

Original Article

Cyano-acrylate vein closure (*VenaSeal*) vs. endovenous laser ablation for great saphenous vein incompetence

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Abstract

Aim: *Primary varicose vein* is still one of the most prevalent venous disorders, faced daily in the surgical practice. Shifting from surgical intervention to endovenous interventions (thermal or non-thermal) is currently the standard practice because of their better results and patients' satisfaction. The aim of our study is to compare *vein closure rate and overall venous thrombosis*, 12 months after either Cyanoacrylate or endovenous laser treatment for Great Saphenous vein incompetence.

Material and Methods: The study was a retrospective study analyzing the data of 126 lower limbs in 120 patients with Great Saphenous vein (GSV) incompetence who underwent either Cyanoacrylate closure (CAC) or Endovenous Laser Ablation (EVLA) and were followed for 12 months between Jan. 2022 and March 2025. Vein closure and thrombosis rates were our primary endpoints. Sixty patients with 66 limbs had EVLA. We used (*VenaSeal*, Medtronic) for CAC and (*Ceralas E Biolitec 1470nm WL*, *ELVeS*, *Radial fiber Diode*) for EVLA.

Results: A total of 126 lower limbs in 120 patients were treated, the patients were between 18 and 65 years old (mean age was 38 +/- 12 years) and 65% of them were females. They were followed for 12 months (48% had complete 12-month follow up). *Vein closure rates* were 100% in both modalities (*1-month period*), 97% in EVLA and 100% in CAC-patients (*6-month period*) and 94% in EVLA-patients and 96% in CAC-patients (*12-month period*). It was found that 3% of EVLA-patients had Endovenous Heat Induced thrombosis (EHIT) and 2% of CAC-patients had Endovenous Glue Induced Thrombosis (EGIT) with *no incidence of Deep Vein Thrombosis (DVT) during the follow up period*.

Conclusion: Cyanoacrylate vein closure results were *not inferior* to laser vein treatment in great saphenous varicose veins, nevertheless *Cyanoacrylate surpassed Laser treatment in six and twelve-month vein closure rate*. Both modalities were safe and free of major venous thrombosis.

Keywords: Varicose veins, endovenous therapy, laser thermocoagulation, cyanoacrylate

INTRODUCTION

Varicose veins is a prevalent venous disorder, almost one third of the population suffers from varicose veins [1]. 60% of patients with truncal vein reflux have great saphenous vein (GSV) reflux [2]. Once, surgery had been the gold standard for treatment, till the advent of endovenous treatments such as thermal ablation, chemical or mechano-chemical.

I- Endovenous Laser Ablation (EVLA), introduced in the late nineties, has a widespread success and acceptance among patients

and physicians. EVLA depends on *heat generation*, burning the intima, leading to luminal fibrosis and obliteration. Thermal damage to the surrounding tissues supervenes if the saphenous fascial compartment is not cooled down with the *tumescent solution*. Post-procedure limb *compression* is mandatory to mitigate tissue swelling, ecchymosis as well ensuring vein wall apposition and adherence, preventing early vein recanalization.

II- Cyanoacrylate vein closure (CAC), which has been used since 2013, relies on the *gluing property* of (N-Butyl-2-Cyano-Acrylate

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NBCA) with fast instantaneous vein wall adherence followed with permanent vein fibrosis. Vein wall closure does not depend on limb compression. Also, it does not produce excessive heat that could damage the surrounding tissues. *Neither tumescent solution nor compression with elastic stocking is needed.*

The aim of our study was to prove that cyanoacrylate vein closure rate was not inferior to the observed rate in patients treated with the endovenous Laser for Great Saphenous Vein incompetence.

MATERIAL AND METHODS

Study design and population

In this single-center (Kasr AlAiny School of Medicine and Teaching Hospitals, Cairo University, Egypt), retrospective comparative study, the data of 120 patients with GSV incompetence in 126 limbs, whom had either Cyanoacrylate vein closure CAC or Endovenous Laser Ablation EVLA between *January 2022* and *March 2025* were collected. 66 limbs in 60 patients had EVLA in comparison to 60 limbs in 60 patients with CAC. The *patients' data* were obtained from our institution data base (documentations and medical records).

We conducted our study according to our *Scientific and Ethical committee approval* (N-14-2025, of Kasr AlAiny School of Medicine, Cairo University) and complying with the *terms of Helsinki Declaration*.

