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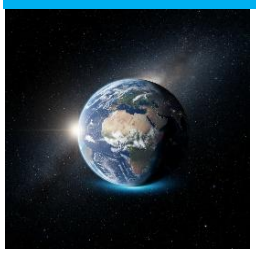

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# Non-thermal, minimally invasive methods for the treatment of chronic venous insufficiency of the lower limbs – analysis of efficacy and safety

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## Abstract

**Introduction** Chronic venous insufficiency of the lower limbs (CVI) is a common disorder of the venous system, leading to significant clinical symptoms and reduced quality of life in patients. In recent years, there has been rapid development of minimally invasive endovascular methods, particularly non-thermal techniques, which provide an alternative to conventional surgical treatment and thermal ablation.

**Aim** The aim of this study was to analyze the effectiveness and safety of non-thermal, minimally invasive methods for treating chronic venous insufficiency of the lower limbs, with particular emphasis on ultrasound-guided foam sclerotherapy (UGFS), cyanoacrylate adhesive embolization (CAC), and mechanochemical ablation (MOCA).

**Results** Non-thermal methods for treating chronic venous insufficiency demonstrate high short-term effectiveness and a favorable safety profile. Foam sclerotherapy, cyanoacrylate adhesive embolization, and mechanochemical techniques enable effective closure of incompetent veins, significant symptom reduction, and improvement in quality of life, with minimal peri-procedural pain and a rapid return to daily activities.

**Conclusions** Non-thermal, minimally invasive techniques constitute a safe and effective alternative to surgical treatment and thermal methods, particularly for patients who prefer less invasive approaches and shorter recovery times. Their limitation remains lower long-term durability compared to thermal ablation, which necessitates individualized method selection and further comparative studies.

**Keywords** chronic venous insufficiency, lower limb varicose veins, minimally invasive treatment, non-thermal methods, foam sclerotherapy, mechanochemical ablation, cyanoacrylate adhesive

## Introduction

Chronic venous insufficiency of the lower limbs (CVI) constitutes a significant health problem in the general population. Its pathogenesis is primarily associated with venous valve incompetence leading to reflux, impaired venous outflow, and dysfunction of the calf muscle

pump, resulting, among other factors, from immobility or obesity. These mechanisms lead to the development of venous hypertension, referred to as ambulatory venous hypertension (AVH) [1][2]. Clinical symptoms such as dull pain, burning sensation, itching, throbbing, and lower limb edema—typically worsening in the evening—can significantly reduce patients' quality of life [1][3].

The most important risk factors for the development of CVI include advanced age, obesity, female sex, pregnancy, and a sedentary lifestyle [1][2]. Contrary to the long-standing belief that this condition is purely cosmetic, in advanced stages it may lead to serious complications, including venous ulcers and, in extreme cases, even limb loss [4].

The classical surgical treatment, namely stripping, requires two incisions in the thigh and lower leg, insertion of a probe into the lumen of the great saphenous vein (GSV) or small saphenous vein (SSV), attachment to the proximal end of the vessel, and removal of the vein by pulling it out through the incision in the lower leg [1]. This procedure is associated with significant surgical trauma and the risk of saphenous nerve injury, which may result in sensory disturbances along the medial aspect of the lower limb [5].

In recent years, depending on the stage of the disease, minimally invasive techniques have gained increasing importance, offering lower patient burden, reduced risk of complications, and clinical effectiveness comparable to surgical treatment. Among these, particular attention is given to non-thermal methods such as ultrasound-guided foam sclerotherapy (UGFS), cyanoacrylate adhesive ablation (CAC), and mechanochemical ablation (MOCA), which do not require thermal energy or tumescent anesthesia. Thermal methods, including endovenous thermal ablation using radiofrequency (RFA) or laser (EVLA), remain an alternative [4][6].

This review article focuses on minimally invasive, non-thermal treatment methods for venous disease, with particular emphasis on their mechanisms of action as well as an analysis of their effectiveness, safety, and complication profiles.

