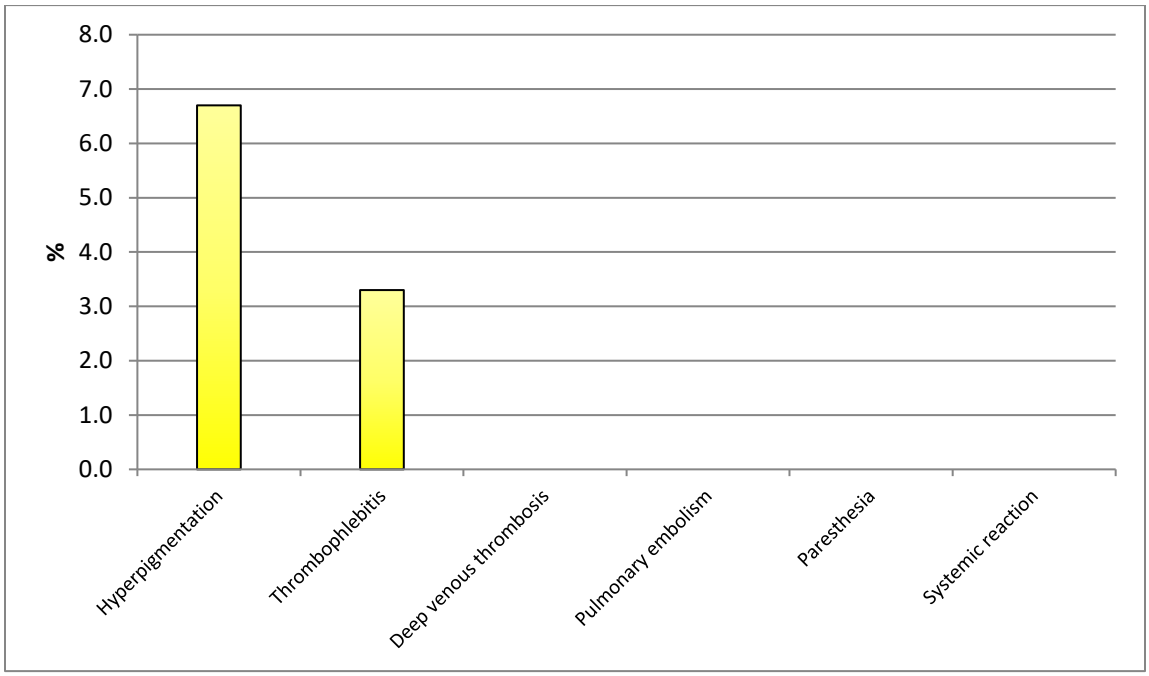

Fig.3. Distribution of studied sample according to Complications.

Regarding to recurrence, we can classify it into clinical recurrence and radiological recurrence . Clinical recurrence can be assessed by CEAP classification or Venous clinical severity score, whereas radiological recurrence can be assessed by venous duplex (partial recanalization of GSV with reflux

Total recanalization of GSV with reflux). Rgarding to clinical recurrence ,the majority of patients show improvement according to CEAP classicfication only 2 patients (3.3%) and 3 patients(5.0%) in C3 in C2 and VCSS , only one patient(1.7%) showed no improvement in CEAP classification that could be attributed to relative large vein diameter. Regarding to radiological recurrence (partial recanalization of GSV with reflux

Total recanalization of GSV with reflux) ,there was 6 patients (10.0%) at one week of follow up ,that increased to be 12 patients (20.0%) .

Regarding Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification of the investigated patients. Initial assessment revealed that, at baseline, 30 individuals (50.0%) were categorized as C2, 24 individuals (40.0%) as C3, and 6 individuals (10.0%) as C4. Over the course of one year, this distribution improved, with 36 individuals (60.0%) classified as C0, 19 individuals (31.6%) as C1, 2 individuals (3.3%) as C2, and 3 individuals (5.0%) as C3. The Venous Clinical Severity Score (VCSS) of the studied patients at baseline demonstrated a range between 2 and 9, with a mean value of 4.75±1.46. Significantly, after one year, the VCSS exhibited a notable reduction, with a mean value of 1.39±1.41 (**Table.3**).

