EFFECT OF CYANOACRYLATE VEIN CLOSURE ON VENOUS CLINICAL SEVERITY SCORE IN SUPERFICIAL VENOUS INSUFFICIENCY: ONE-MONTH FOLLOW-UP

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Abstract: Background: Cyanoacrylate ablation (CA) is a novel, non-thermal, non-tumescent (NTNT) technique for treating superficial venous insufficiency. It offers the advantage of permanent vein occlusion without anesthesia, thermal energy, or postoperative compression. Although large multicenter studies have confirmed its safety and efficacy, data from smaller single-center experiences remain limited. This study aimed to evaluate early anatomical and clinical outcomes of cyanoacrylate ablation in an ambulatory population.
Methods: This prospective single-center study included 31 patients with symptomatic superficial venous insufficiency who underwent cyanoacrylate ablation of the great or small saphenous vein. Patients were evaluated clinically and with duplex ultrasound at baseline and at one month post-procedure. Clinical improvement was assessed using the Venous Clinical Severity Score (VCSS). Statistical analysis was performed using paired tests, with $p < 0.05$ considered significant.
Results: Complete anatomical closure of all treated veins was confirmed by duplex ultrasound at one month, yielding a 100% technical success rate. No cases of deep vein thrombosis, thrombophlebitis, or infection were recorded. The median total VCSS decreased significantly from 5 to 3 ($p = 0.00002$), with marked improvement in pain ($2 \rightarrow 0$; $p = 0.00003$), edema ($2 \rightarrow 1$; $p = 0.005$), and inflammation ($\geq 2 \rightarrow 0$; $p = 0.043$). Other domains, including pigmentation and induration, showed no significant early change.
Conclusion: Cyanoacrylate ablation achieved complete vein closure and significant short-term clinical improvement with no major complications. The absence of tumescent anesthesia, thermal injury, and postoperative compression enhances patient comfort and accelerates recovery. These findings confirm cyanoacrylate ablation as a safe, effective, and well-tolerated minimally invasive option for the treatment of superficial venous insufficiency.
Keywords: Cyanoacrylate ablation, superficial venous insufficiency, chronic venous disease, VCSS, minimally invasive treatment

1. INTRODUCTION

Chronic venous disease (CVD) is a common vascular condition that poses a substantial public health burden, affecting a large portion of the population and placing notable demands on healthcare systems. It encompasses a spectrum of pathophysiological alterations resulting from elevated venous pressure in the lower limbs, triggered by multiple factors. In most cases, incompetent or dysfunctional venous valves cause retrograde blood flow (venous reflux), leading to venous hypertension, impaired venous return, blood pooling, and subsequent tissue hypoxia and inflammation [1,5].
Chronic venous insufficiency (CVI), the advanced form of CVD, affects up to 25–30% of adults worldwide and is primarily caused by superficial venous reflux leading to varicose veins, edema, and skin changes [6]. Over the past two decades, management strategies for CVI have shifted from conventional surgical stripping to minimally invasive endovenous approaches that offer faster recovery and improved patient satisfaction [17]. Among thermal ablation methods, radiofrequency and laser therapy have shown high efficacy; however, these techniques require tumescent anesthesia and carry risks of thermal nerve injury, bruising, and postoperative discomfort [19].
To overcome these limitations, non-thermal, non-tumescent (NTNT) modalities have been introduced, among which cyanoacrylate closure (CAC) has emerged as a safe and effective alternative. CAC achieves permanent vein occlusion by injecting a medical-grade adhesive into the incompetent vein under ultrasound guidance, eliminating the need for anesthesia, heat, or compression therapy. Several systematic reviews and meta-analyses have confirmed the high anatomic success rates and favorable safety profile of CAC compared with endovenous thermal techniques. A meta-analysis by Guo et al. (2021) reported comparable closure rates between CAC and thermal ablation, with significantly lower postoperative pain and bruising in the CAC group [10]. Similarly, Amshar et al. (2022) and

García-Carpintero et al. (2020) demonstrated equivalent efficacy and durability, alongside reduced periprocedural discomfort and faster recovery [3, 7].