## Materials and methods

The analysis was conducted using data obtained from clinical trials, meta-analyses, and systematic reviews published between concerning chronic venous insufficiency of the lower limbs and its invasive treatment. Information was collected from medical databases such as

PubMed, Google Scholar, and Scopus. The following keywords were used in the search: “chronic venous insufficiency,” “varicose veins,” “mechanochemical ablation,” “foam sclerotherapy,” “varicose veins closure,” and “cyanoacrylate glue varicose veins”. Each method was evaluated in terms of vessel closure durability, improvement in symptom control, and the incidence of complications. The severity of varicose vein symptoms was assessed using the Aberdeen Varicose Vein Severity Score (AVSS) and the Venous Clinical Severity Score (VCSS). The SF-12® and SF-36 scales were used to assess changes in mental and physical health following treatment.

**Foam Sclerotherapy**

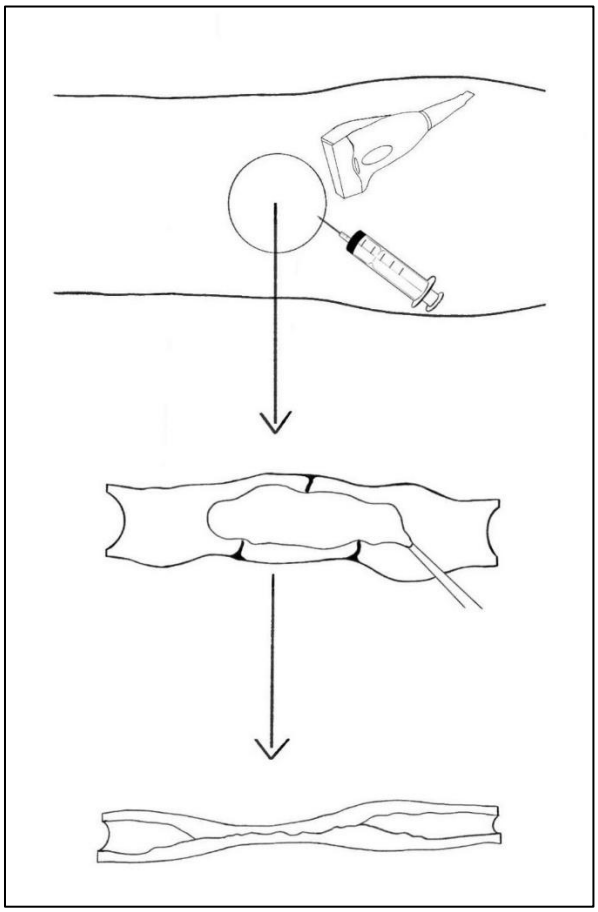
Sclerotherapy of veins involves the percutaneous administration of a sclerosing agent into the lumen of a diseased vein, causing localized endothelial damage and exposure of deeper layers of the vessel wall, leading to its closure through fibrosis and gradual resorption [4][7]. The sclerosing agent may be administered in liquid form or as a mixture of liquid and gas, most commonly air or carbon dioxide. The most frequently used sclerosants include polidocanol and sodium tetradecyl sulfate (STS) [7]. Foam is obtained by mixing the sclerosant with gas in a ratio of 1:4–5 [8].

In foam sclerotherapy, the produced foam displaces blood from the vessel lumen, ensuring prolonged contact of the sclerosant with the vein wall, which translates into higher treatment efficacy, particularly in larger-caliber veins such as the great saphenous vein trunk [9]. This method allows treatment of longer and larger vein segments using a smaller amount of sclerosant, and its effectiveness in closing large vessels exceeds that of conventional liquid sclerotherapy [9]. The use of ultrasound enables confirmation of proper needle placement within the vein lumen, assessment of vessel spasm, and monitoring of sclerosant distribution during injection. Multiple injections of small volumes are recommended to reduce the risk of unintended foam migration into the deep venous system. Patients should take a short walk immediately after the procedure and are encouraged to maintain regular physical activity—at least once per hour—during the first two weeks following treatment [10].

Sclerotherapy is characterized by a high safety profile, with a very low incidence of serious complications (<0.01%). The most common adverse effects include skin hyperpigmentation, matting (fine red-violet vessels at the treatment site), pain, superficial vein thrombosis, allergic

reactions, urticaria, and local ulceration. Systemic complications such as deep vein thrombosis, pulmonary embolism, stroke, anaphylaxis, or skin necrosis are rare [11]. The risk of complications increases with higher concentrations of the sclerosant [7].