The patients (65% were females) were between 18 and 65 years old (Mean age was 38 years $\pm$ 12), with primary non-recurrent varicose veins of GSV with diameter 4-10mm and bilateral in 6 patients. Patients fit for surgery were those with mild varicose veins (CEAP C2-3, 95% were C2) and revised Venous Clinical Severity Score (VCSS) of 3-6.

Evaluation: Physical examination, Venous duplex and consent were done before the procedure. *Venous duplex U/S* investigated GSV *incompetence* (Reflux time more than 0.5s at the Saphenofemoral junction (SFJ) or in 10cm vein-length segment were considered significant), *diameter* (5cm from SFJ, in standing position) and deep vein *patency*. CEAP and revised VCSS were calculated for each patient. *Informed Consent* included patient's *identification* (Name, sex, age and Medical Record Number MRN), *procedure* and its indication and possible complications (Common complications if more than 10% or major complications). In our practice, long-haul flights, long trips more than 4 hours or oral contraceptive pills were discouraged after any procedure, but if mandatory, prophylactic anticoagulation with Enoxaparin Subcutaneous (SC) was prescribed.

Premedication: with SC Heparin before the procedure, additional dose was given if the patient was reluctant or unable to walk independently post-procedure.

Procedure: done in the Operation room (OR) under local anaesthesia with conscious sedation. Procedures were limited

to the above knee vein segment in EVLA-patients (to avoid saphenous neuropathy), whole vein was treated in CAC-patients according to the level of the incompetence. Operative duplex Ultrasound (U/S) to locate GSV, Saphenofemoral junction SFJ and Common Femoral Vein (CFV). U/S guided vein cannulation then laser fiber or the VenaSeal introducing catheter advanced 3-5cm away from SFJ.

In laser ablation procedure, we used *Biolitec Ceralas E 1470nm WL generator, ELVeS, Radial fiber Diode*. We preferred to use Pulse Mode than Continuous Mode. 200-300ml of *Tumescent fluid* was injected around the GSV, preferably in the saphenous compartment. The solution composed of 20ml of 1% Lignocaine, 1ml of Adrenaline 1/1000 and 20ml of 8.4% NaHCO₃ in 500ml of cold 0.9% NaCl solution. Laser fiber tip put 3-5 cm away from SFJ. The laser generator was set to 10-8W, aiming Linear Endovenous Energy Density (LEED) of 60-90 J/cm. After the procedure, the whole limb was wrapped in elastic bandage, to be maintained for 2-3 days then to be replaced with Class-II elastic stocking for 3-4 weeks after the procedure.

In Cyanoacrylate procedure, we used *VenaSeal, Medtronic* with no tumescence nor post-procedure compression. Cyanoacrylate catheter tip was placed 5cm from SFJ, SFJ was compressed with the U/S probe to prevent Cyanoacrylate migration into the CFA. Three drops of the Cyanoacrylate were injected, one drop 1cm apart in the first 3-5cm of the vein and manually compressed for 3 minutes, keeping the catheter tip 3cm away from the last drop. After elapse of the 3minutes, one drop for every 3cm of the vein with 30 seconds compression or 1 minute compression for 3 successive drops (In 9-10 cm of the vein) were instilled. At the end of the procedure, manual compression was performed over the treated vein for additional 5-10 minutes to ensure vein obliteration. *No need for banding or elastic stocking post-procedure.*

In both groups, we ensured that there was *no or minimal flow inside the GSV* with preserved CFV flow with no Cyanoacrylate protrusion.

Post-procedure: All patients were encouraged to walk once they were able to do so. Limb bandaging then elastic stocking compressing were only used in EVLA-patients. Paracetamol and Ibuprofen were prescribed post-procedure on demand for EVLA-patients but in regular dose for CAC-patients for one week (to lessen Cyanoacrylate allergic tissue reaction).

Follow up: for 12 months after the procedure. Within 48-72 hours, all patients had venous duplex to exclude Deep Vein Thrombosis (DVT) and to document the vein closure. *1-month, 6-month and final 12-month visit* were made for clinical assessment with duplex U/S to check for vein closure. Closer and frequent follow up visits were scheduled in patients with vein thrombosis or other compelling complications (skin reaction or neuralgia). Successful vein closure was defined as absence of blood flow

(antegrade or retrograde) in the treated vein segment (the whole segment or less than 5cm length) with vein obliteration and fibrosis.

Statistical analysis:

We used the IBM SPSS version 21.0 software (IBM Corp., USA). The normal distribution of the data was analyzed using the Shapiro-Wilk test and coefficient of variation. p-value of 0.05 was considered statistically significant.

