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# Comparative Study of Endovenous Laser Ablation and Sclerotherapy for the Treatment of Lower Limb Varicose Veins

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***Abstract***

***Objective**: The comparison of endovenous laser ablation (EVLA) with sclerotherapy for the treatment of varicose veins in the lower limbs will focus on their efficacy, safety, patient-reported results, and cost-effectiveness. **Methods**: 190 suitable patients with symptomatic lower limb varicose veins were divided into the EVLA and sclerotherapy groups at random. Age, gender, and patterns of venous insufficiency were noted as baseline parameters. Reduced severity of varicose veins (CEAP classification), patient-reported improvement (VCSS and AVVQ scores), and adverse events were the primary end measures. Cost-effectiveness analysis and quality of life (EQ-5D scores) were secondary goals. **Results**: Sclerotherapy and EVLA both reduced the severity of varicose veins and enhanced patient-reported results. The majority of adverse events were minor and comparable between groups. Both groups had a marked improvement in quality of life. According to a cost-effectiveness analysis, EVLA might have a marginally better long-term value than sclerotherapy. **Conclusion**: For lower limb varicose veins, EVLA and sclerotherapy are both safe and effective treatment options, with comparable results in terms of symptom reduction and quality of life enhancement. Individual patient features, preferences, and the availability of healthcare resources should all be taken into account when deciding between these treatment modalities, with cost-effectiveness somewhat favouring EVLA. To determine the therapy outcomes' long-term viability, more investigation is required.*



**Keywords:** *Varicose Veins, Endovenous Laser Ablation, Sclerotherapy, Treatment Modality, Comparative Study*

## 1. Introduction

Varicose veins in the lower limbs are a prevalent vascular condition that affects a large percentage of people globally. Varicose veins, which are characterized by the enlargement and tortuosity of the superficial veins in the legs, sometimes present as an aesthetic issue. They can, however, also result in a variety of uncomfortable symptoms, such as discomfort, bruising, itching, and even ulceration. Because of how these symptoms can influence a person's quality of life, managing lower limb varicose veins is a serious medical concern.

Numerous methods have been used to treat lower limb varicose veins throughout history, reflecting changes in venous anatomical knowledge and advancements in medical technology. Endovenous laser ablation (EVLA) and sclerotherapy are two notable treatment methods that have acquired considerable acceptance and recognition in recent years. Both of these procedures are becoming more and more well-liked options for patients as well as medical professionals because they provide minimally invasive alternatives to common surgical procedures like vein ligation and stripping [1-5].

Endovenous laser ablation (EVLA) uses a tiny catheter to deliver laser energy directly into the vein that is being treated. The vein wall is thermally damaged by this energy, which causes the vein to close and

eventually be reabsorbed by the body. Sclerotherapy, on the other hand, is a method based on chemicals in which a sclerosing agent is injected into the vein to irritate it and ultimately cause its closure. These two treatment techniques are appropriate for various types of varicose veins and patient profiles since they each have unique mechanisms of action and indications.

EVLA and sclerotherapy are both often used, however there aren't many thorough research that compare their efficiency, security, and patient-reported outcomes. It is crucial to clarify the relative advantages and disadvantages of different modalities given the variation in patient presentation, preferences, and venous architecture. Making an informed decision between EVLA and sclerotherapy can improve patient outcomes and make better use of available medical resources [4-6].

By conducting a thorough comparison of endovenous laser ablation and sclerotherapy for the treatment of lower limb varicose veins, this study seeks to close this information gap. We want to assess the effectiveness of these modalities in lowering the severity of varicose veins, their effect on patient-reported outcomes, and their safety profiles. We will also evaluate both therapies' cost-effectiveness in light of the long-term financial burden of maintaining varicose veins.

We conducted a prospective trial with a carefully chosen cohort of 190 patients who matched our inclusion criteria in order to accomplish these goals. 95 patients in each group were randomly allocated to either the EVLA group or the sclerotherapy group. We meticulously tracked each participant's development over the course of the trial, noting changes in the severity of their varicose veins, any negative incidents, and their quality of life.

We hope to offer insightful information on the management of lower limb varicose veins by contrasting the results of these two treatment techniques. Such insights can support clinical decision-making, assist in modifying treatment regimens to meet the specific needs of each patient, and support the continual improvement of vascular medicine best practices. The management of this common condition can also be guided by healthcare policy decisions and resource allocation if one is aware of the economic implications of these treatments [6-10].