**Figure 1**. Mechanism of action in Ultrasound-Guided Foam Sclerotherapy (UGFS).



In the study by Darke and Baker (2006), early efficacy and safety of ultrasound-guided foam sclerotherapy (UGFS) were evaluated in patients with lower limb varicose veins. The analysis included 192 patients, the majority of whom underwent UGFS, covering a total of 220 treated limbs. Polidocanol foam was used (1% for superficial veins, 3% for saphenous trunks), administered under ultrasound guidance, with a maximum volume of 14 mL per procedure.

Efficacy was assessed up to 6 weeks after treatment, with complete success defined as closure of the saphenous vein trunk and/or ≥85% of varicose veins. Complete closure was achieved in 91% of limbs after a maximum of three sessions, while most remaining cases showed a partial therapeutic response.

The safety profile was acceptable. Serious complications were rare and transient (visual disturbances, chest discomfort), while the most common adverse effects included phlebitis and hyperpigmentation, mainly relevant from a cosmetic standpoint.

The authors conclude that although the results are preliminary, the demonstrated initial efficacy is significant. Based on the applied protocol, ultrasound-guided foam sclerotherapy appears to be a safe and effective short-term treatment method for a broad and representative group of patients with lower limb varicose veins [12].

In the study by Darvall et al. (2013), the long-term efficacy of UGFS was assessed over a follow-up period of 5–8 years. The aim was to determine long-term outcomes in terms of the need for retreatment, disease-specific and general quality of life, symptom improvement, fulfillment of patient expectations, and overall satisfaction. This prospective cohort study included 351 patients (479 limbs) treated between 2004 and 2007. The median foam volume administered was 10 mL, and approximately 21% of limbs required additional treatment, mainly in the form of further injections into residual varicosities or, less frequently, into an incompletely closed venous trunk.

The estimated proportion of limbs requiring retreatment after 5 years was 15.3%. A sustained improvement in disease-specific quality of life (AVSS) was observed over long-term follow-up, with 88.5% of patients reporting improvement. General quality of life assessed using the SF-12 scale showed a stable mental component and improvement in the physical component in patients without significant comorbidities. The majority of patients (79–94%) rated symptom improvement as meeting or exceeding expectations, and 82% reported very high satisfaction with treatment, confirming the long-term effectiveness of UGFS.

In conclusion, the authors state that UGFS is an effective and safe long-term treatment method for lower limb varicose veins, with sustained quality-of-life improvement and high patient satisfaction. The need for retreatment due to recurrence affected only a small proportion of limbs and was comparable to outcomes observed after EVLA, RFA, and surgical treatment [13].

**Cyanoacrylate Glue**

Embolization of varicose veins using N-butyl cyanoacrylate (NBCA) involves endovascular closure of an incompetent vein through the administration of a specialized tissue adhesive into

its lumen, which rapidly polymerizes upon contact with blood. This process leads to permanent vessel occlusion, induction of a local inflammatory response, and fibrosis of the vein wall [14][15]. Endovascular application of cyanoacrylate is currently the only non-thermal vein closure method that does not use traditional sclerosants, instead employing a patented medical adhesive administered intravenously to achieve durable vessel occlusion.

The use of this technique eliminates the risk of thermal injury to adjacent neural structures, particularly during treatment of the small saphenous vein, where such complications may occur with thermal procedures. An additional advantage is the lack of need for tumescent anesthesia, which reduces patient discomfort associated with multiple needle punctures [14].

Currently, two main cyanoacrylate embolization (CAE) systems are used: the VenaSeal™ closure system (Medtronic, Minnesota, USA) and the VariClose® system [16]. The procedure is performed under duplex Doppler ultrasound (CDUS) guidance and begins with gaining access to the incompetent vein, most commonly the great saphenous vein, using a vascular sheath. After introducing the delivery catheter near the saphenofemoral junction (SFJ), its tip is typically withdrawn approximately 5 cm distally from the SFJ.

Subsequently, under continuous ultrasound guidance and with manual compression over the treated vein segment, NBCA adhesive is administered in aliquots into the vessel lumen while gradually withdrawing the catheter. Maintaining compression for several dozen seconds after the final application ensures effective closure of the entire target venous segment. Continuous CDUS guidance is mandatory at every stage of the procedure.

Patients are mobilized immediately after the procedure, and routine use of compression stockings is not required. The limited number of punctures and minimal post-procedural changes, such as hematomas or bruising, translate into low pain levels and rapid return to daily activities. Consequently, cyanoacrylate treatment aligns well with the concept of day-case surgery (“walk-in, walk-out”). Despite a standardized procedural framework, some steps may vary depending on the system used; therefore, strict adherence to manufacturer guidelines is recommended [14][17].