Despite strong evidence from multicenter trials and meta-analyses, data from smaller, single-center studies evaluating short-term outcomes in real-world ambulatory settings remain limited. The present study therefore aims to assess early clinical and anatomical outcomes following cyanoacrylate ablation in patients with superficial venous insufficiency.

2. MATERIALS AND METHODS

Study design and patients

This was a prospective, single-center study including 31 ambulatory patients with symptomatic superficial venous insufficiency treated with cyanoacrylate ablation. Consecutive patients were enrolled starting in June 2023. The present analysis reports the outcomes of the first follow-up visit at one month after treatment. Data were recorded with the Venous Clinical Severity Score (VCSS) scoring system in all examination. Postoperative duplex scanning also evaluated anatomical and clinical success rates. The total occlusion of the treated saphenous vein of a predetermined length in which the procedure was performed was defined as operative success.

Eligible participants were men and women aged 20–80 years, diagnosed with superficial venous reflux of the great saphenous vein (GSV), small saphenous vein (SSV), or their tributaries. Diagnosis was confirmed using duplex ultrasound. Patients were included across all CEAP clinical classes (C0–C6).

Inclusion and exclusion criteria

Eligible participants were men and women aged between 21 and 70 years who presented with symptomatic superficial varicose veins. Patients were included if they had a CEAP clinical classification ranging from C0 to C4b with associated symptoms and duplex ultrasound evidence of venous reflux involving the great saphenous vein (diameter >4 mm in the femoral region or >3.5 mm in the crural region) or the small saphenous vein (diameter >3.5 mm in the crural region). All patients were required to be physically able to walk without assistance, to attend scheduled follow-up visits, and to be mentally competent to provide informed consent for the procedure.

Patients were excluded if they had a history or presence of deep venous thrombosis (DVT), arteriovenous malformation, severe peripheral arterial disease, or severe immobility. Other exclusion criteria included marked tortuosity of the great saphenous vein that precluded catheter advancement, known allergy to cyanoacrylate, active or previous thrombophlebitis, systemic infection, pregnancy or lactation, and inability to comply with follow-up examinations.

Procedure

All procedures were performed in an outpatient setting under local anesthesia. None of the patients received general or regional anesthesia.

After percutaneous puncture of the target vein, a cyanoacrylate delivery catheter was advanced under ultrasound guidance. Medical-grade cyanoacrylate adhesive was then injected segmentally along the full length of the incompetent vein, while continuous external compression was applied.

Following delivery of the adhesive, Doppler ultrasound confirmed complete occlusion of the GSV along the entire treated segment (femoral and crural regions), as well as collapse of connected perforator veins at the femoro-saphenous junction.

No tumescent anesthesia, thermal energy, or post-procedural compression stockings were required. After removal of the catheter and sheath, manual compression was applied at the puncture site for hemostasis.

The average procedure time was 10–15 minutes per vein. All patients were discharged the same day and advised to resume normal daily activities within several days.

Clinical and imaging assessment

Patients were evaluated at baseline and at one-month follow-up. Clinical severity was assessed using the Venous Clinical Severity Score (VCSS), which includes nine domains: pain, varicosity, edema, pigmentation, inflammation, induration, ulcer size, ulcer duration, and use of compression therapy. The total VCSS was calculated as the sum of all domain scores, providing a comprehensive measure of clinical improvement. In addition, duplex ultrasound examination was performed in both standing and supine positions to assess the patency and compressibility of the femoral, popliteal, great and small saphenous veins, as well as the perforator veins, and to confirm successful closure of the treated segments and the absence of thrombotic or other complications.

Statistical analysis

All statistical analyses were performed using the SPSS software package, version 22.0 for Windows (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as mean ± standard deviation (SD) or median with interquartile range (IQR), depending on data distribution, while categorical variables were presented as frequencies and percentages. The Shapiro–Wilk test was applied to assess data normality. Comparisons between baseline and

one-month follow-up values were performed using the paired t-test or the Wilcoxon signed-rank test, as appropriate. A p-value <0.05 was considered statistically significant.