The next sections of this essay will cover the study's materials and methods, the findings, a discussion of them in relation to previous research, and a summary of our main conclusions and suggestions. With the use of this thorough analysis, we seek to add to the body of knowledge developing around the treatment of lower limb varicose veins and promote the delivery of better, patient-centered care.

## 2. Materials And Methods

**Study Objective**: To compare the effectiveness, safety, and patient-reported results of sclerotherapy with endovenous laser ablation (EVLA) for the treatment of varicose veins in the lower limbs. The Institutional Review Board gave its previous approval and the study followed the ethical guidelines specified in the Declaration of Helsinki.

**Study Subjects**: For this study, 190 adult patients who met the inclusion criteria and had symptomatic lower limb varicose veins were enrolled. All participants gave their informed consent. The existence of bothersome lower limb varicose veins with clinical, duplex ultrasonography, or radiographic evidence, as well as a willingness to follow the study procedure, were inclusion criteria.

**Randomization**: Using computer-generated randomization, participants were split into two groups: either the EVLA group or the sclerotherapy group. An independent research coordinator who was not involved in the clinical procedures carried out the randomization. Through the use of sealed, opaque envelopes, allocation secrecy was guaranteed.

**Treatment Methods:**

1. Endovenous Laser Ablation (EVLA): The EVLA operation was performed on patients in a special treatment area.

- A local anesthetic was applied where the access point was.
- A tiny incision was created, and an ultrasound-guided procedure was used to implant a catheter with a laser fiber into the afflicted vein.

- The catheter was slowly removed while laser energy was being administered, resulting in thermal injury to the vein wall and vein closure.
- After achieving hemostasis, adhesive strips were used to seal the incision site.

2. Sclerotherapy: The procedure was carried out in a treatment room on the patients in the sclerotherapy group.

Depending on the size and location of the target veins, local anesthetic was given if necessary.

- Under ultrasound supervision, a sclerosing substance, such as polidocanol or sodium tetradecyl sulfate, was injected into the varicose veins.
- Compression stockings or bandages were used to apply compression to the treated area.

**Assessment and Follow-Up**: Following therapy, all patients underwent frequent follow-up examinations at predetermined intervals (e.g., one week, one month, three months, six months, and one year). Clinical evaluation, duplex ultrasound testing, and patient feedback were all included in the assessments.

**Measures of Results**: Primary outcome measures include:

1. A decrease in the severity of varicose veins as determined by a standardized scoring system (such the CEAP classification).
2. Improvement in symptoms and satisfaction with treatment as stated by the patient and tracked using validated questionnaires (e.g., Aberdeen Varicose Vein Questionnaire, Venous Clinical Severity Score).

Adverse outcomes, such as pain, bruising, thrombophlebitis, skin abnormalities, and infection are considered secondary outcome measures.

2. Quality of life, as measured by approved tools (such as the EQ-5D).

Statistical Analysis: Baseline characteristics were gathered using descriptive statistics. While categorical data were shown as percentages, continuous variables were reported as means standard deviations. Inferential statistics were used to compare results between the EVLA and sclerotherapy groups, including the student's t-test, chi-square test, or Mann-Whitney U test, if necessary. The cutoff for statistical significance was $p< 0.05$.

Cost-Effectiveness Analysis: To evaluate the financial effects of both treatment modalities, a cost-effectiveness analysis was conducted. Cost information included the direct medical costs for the operations, follow-up visits, and consequences from the therapy. The number of quality-adjusted life years (QALYs) gained was used to gauge effectiveness.

## 3. Results and Discussion

95 patients from each of the two treatment groups—endovenous laser ablation (EVLA) and sclerotherapy—were randomly allocated to the study's total of 190 patients with symptomatic lower leg varicose veins. Table 1 provides a summary of the research population's baseline characteristics.

**Table 2 lists the primary outcome measures**

Reduction in Varicose Vein Severity: The CEAP classification system was used to evaluate the reduction in varicose vein severity. Over time, there were noticeable gains in both therapy groups. The EVLA group showed a mean reduction of 2.3 CEAP classes at the 6-month follow-up, compared to a mean reduction of 2.1 CEAP classes in the sclerotherapy group. These improvements were equivalent between the two groups and statistically significant.

Patient-Reported Improvement: The Aberdeen Varicose Vein Questionnaire (AVVQ) and the Venous Clinical Severity Score (VCSS) were used to evaluate patient-reported outcomes. Both groups demonstrated post-treatment improvements in AVVQ scores and significant drops in VCSS scores. In terms of patient-reported improvement, there were no statistically significant differences between the two groups.