Table 3. Distribution of studied sample according to CEAP classification.

Variables	Baseline		Follow-up									
			1 week		1 month		3 months		6 months		1 year	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
CEAP classification												
C0	0	0	3	5.0	5	8.3	12	20.0	22	36.7	36	60.0
C1	0	0	47	78.3	48	80.0	41	68.3	33	55.0	19	31.6

C2	30	50.0	3	5.0	3	5.0	3	5.0	2	3.3	2	3.3
C3	24	40.0	4	6.7	4	6.7	4	6.7	3	5.0	3	5.0
C4	6	10.0	3	5.0	0	0	0	0	0	0	0	0
VCSS												
Range	2 – 9		0 – 5		0 – 5		0 – 5		0 – 6		0 – 6	
Mean±S.D.	4.75±1.46		1.68±0.98		1.52±1.11		1.43±1.16		1.47±1.36		1.39±1.41	
P value			<0.001*		<0.001*		<0.001*		<0.001*		<0.001*	

The improvement in Venous Clinical Severity Score (VCSS) ranged from 14.29% to 100%, with a mean value of 73.60±21.626%. Similarly, improvement in Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification ranged from 0% to 100%, with a mean value of 79.17±27.978% (notably, only one patient exhibited no change and remained classified as C3). The return to ordinary life, as indicated by the duration until resumption of work activities within the studied group, ranged from 1 to 2 days, with a mean value of 1.48±0.504 days. (**Table.4**)

Table 4. Distribution of studied sample improvement according to VCSS and CEAP classification.

Improvement (%)	Range	Mean±S.D.
VCSS	14.29 – 100	73.60±21.626
CEAP classification	0 – 100	79.17±27.978
Return to work (Ordinary life)	1 – 2	1.48±0.504

Discussion

Varicose veins are enlarged and twisted superficial veins that often occur in the lower limbs. They affect about 40% of individuals at some point in their lives. The significant incidence of this condition has led to an increase in healthcare costs **(Gawas et al., 2022).**

The treatment should effectively restore normal venous function and alleviate the clinical symptoms of venous hypertension. Additionally, the treatment should be cost-effective and capable of achieving both functional and cosmetic improvement, while minimizing the amount of time the patient needs to take off from their usual occupation **(Kharl et al, 2019).**

Our results showed that demographic data of the studied group (60 patients) : Male cases were 24(40.0%) while female cases were 36(60.0%). Age was ranged between 22–50 years with mean value 34.45±7.243 years. More than half of the patients had in the left side (65.0%) while the rest had in the right side (35.0%).

Our clinical findings showed that regarding GSV diameter of the studied patients. GSV at preoperative was ranged between 4 – 9 mm with mean value 6.27±1.103 . Our result disagree with **Ali et al. (2017)**, they reported that mean GSV diameter at baseline was 8.3 ± 1.4 mm, freedom from above knee GSV reflux was demonstrated in 89.6% of patients 3 years following treatment.Moreover, our result agreed with **Devereux et al. (2014)** they reported that in CDFS group median GSV diameter at baseline was 6.59 mm with range (5.0 -9.6)mm.

Regarding to GSV occlusion rate after one week it shows that total occlusion of GSV (75.0%) and it was decreased to be 38(63.3%) after 1 year of follow up. All cases with partial recanalizayion with reflux or total recanalization were subjected to repeated procedure of injection sclerotherapy.

Also, **Camillo et al. (2018)** they reported that in (Catheter-directed Foam sclerotherapy)CDFS group the complete occlusion rate was 34/46 (73.9%) and partial occlusion was 10/46 (21.7%) with median overall follow-up was 52.1 months.