This method is considered safe and is associated with a low risk of serious complications. The most commonly observed adverse effects include mild inflammatory reactions resembling phlebitis, transient pain, swelling, and occasionally superficial thrombophlebitis. A rare complication is the formation of a cyanoacrylate granuloma at the puncture site, which may

lead to a localized abscess and in some cases require surgical removal of the adhesive material [18]. The risk of severe complications such as deep vein thrombosis or pulmonary embolism remains very low and comparable to other endovascular methods; moreover, most reported cases were associated with concomitant foam sclerotherapy rather than cyanoacrylate use alone [19].

In the study by Yiu Che Chan et al. (2017), the effectiveness of cyanoacrylate glue in the treatment of great saphenous vein (GSV) insufficiency and risk factors for recanalization were evaluated. The analysis included 108 limbs in 55 patients treated on an outpatient basis between 2014 and 2016, mostly with bilateral varicose veins. The most common clinical stages were C3–C4a, and disease severity was mild to moderate according to VCSS and AVVQ.

Clinical and duplex follow-up was conducted up to 24 months. GSV closure rates were 97.2% at 1 week, 92.3% at 1 month, 89.2% at 6 months, and 75.7% at 12 months. Clinical recurrence was observed in four patients. The only significant predictor of recanalization was a GSV diameter $\geq$ 6.6 mm (HR 12.1; $p = 0.016$).

Complications were rare and mild (isolated cases of thrombus extension and superficial thrombophlebitis). The procedure was associated with minimal postoperative pain and minor bruising. Significant clinical improvement was observed, reflected by a marked reduction in VCSS and AVVQ scores during follow-up, with stable quality-of-life outcomes on the SF-36 scale.

According to the authors, the study demonstrated that endovascular treatment of incompetent GSV using cyanoacrylate is safe and effective, including in cases of bilateral disease. A median GSV diameter of 6.6 mm was identified as a statistically significant predictor of later recanalization, although the exact mechanism remains unclear [20].

The study by Jin Ho Hwang et al. (2019) evaluated the effectiveness and safety of cyanoacrylate glue in treating incompetent GSV without adjunctive procedures, as well as varicose vein regression following treatment. This retrospective analysis included 63 limbs in 48 patients treated between 2016 and 2017, primarily with GSV reflux >0.5 s and a mean vein diameter of 6.9 mm. Most limbs presented with visible varicosities, and disease severity corresponded mainly to stages C1–C3.

Immediately after the procedure, complete GSV closure was achieved in all limbs. During a mean follow-up of 8.4 months, no recanalization was observed. Rapid and significant clinical improvement was noted, with VCSS decreasing from 4.0 to 0.4 at 12 months. Varicose vein regression occurred gradually, reaching 71.7% at 3 months, and was significantly more frequent when treatment included the junction of varicosities with the venous trunk and when access was obtained at more distal levels—40% in the thigh, 58.3% at the knee, 72.7% in the proximal calf, 82.4% in the mid-calf, and 87.5% in the distal calf.

Only two patients required additional treatment (sclerotherapy). Adverse effects were mild and transient, most commonly phlebitis and localized pain. No serious thromboembolic or neurological complications were observed.

The study results indicate that treatment of the GSV using cyanoacrylate glue is an effective and safe method in the short- and mid-term, leading to a high rate of complete varicose vein regression and a low risk of complications. Complete regression is more frequently observed when the procedure includes treatment of the varicosity inflow into the venous trunk and when distal venous access is achieved [21].

**Mechanochemical Methods**

Mechanochemical methods such as ClariVein® and Flebogrif were developed to combine the advantages of thermal ablation and ultrasound-guided sclerotherapy while minimizing their limitations in the treatment of saphenous vein insufficiency. These systems enable standard percutaneous access, endovenous treatment, the use of only local anesthesia (without tumescent anesthesia), and reduced procedure time [22]. The absence of thermal energy minimizes the risk of nerve injury, while the mechanical component eliminates the need for tumescent anesthesia and improves the effectiveness compared to conventional sclerotherapy [23].