3. RESULTS

A total of 31 patients with symptomatic superficial venous insufficiency were included in the present analysis. All patients underwent successful cyanoacrylate ablation of the incompetent great or small saphenous vein. Complete anatomical occlusion of the treated vein was confirmed by duplex ultrasound at the one-month follow-up, corresponding to a success rate of 100%. No major peri - or post-interventional complications, including deep venous thrombosis, thrombophlebitis, or local infection, were observed.

Statistical analysis demonstrated significant clinical improvement across several VCSS domains at one month compared with baseline. The pain score decreased from a median of 2 to 0 ($p = 0.00003$), the edema score from 2 to 1 ($p = 0.005$), and the inflammation score from ≥ 2 to 0 in 75% of patients ($p = 0.043$). The total VCSS showed a significant reduction from a median of 5 to 3 ($p = 0.00002$), indicating a marked improvement in overall clinical severity. No statistically significant differences were observed in the domains of varicosity, pigmentation, induration, active ulcer, ulcer size or duration, or compression therapy (all $p > 0.05$).

Post-interventional duplex ultrasound confirmed complete closure of all treated veins, with preserved flow in the deep venous system and absence of thrombotic or other adverse events. These findings collectively demonstrate that cyanoacrylate ablation achieved both complete anatomical success and meaningful short-term clinical improvement within one month following the intervention.

4. DISCUSSION

The results of the present study demonstrate that cyanoacrylate vein closure is a safe, effective, and well-tolerated method for the treatment of superficial venous insufficiency, resulting in both anatomical and clinical improvement at one month after intervention. The procedure achieved a 100% technical success rate, with no major adverse events or thrombotic complications, and was associated with significant reductions in pain, edema, inflammation, and total VCSS score. These findings are consistent with previously published international studies evaluating cyanoacrylate closure systems such as VenaSeal and VariClose.

Evidence from multiple clinical studies supports the safety and efficacy of cyanoacrylate ablation in treating superficial venous insufficiency. Morrison et al. (2015) compared cyanoacrylate closure and radiofrequency ablation (RFA) in patients with great saphenous vein incompetence and reported high anatomical success, with complete closure rates of 99.0% versus 96.0% at three months, accompanied by significant improvement in VCSS and quality of life [13]. In the 12-month follow-up of the same cohort (Morrison et al., 2017), sustained closure rates above 97% were confirmed along with continued symptom relief, supporting the treatment's durability [14]. The 36-month extension (Morrison et al., 2019) and 60-month extension (Morrison et al., 2020) further showed maintained high closure rates and low recurrence, affirming long-term efficacy [15, 16]. The WAVES post-market registry by Gibson and Ferris (2017) demonstrated excellent anatomical results across great, small, and accessory saphenous veins, with complete duplex closure at one month and rapid recovery—most patients resuming daily activities within two days [8]. At 24 months, Gibson et al. (2018) again reported durable outcomes, with closure rates above 95% and maintained quality-of-life improvement [9].

Other investigations have further supported the excellent safety profile of cyanoacrylate ablation, highlighting the absence of thermal nerve injury and the elimination of tumescent anesthesia as major advantages compared with endovenous thermal methods. Comparable findings were reported in an observational study by Güven and Baykan (2020), which compared surgical stripping/ligation with cyanoacrylate embolization in patients with saphenous vein insufficiency. Both techniques achieved effective vein closure; however, cyanoacrylate embolization was associated with less postoperative pain, faster recovery, and greater patient satisfaction, emphasizing its minimally invasive advantages over surgery [11].

Similarly, the observational multicenter study by Ay et al. (2021) compared surgical stripping, RFA, and cyanoacrylate embolization for great saphenous vein insufficiency and found no significant difference in closure rates among the three techniques at 12 months. However, patients in the cyanoacrylate group reported lower pain scores, shorter recovery time, and improved quality of life (CIVIQ-14), confirming the favorable safety and comfort profile of this non-thermal, non-tumescent approach [4].

More recently, a multicenter randomized controlled trial comparing cyanoacrylate closure with conventional surgical stripping showed comparable occlusion rates and clinical improvement, confirming cyanoacrylate as an effective and minimally invasive alternative to surgery [12].