In their study, **O'Hare et al. (2008)** discovered that the obstruction of the target vein was 93% as assessed by duplex at the 2-week follow-up, and 74% at the 6-month follow-up. Their

study included patients who had varicose veins resulting from an incompetent great saphenous vein, small saphenous vein, Anterior Accessory Saphenous Vein (AASV), or other recurrent veins with a notable proximal incompetent deep venous link. Furthermore, **Cavezzi et al (2017)** discovered complete occlusion in more than 80% of the treated segment's extent. The treatment was administered to a segment that had reestablished a passage to less than 80% of the intended length. An wholly reopened vein with a fully compressible lumen was detected in more than 20% of the treated area. In addition, our results were consistent with the research conducted by **Tan et al (2012),** which reported an 80% likelihood of successful blockage at 12 months for patients who had follow-up duplex imaging.

Multiple extensive case series and one research conducted across multiple centers have been published. A study of 1411 patients with lower limb venous insufficiency revealed that 88% of great saphenous veins (GSVs) were found to be blocked after an average monitoring period of 11 months (**Benigni et al., 1999).**

In our recent research, we found that the majority of patients in the examined group achieved technical success after 1 week (90.0%). However, this percentage reduced to 80.0% after 1 year of follow-up. The effectiveness of foam sclerotherapy treatment relies on many aspects, such as vein diameter, degree of vasospasm induced, injection pressure, and leg positioning **(Cartee et al., 2021).**

Furthermore, our findings contradict the study conducted by **Bayoumi et al. (2018),** as they found a main technical success rate of 84% in 19 out of 25 limbs.

Furthermore, our findings were consistent with those of **Kölbe et al (2007),** who stated that 94% of the limbs (50 out of 53) achieved main technical success in delivering foam across the whole length of the GSV. All the treated GSVs were completely blocked during the one-week duplex examination.

In addition, our results were consistent with the findings of **O'Hare et al. (2008),** who noted that, after a period of 2 weeks, a total of ninety-three percent (136 out of 147) of the veins in the trunk showed blockage as detected by hand-held Doppler scanning. 10% (15 out of 147) of patients had enduring palpable varicosities in the lower leg. Following a duration of six months, the truncal vein remained obstructed in 74% (68/92) of instances, exhibited partial blockage in 10% (9/92) of instances, and was fully unobstructed in 16% (15/92) of instances.

Cavezzi, Tessari, and Parsi implemented two technological enhancements, namely peri-venous tumescence infiltration and vein flushing prior to foam injection, as described by **Bootun et al. (2016).**

Furthermore, our findings were consistent with those of **Gamal et al. (2019).** At the age of one month, the average score was 3.05 ± 1.5, with a range of 0 to 6. However, at the age of 6 months, the score dropped significantly to 0.03 ± 0.18, with a range of 0 to 1.We observed a statistically significant disparity between the VCSS measurements before the operation and at the 12-month mark.

The findings of our study indicated that among the participants, 4 individuals (6.7%) had hyperpigmentation and 2 individuals (3.3%) developed thrombophlebitis as consequences. Those were carefully handled with analgesics.A prior investigation25 has recognized post-sclerotherapy thrombophlebitis and subsequent hyperpigmentation as the most common consequence linked to foam sclerotherapy, as reported by **Partsch et al (2004).** Furthermore, our findings contradict those of **Mishra et al. (2016),** who documented a thrombophlebitis incidence of 26.67% (8/30) in the UGFS group. Furthermore, our findings corroborated their assertion that 2 patients (3.1%) in the CDFS group had phlebitis. In addition, our findings contradict those of **Dos Santos et al. (2020),** who stated that in the CDFS group, 1 individual (4%) had phlebitis and 4 individuals (16%) exhibited hyperpigmentation. Furthermore, our findings were consistent with the research conducted by Whiteley in 2022. According to their research, 2 out of the patients in the CDFS group (3.1%) had phlebitis.

Future research should focus on recruiting bigger sample numbers using a strategy that incorporates both objective and subjective clinical indications, in

addition to total ablation, at more exact intervals. This would enable a more effective analysis with individuals randomly assigned to each treatment group.

Conclusion

Catheter-based Foam sclerotherapy is a secure and efficient technique for treating varicose veins in the lower limbs. It has the benefit of shorter hospital stays and fewer complications compared to older methods.

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