ClariVein requires superficial local anesthesia at the catheter insertion site to allow skin puncture and catheter introduction. The wire tip is positioned approximately 1.5 cm below the saphenofemoral junction (confirmed by ultrasound) and set into rotational motion at a speed of 3500 rpm. After 2–3 seconds, the device is gradually withdrawn at a rate of 1 cm every 5 seconds, with simultaneous continuous administration of the sclerosant, while the angled wire remains in rotational motion. Mechanical endothelial damage combined with induced vasospasm enhances the efficacy of the sclerosant (STS or polidocanol) [23][24].

The study by Deijen et al. (2015) evaluated the early efficacy and safety of mechanochemical ablation (MOCA) in treating incompetent superficial veins. The analysis included 449 patients with 558 treated limbs and 570 incompetent veins. The median follow-up was 54 days, and duplex ultrasound was performed in the majority of patients.

Complete occlusion was achieved in 90% of treated veins, with higher effectiveness for the great saphenous vein (92%) compared to the small saphenous vein (84%). Comparing outcomes between two centers (6-week vs. 3-month follow-up), closure rates were 92% and 87%, respectively ($P = 0.063$). In separate analyses, occlusion rates for GSV were 94.5% at 6 weeks and 89% at 3 months ($P = 0.047$), while for SSV they were 85% and 80.5% ($P = 0.52$).

The procedure demonstrated a favorable safety profile. No perioperative complications were observed, and the most common adverse event was superficial thrombophlebitis, occurring in 12 patients. Serious thromboembolic events were rare and did not result in permanent sequelae.

The authors concluded that MOCA is an effective and safe technique for treating incompetent great and small saphenous veins, with an occlusion rate of approximately 90%, comparable to other MOCA studies and meta-analyses of endovascular techniques [25].

The study by Kim et al. (2016) assessed the effectiveness of mechanochemical ablation of the great saphenous vein over a two-year follow-up in patients with symptomatic chronic venous disease (CEAP $\geq$ C2). The analysis included patients with GSV reflux >0.5 s and vein diameter of 4–12 mm, treated on an outpatient basis after prior conservative management.

A total of 126 patients were enrolled, of whom 65 completed the 24-month follow-up. GSV closure rates were 100% at 1 week, 98% at 3 months, 95% at 12 months, and 92% at 24 months. Life-table analysis demonstrated a 24-month efficacy of 89%. Recanalization was rare and usually partial. During follow-up, a small proportion of patients required additional sclerotherapy for symptomatic varicose veins.

At 24 months, 63% of patients had no residual varicose veins, and 83% were asymptomatic. Improvements in CEAP classification and VCSS scores were statistically significant at all follow-up points ($P < 0.001$). The safety profile was favorable, with no severe complications reported. Superficial thrombophlebitis occurred in 10% of patients, while ecchymosis or subcutaneous hematoma was observed in 9%. One patient developed a hematoma at the puncture site. All adverse events were mild and transient.

Considering the peri-procedural benefits and sustained vein closure rates exceeding 90% over two years, the authors concluded that MOCA represents a highly effective therapeutic option for the treatment of great saphenous vein insufficiency [26].

## Discussion

A review of available studies on non-thermal methods for the treatment of chronic venous insufficiency demonstrates their high short-term vein closure efficacy, low complication rates, and faster return to daily activities compared to surgical treatment and thermal techniques. However, a limitation of these approaches remains a lower long-term durability of vein closure and a greater dependence of outcomes on operator experience.

Ultrasound-guided foam sclerotherapy is an effective and safe non-thermal treatment method for chronic venous insufficiency. Short-term vein closure rates range from 72–89% within 12 months, while clinical studies have reported complete occlusion in up to 91% of limbs after a maximum of three treatment sessions [27]. The method leads to significant clinical improvement—88.5% of patients report symptom reduction—and the need for retreatment after 5 years affects approximately 15% of limbs [7][13]. Its safety profile is favorable, with severe complication rates below 0.01%; however, in long-term follow-up (5–8 years), recurrence of reflux is more frequent than after thermal ablation or surgical treatment [7][28].

Endovascular treatment of incompetent veins using cyanoacrylate glue is characterized by high short-term efficacy and a favorable safety profile. Clinical studies report great saphenous vein closure rates of 97–100% immediately after the procedure, with short- and mid-term outcomes remaining at approximately 89–92% at 6 months and 75–90% at 12 months [20]. In two-year follow-up, some studies have shown no recanalization or only isolated cases of reflux recurrence. The method leads to significant clinical improvement, with VCSS decreasing from approximately 6.2 to 1.4 points within 12 months, along with marked symptom reduction. The safety profile is favorable; the most common adverse event is localized phlebitis (10–17%), while serious thromboembolic complications are very rare and comparable to other endovascular techniques [21].