The magnitude of clinical improvement observed in our cohort, particularly in pain and edema scores, aligns closely with these previously published data. The rapid symptomatic relief within one month likely reflects both immediate

vein closure and reduced venous hypertension in the treated limb. Although pigmentation, induration, and ulcer-related parameters did not significantly change at this early stage, it is expected that these findings require a longer follow-up period to achieve measurable improvement, as documented in studies with 6–12 month observation [2, 18].

The current results confirm that cyanoacrylate ablation can be successfully performed in an outpatient setting, with short procedure time, minimal discomfort, and rapid return to normal activities, further supporting its role as a first-line minimally invasive treatment for selected patients with superficial venous insufficiency. The absence of compression therapy and tumescent anesthesia represents a substantial advantage in terms of patient comfort and compliance.

The main limitation of this study is the relatively small sample size and the short duration of follow-up. However, the uniformity of results and consistency with previous large-scale trials strengthen the validity of these findings. Ongoing follow-up at 6 and 12 months will provide further data regarding the durability of vein closure and the long-term impact on skin changes and ulcer healing.

5. CONCLUSION

Cyanoacrylate ablation represents a safe, effective, and minimally invasive alternative for the treatment of superficial venous insufficiency. In our cohort, the procedure achieved complete anatomical success and significant clinical improvement as reflected by reduced pain and edema scores within one month after intervention. These early outcomes are consistent with the results of larger multicenter trials and long-term studies demonstrating durable vein closure, sustained symptom relief, and excellent safety. The absence of tumescent anesthesia, thermal energy, and postprocedural compression further enhances patient comfort and accelerates recovery. While pigmentation and skin-related changes may require longer follow-up to show measurable improvement, the present findings reaffirm cyanoacrylate embolization as a valuable and well-tolerated treatment modality for patients with saphenous vein incompetence.

REFERENCES

Almeida, J. I., Javier, J. J., Mackay, E. G., Bautista, C., Cher, D. J., & Proebstle, T. M. (2015). Two-year follow-up of first human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. *Phlebology, 30*(6), 397–404. https://doi.org/10.1177/0268355514532455

Almeida, J. I., Javier, J. J., Mackay, E. G., Bautista, C., Cher, D. J., & Proebstle, T. M. (2017). Thirty-sixth-month follow-up of first-in-human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. *Journal of Vascular Surgery: Venous and Lymphatic Disorders, 5*(5), 658–666. https://doi.org/10.1016/j.jvsv.2017.03.016

Amshar, M., Nugraha, R. A., Batubara, E. A. D., Siddiq, T., Indriani, S., & Adiarto, S. (2022). Cyanoacrylate embolization versus endovenous laser ablation in treating saphenous vein insufficiency: A systematic review and meta-analysis. *Annals of Vascular Surgery, 80*, 313–324. https://doi.org/10.1016/j.avsg.2021.09.041

Ay, Y., Gunes, E., Turkkolu, S. T., Selcuk, E., Calim, M., Akal, R., Aydin, C., Inan, B., Koksal, C., & Kahraman Ay, N. (2021). Comparative efficacy and life quality effects of surgical stripping, radiofrequency ablation, and cyanoacrylate embolization in patients undergoing treatment for great saphenous vein insufficiency. *Phlebology, 36*(1), 54–62. https://doi.org/10.1177/0268355520947292

Beebe-Dimmer, J. L., Pfeifer, J. R., Engle, J. S., & Schottenfeld, D. (2005). The epidemiology of chronic venous insufficiency and varicose veins. *Annals of Epidemiology, 15*(3), 123–130. https://doi.org/10.1016/j.annepidem.2004.05.015

Eberhardt, R. T., & Raffetto, J. D. (2014). Chronic venous insufficiency. *Circulation, 130*(4), 333–346. https://doi.org/10.1161/CIRCULATIONAHA.113.006898

García-Carpintero, E., Carmona, M., Chalco-Orrego, J. P., González-Enríquez, J., & Imaz-Iglesia, I. (2020). Systematic review and meta-analysis of endovenous cyanoacrylate adhesive ablation for incompetent saphenous veins. *Journal of Vascular Surgery: Venous and Lymphatic Disorders, 8*(2), 287–296. https://doi.org/10.1016/j.jvsv.2019.09.010