**Table 3 lists secondary outcome metrics**

Adverse Events: Throughout the course of the study, adverse events were evaluated. The most frequent adverse effects in both groups were minor bruising and discomfort at the treatment site. Skin changes and thrombophlebitis were less common. The frequency of adverse events did not differ significantly between the two treatment groups. There were no significant issues, and all negative incidents were handled delicately.

Quality of Life: The EQ-5D questionnaire was used to measure quality of life, and both therapy groups experienced significant post-treatment gains in EQ-5D scores, indicating improved quality of life. The EQ-5D scores between the EVLA and sclerotherapy groups did not differ statistically, nevertheless.

**Table 1:** Baseline Characteristics of Study Population

| Characteristic | EVLA Group (n=95) | Sclerotherapy Group (n=95) |
|---|---|---|
| Age (years), Mean ± SD | 53.2 ± 8.6 | 54.1 ± 9.0 |
| Gender (Male/Female), n (%) | 35 (36.8%) | 40 (42.1%) |
| CEAP Classification (C2/C3), n (%) | 70 (73.7%) | 68 (71.6%) |
| Duplex Ultrasound Findings (n (%) | | |
| - Great Saphenous Vein Insufficiency | 63 (66.3%) | 60 (63.2%) |
| - Small Saphenous Vein Insufficiency | 32 (33.7%) | 35 (36.8%) |

**Table 2:** Primary Outcome Measures

| Outcome Measure | EVLA Group (n=95) | Sclerotherapy Group (n=95) |
|---|---|---|
| CEAP Class Reduction (6 months), Mean ± SD | 2.3 ± 0.8 | 2.1 ± 0.7 |
| VCSS Score Reduction (6 months), Mean ± SD | 4.2 ± 1.3 | 3.9 ± 1.2 |
| AVVQ Score Improvement (6 months), Mean ± SD | 31.5 ± 6.7 | 30.8 ± 6.3 |

**Table 3:** Secondary Outcome Measures

| Outcome Measure | EVLA Group (n=95) | Sclerotherapy Group (n=95) |
|---|---|---|
| Adverse Events, n (%) | | |
| - Pain | 15 (15.8%) | 14 (14.7%) |
| - Bruising | 12 (12.6%) | 13 (13.7%) |
| - Thrombophlebitis | 4 (4.2%) | 5 (5.3%) |
| - Skin Changes | 3 (3.2%) | 2 (2.1%) |
| EQ-5D Score Improvement (6 months), Mean ± SD | 0.12 ± 0.07 | 0.11 ± 0.06 |

Endovenous laser ablation (EVLA) and sclerotherapy have emerged as two important minimally invasive treatment methods in the management of lower limb varicose veins throughout the years. This discussion focuses on the efficacy, safety, patient-reported outcomes, and cost-effectiveness of these treatments, and seeks to give a thorough review of the study's findings in the context of prior literature.

**EVLA and Sclerotherapy's effectiveness**: Our study's findings show that sclerotherapy and EVLA are equally successful in lowering the severity of lower limb varicose veins, as seen by noticeably better CEAP class reduction and patient-reported outcomes. These results support earlier studies and demonstrate the effectiveness of these therapy approaches [11–13].

The mean decreases in CEAP classes in the EVLA and sclerotherapy groups, respectively, were 2.3 and 2.1, according to our study. CEAP class reduction is a commonly used indicator of varicose vein severity improvement. These decreases are consistent with other trials showing comparable results [14,15] and reflect significant clinical benefits.

When evaluating the effects of treatments in the real world, patient-reported outcomes are essential. Both the EVLA and sclerotherapy groups in our study demonstrated appreciable drops in VCSS scores

and gains in AVVQ scores. These results are in line with other studies that stressed the significance of patient-reported outcomes [6][7] and demonstrate the beneficial effects of these treatments on patients' symptoms, functional status, and quality of life.

**Safety profiles** Safety is one of the most important factors to take into account when choosing a treatment method for varicose veins in the lower limbs. Our research revealed that both EVLA and sclerotherapy had acceptable safety profiles, with minor pain and bruising at the treatment site being the most typical side effects. These results are in line with earlier studies' findings of low frequencies of significant side effects from these therapies [8,9,11-15].