Mechanochemical ablation is an effective and safe method for treating chronic venous insufficiency of the lower limbs, particularly incompetence of the great and small saphenous veins. It achieves high rates of vessel closure in both short- and mid-term follow-up, comparable

to other endovascular techniques. Studies report complete occlusion in approximately 90% of treated veins, with higher efficacy for the great saphenous vein (92%) than for the small saphenous vein (84%) in short-term follow-up [25]. In longer-term observation, MOCA maintains high effectiveness: in the study by Kim et al., GSV closure rates were 95% at 12 months and 92% at 24 months, with survival analysis showing a 24-month success rate of 89% [26].

**Table 1.** Comparison of non-thermal, minimally invasive CVI treatment methods

| | **Foam Sclerotherapy (UGFS)** | **Cyanoacrylate Glue (CAC)** | **Mechanochemical Ablation (MOCA)** |
|---|---|---|---|
| **Mechanism of Action** | Percutaneous administration of a sclerosant into the vein lumen causing endothelial damage, fibrosis, and resorption. | Endovascular closure using a tissue adhesive (NBCA) that polymerizes on contact with blood, leading to permanent occlusion and fibrosis. | Combined mechanical endothelial damage via a rotating wire and simultaneous chemical sclerosis. |
| **Short-term Efficacy** | Complete closure achieved in 91% of limbs after a maximum of three treatment sessions. | Immediate closure rates of 97–100% reported following the procedure. | Approximately 90% overall vessel closure rate (92% for GSV and 84% for SSV). |
| **Durability (12–24 months)** | Short-term vein closure rates range from 72–89% within 12 months. | Vein closure remains at approximately 75–90% at 12 months. | Closure rates of 95% at 12 months and 92% at 24 months. |
| **Anesthesia Requirements** | Does not require thermal energy or tumescent anesthesia. | Does not require thermal energy or tumescent anesthesia. | Requires only local anesthesia at the catheter insertion site; no tumescent anesthesia needed. |

| | Foam Sclerotherapy (UGFS) | Cyanoacrylate Glue (CAC) | Mechanochemical Ablation (MOCA) |
|---|---|---|---|
| **Common Complications** | Skin hyperpigmentation, matting, pain, and superficial vein thrombosis. | Localized phlebitis (10–17%), transient pain, and rare cyanoacrylate granulomas. | Superficial thrombophlebitis (10–12%) and transient ecchymosis or subcutaneous hematoma (9%). |

## Conclusions

There is a lack of direct, high-quality randomized studies comparing individual non-thermal methods with one another; the available data are derived mainly from studies comparing these techniques with thermal ablation or surgical treatment. Further randomized trials with long-term follow-up are needed to clearly determine the superiority of specific non-thermal methods across different patient populations.

Compared to other treatment modalities, non-thermal techniques provide relatively high effectiveness in the treatment of chronic venous insufficiency, offering faster return to daily activities, less peri-procedural pain, and lower complication rates. However, in the long term, they are associated with lower rates of sustained vein closure. Therefore, the choice of treatment method should be individualized, taking into account patient expectations, risk profile, and the need for durability of the therapeutic effect.

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### Authors’contribution:

All authors contributed equally to the conception, writing, and revision of the manuscript and approved the final version for publication.


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## Conflicts of Interest

The authors declare no conflict of interest.

## List of Abbreviations

- **CVI** – Chronic Venous Insufficiency
- **AVH** – Ambulatory Venous Hypertension
- **GSV** – Great Saphenous Vein
- **SSV** – Small Saphenous Vein
- **UGFS** – Ultrasound-Guided Foam Sclerotherapy
- **MOCA** – Mechanochemical Ablation
- **RFA** – Radiofrequency Ablation
- **EVLA** – Endovenous Laser Ablation

- **AVSS** – Aberdeen Varicose Vein Severity Score
- **VCSS** – Venous Clinical Severity Score
- **STS** – Sodium Tetradecyl Sulfate
- **NBCA** – N-Butyl Cyanoacrylate
- **CAE** – Cyanoacrylate Adhesive Embolization
- **CDUS** – Color Duplex Ultrasound / Duplex Doppler Ultrasound
- **SFJ** – Saphenofemoral Junction

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