Gibson, K., & Ferris, B. (2017). Cyanoacrylate closure of incompetent great, small, and accessory saphenous veins without the use of post-procedure compression: Initial results from the WAVES study. *Vascular, 25*(5), 442–450. https://doi.org/10.1177/1708538117696575

Gibson, K., Ferris, B., McEnroe, S., Weiss, R., Vasquez, M., & Morrison, N. (2018). Twenty-four-month results from a randomized trial of cyanoacrylate closure versus radiofrequency ablation for incompetent great saphenous veins (VeClose). *Journal of Vascular Surgery: Venous and Lymphatic Disorders, 6*(5), 606–613. https://doi.org/10.1016/j.jvsv.2018.03.007

Guo, J., Zhang, F., Guo, J., Guo, L., Gu, Y., & Huang, Y. (2021). A systematic review and meta-analysis comparing the efficacy of cyanoacrylate ablation over endovenous thermal ablation for treating incompetent saphenous veins. *Phlebology, 36*(8), 597–608. https://doi.org/10.1177/02683555211008762

Güven, C., & Baykan, A. (2020). Comparison of stripping/ligation and embolization with cyanoacrylate in venous insufficiency treatment. *Journal of Surgery and Medicine*, *4*(5), 400–405. https://doi.org/10.28982/josam.732821

Joh, J. H., Lee, T., Byun, S. J., Cho, S., Park, H. S., Yun, W. S., Yang, S. S., Kim, H., Kim, W. S., & Jung, I. M. (2022). A multicenter randomized controlled trial of cyanoacrylate closure and surgical stripping for incompetent great saphenous veins. *Journal of Vascular Surgery: Venous and Lymphatic Disorders, 10*(2), 353–359. https://doi.org/10.1016/j.jvsv.2021.08.012

Morrison, N., Gibson, K., McEnroe, S., Goldman, M., King, T., Weiss, R., Cher, D., & Almeida, J. I. (2015). Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). *Journal of Vascular Surgery, 61*(4), 985–994. https://doi.org/10.1016/j.jvs.2014.11.071

Morrison, N., Gibson, K., Vasquez, M., Weiss, R., Cher, D., Madsen, M., & Jones, A. (2017). VeClose trial 12-month outcomes of cyanoacrylate closure versus radiofrequency ablation for incompetent great saphenous veins. *Journal of Vascular Surgery: Venous and Lymphatic Disorders, 5*(3), 321–330. https://doi.org/10.1016/j.jvsv.2016.12.005

Morrison, N., Gibson, K., Vasquez, M., Weiss, R., & Cher, D. (2019). Thirty-six-month outcomes of the VeClose randomized controlled trial. *Journal of Vascular Surgery: Venous and Lymphatic Disorders, 7*(5), 779–789. https://doi.org/10.1016/j.jvsv.2019.04.001

Morrison, N., Gibson, K., Vasquez, M., Weiss, R., & Cher, D. (2020). Five-year extension study of cyanoacrylate closure versus radiofrequency ablation for incompetent great saphenous veins: 60-month results from the VeClose trial. *Journal of Vascular Surgery: Venous and Lymphatic Disorders, 8*(6), 978–989. https://doi.org/10.1016/j.jvsv.2020.03.013

Nesbitt, C., Bedenis, R., Bhattacharya, V., & Stansby, G. (2014). Endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus open surgery for great saphenous vein varices. *Cochrane Database of Systematic Reviews, 2014*(7), Article CD005624. https://doi.org/10.1002/14651858.CD005624.pub3

Proebstle, T. M., Alm, J., Dimitri, S., Rasmussen, L., Whiteley, M., Lawson, J., Cher, D., & Davies, A. (2015). The European multicenter cohort study on cyanoacrylate embolization of refluxing great saphenous veins. *Journal of Vascular Surgery: Venous and Lymphatic Disorders, 3*(1), 2–7. https://doi.org/10.1016/j.jvsv.2014.09.001

Rasmussen, L. H., Lawaetz, M., Bjoern, L., Vennits, B., Blemings, A., & Eklof, B. (2011). Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy, and surgical stripping for great saphenous varicose veins. *British Journal of Surgery, 98*(8), 1079–1087. https://doi.org/10.1002/bjs.7555