There were no significant variations in the frequency of adverse events between the two treatment groups, and thrombophlebitis and skin changes were less common adverse events in our study. This shows that people tolerate EVLA and sclerotherapy similarly, with little chance of serious side effects.

**Patient-Reported Results and Life Quality**: The primary objective of treating lower limb varicose veins is to enhance patients' quality of life. Patient-reported outcomes were evaluated in our study using the VCSS and AVVQ questionnaires, and both therapy groups showed a significant improvement in these scores. When choosing a course of treatment, clinicians should take into account both clinical outcomes and these improvements in symptoms, functional status, and quality of life because they are very important to patients.

Both the EVLA and sclerotherapy groups demonstrated appreciable gains on the EQ-5D questionnaire, which assesses general health-related quality of life. Both therapies improved quality of life, even though there were no statistically significant variations in EQ-5D ratings between the two groups.

**Cost-Effectiveness**: In making healthcare decisions, the financial ramifications of various treatment options are becoming more crucial. Our cost-effectiveness analysis showed that the direct medical expenses for EVLA and sclerotherapy were comparable. In contrast to sclerotherapy, EVLA obtained slightly more quality-adjusted life years (QALYs) and proved to be slightly more cost-effective. This data implies that although while EVLA may have slightly higher initial expenditures, it may provide superior long-term value in terms of better patient outcomes.

**Limitations**: There are a few restrictions that should be understood. First off, the follow-up period in this trial was rather brief, so it is yet unknown whether treatment outcomes will last over the long term. Second, the study was carried out in a single-center context, which would limit how broadly the results can be applied. Third, the allocation of patients to treatment groups might have been affected by selection bias. Last but not least, social viewpoints and indirect expenses were excluded from the cost-effectiveness analysis, which solely took into account direct medical costs.

## 4. Conclusion

In the treatment of lower limb varicose veins, endovenous laser ablation (EVLA) and sclerotherapy have both shown efficacy, safety, and favourable effects on patient-reported outcomes. The features, preferences, and accessibility of healthcare resources for each individual patient should be taken into account while choosing amongst different modalities. Our cost-effectiveness analysis leads us to believe that EVLA might provide a somewhat greater long-term value; however, more investigation is required to corroborate this conclusion and evaluate long-term durability. This study highlights the significance of taking into account both clinical and patient-centered outcomes in treatment decision-making and adds to the expanding body of research supporting the use of minimally invasive treatments for lower leg varicose veins.

## References:


1. Weber B, Marquart E, Deinsberger J, Tzaneva S, Böhler K. Comparative analysisof endovenous laser ablation versus ultrasound-guided foam sclerotherapy for thetreatment of venous leg ulcers. Dermatol Ther. 2022 Apr;35(4):e15322. https://doi.org/10.1111/dth.15322. Epub 2022 Jan 27. PMID: 35040545; PMCID: PMC9285388.
2. Abdul-Haqq R, Almaroof B, Chen BL, Panneton JM, Parent FN. Endovenous laserablation of great saphenous vein and perforator veins improves venous stasisulcer healing. Ann Vasc Surg. 2013 Oct;27(7):932-9. https://doi.org/10.1016/j.avsg.2012.09.014. Epub 2013 May 24. PMID: 23711972.
3. Lawaetz M, Serup J, Lawaetz B, Bjoern L, Blemings A, Eklof B, Rasmussen L.Comparison of endovenous ablation techniques, foam sclerotherapy and surgicalstripping for great saphenous varicose veins.

Extended 5-year follow-up of aRCT. Int Angiol. 2017 Jun;36(3):281-288. https://doi.org/10.23736/S0392-9590.17.03827-5. Epub 2017 Feb 17. PMID: 28217989.

4. Sermsathanasawadi N, Jieamprasertbun J, Pruekprasert K, Chinsakchai K,Wongwanit C, Ruangsetakit C, Mutirangura P. Factors that influence venous legulcer healing and recurrence rate after endovenous radiofrequency ablation ofincompetent saphenous vein. J Vasc Surg Venous Lymphat Disord. 2020May;8(3):452-457. https://doi.org/10.1016/j.jvsv.2019.11.003. Epub 2019 Dec 14. PMID:31843485.
5. Farah MH, Nayfeh T, Urtecho M, Hasan B, Amin M, Sen I, Wang Z, Prokop LJ,Lawrence PF, Gloviczki P, Murad MH. A systematic review supporting the Societyfor Vascular Surgery, the American Venous Forum, and the American Vein andLymphatic Society guidelines on the management of varicose veins. J Vasc SurgVenous Lymphat Disord. 2022 Sep;10(5):1155-1171. https://doi.org/10.1016/j.jvsv.2021.08.011. Epub 2021 Aug 24. PMID: 34450355.
6. Boersma D, Kornmann VN, van Eekeren RR, Tromp E, Ünlü Ç, Reijnen MM, de VriesJP. Treatment Modalities for Small Saphenous Vein Insufficiency: SystematicReview and Meta-analysis. J Endovasc Ther. 2016 Feb;23(1):199-211. https://doi.org/10.1177/1526602815616375. Epub 2015 Nov 12. PMID: 26564912.
7. Lattimer CR, Kalodiki E, Azzam M, Makris GC, Somiayajulu S, Geroulakos G.Interim results on abolishing reflux alongside a randomized clinical trial onlaser ablation with phlebectomies versus foam sclerotherapy. Int Angiol. 2013Aug;32(4):394-403. PMID: 23822942.
8. Biemans AA, Kockaert M, Akkersdijk GP, van den Bos RR, de Maeseneer MG,Cuypers P, Stijnen T, Neumann MH, Nijsten T. Comparing endovenous laserablation, foam sclerotherapy, and conventional surgery for great saphenousvaricose veins. J Vasc Surg. 2013 Sep;58(3):727-34.e1. https://doi.org/10.1016/j.jvs.2012.12.074. Epub 2013 Jun 13. PMID: 23769603
9. van der Velden SK, Biemans AA, De Maeseneer MG, Kockaert MA, Cuypers PW,Hollestein LM, Neumann HA, Nijsten T, van den Bos RR. Five-year results of arandomized clinical trial of conventional surgery, endovenous laser ablation andultrasound-guided foam sclerotherapy in patients with great saphenous varicoseveins. Br J Surg. 2015 Sep;102(10):1184-94. https://doi.org/10.1002/bjs.9867. Epub 2015 Jul1. PMID: 26132315.
10. Yie K. Symptom improvement after cyanoacrylate glue adhesion and endovenouslaser ablation in low-grade CEAP clinical classes. J Vasc Surg Venous LymphatDisord. 2022 Mar;10(2):360-369.e2. https://doi.org/10.1016/j.jvsv.2021.07.002. Epub 2021Jul 14. PMID: 34271248.
11. Hager ES, Washington C, Steinmetz A, Wu T, Singh M, Dillavou E. Factors thatinfluence perforator vein closure rates using radiofrequency ablation, laserablation, or foam sclerotherapy. J Vasc Surg Venous Lymphat Disord. 2016Jan;4(1):51-6. https://doi.org/10.1016/j.jvsv.2015.08.004. PMID: 26946896.
12. Whing J, Nandhra S, Nesbitt C, Stansby G. Interventions for great saphenousvein incompetence. Cochrane Database Syst Rev. 2021 Aug 11;8(8):CD005624. https://doi.org/10.1002/14651858.CD005624.pub4. PMID: 34378180; PMCID: PMC8407488.
13. Watanabe S, Okamura A, Iwamoto M, Nagai H, Sumiyoshi A, Tanaka K, Suzuki S,Tanaka H, Iwakura K, Fujii K. A randomized controlled trial to evaluate thesafety and efficacy of transluminal injection of foam sclerotherapy comparedwith ultrasound-guided foam sclerotherapy during endovenous catheter ablation inpatients with varicose veins. J Vasc Surg Venous Lymphat Disord. 2022Jan;10(1):75-81.e1. https://doi.org/10.1016/j.jvsv.2021.06.017. Epub 2021 Jul 10. PMID:34252576.
14. Hamel-Desnos C, Nyamekye I, Chauzat B, Gracia S, Josnin M, Abbadie F.FOVELASS: A Randomised Trial of Endovenous Laser Ablation Versus PolidocanolFoam for Small Saphenous Vein Incompetence. Eur J Vasc Endovasc Surg. 2023Mar;65(3):415-423. https://doi.org/10.1016/j.ejvs.2022.11.021. Epub 2022 Dec 5. PMID:36470312.
15. Paravastu SC, Horne M, Dodd PD. Endovenous ablation therapy (laser orradiofrequency) or foam sclerotherapy versus conventional surgical repair forshort saphenous varicose veins. Cochrane Database Syst Rev. 2016 Nov29;11(11):CD010878. https://doi.org/10.1002/14651858.CD010878.pub2. PMID: 27898181; PMCID:PMC6464398.