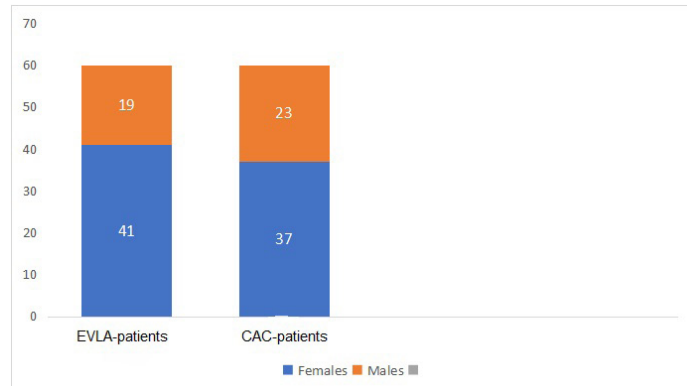


Figure 1. Sex distribution; CAC: Cyanoacrylate closure; EVLA: Endovenous laser ablation

RESULTS

A total of 120 patients with 126 limbs (66 limbs in EVLA) suffering from GSV incompetence had EVLA or CAC and were followed for 12 months for vein closure rates in 1, 6 and 12 months and the occurrence of major venous thrombosis. Vein closure rates after one year were above 90% in both groups with no DVT or significant venous thrombosis. EVLA and CAC results were comparable, slightly better in CAC.



Figure 2. Closure rates; CAC: Cyanoacrylate closure; EVLA: Endovenous laser ablation

Table 1. Overall patients characteristics

Age	Sex	Vein	CEAP	ASA
18-65 years old (38 years old +/-12)	Both sexes, 65% F.	GSV 4-10 mm in diameter	C2(95%) - C3(5%)	I-II
F: Females; GSV: Great saphenous vein; CEAP: Clinical etiological anatomical and patho-physiological classification; ASA: American society of anaesthesiology; C2 95%: Varicose veins; C3 5%: Varicose veins associated foot oedema; ASA I: Healthy; ASA II: With controlled medical condition				

Table 2. EVLA-patients/CAC-patients patients characteristics

Age	Sex	BMI	GSV Diameter	GSV Length
EVLA-patients	41F/19M	Lt. 33 – Rt. 21, Bil. 6	4.5-6mm	35-40mm
CAC-patients	37F/23M	Lt. 42 – Rt.18, Bil. 0	3.5-5mm	50-60mm
CAC: Cyanoacrylate closure; EVLA: Endovenous laser ablation; F: Female; M: Male; BMI: Body mass index; GSV: Great saphenous vein				

Table 3. Results of EVLA-patients/CAC-patients

Column Captions or Objects	EVLA	CAC
No. of limbs/patients	66/60	60/60
Completed 12-month follow up period	31 limbs in 30 patients.	26 limbs in 26 patients.
BMI	24-32	21-30
Female/Male	41-19	37-23
Sides	Lt. 33–Rt. 21, Bilateral in 6 patients	Lt. 42–Rt. 18, Bilateral in 0 patients
Vein diameter	4.5-6 mm	3.5-5 mm
Vein length	35-40 cm	50-60 cm
Tumescence	200-300 ml/Limb	None.
Closure rates	At 1-month, 66/66 limb, 100%.	At 1-month, 60/60 limb, 100%.
	At 6-month, 54/56 limb, 97%.	At 6-month, 46/46 limb, 100%.
	At 12month, 29/31 limb, 94%.	At 12month, 25/26 limb, 96%.
Endovenous thrombosis	2/66 limbs - 3%	1/60 limbs - 2%
DVT rates	At 1-month, 0/66 limb, 0%.	At 1-month, 60/60 limb, 0%.
	At 6-month, 0/56 limb, 0%.	At 6-month, 0/46 limb, 0%.
	At 12month, 0/31 limb, 0%.	At 12month, 0/26 limb, 0%.
Significant ecchymosis	11/66 limbs - 17%	0%
Saphenous Neuropathy	11/60 patients - 18%	0%
Skin reaction	0/66 limbs, 0%	17/60 – 28%
CAC: Cyanoacrylate closure; EVLA: Endovenous laser ablation.; F: Female; M: Male; BMI: Body mass index; DVT: Deep vein thrombosis		

***EVLA:** We had 66 limbs in 60 patients, 41 females and 19 males with a mean age of 42 years (± 20) and Body Mass Index (BMI) of 24-32. The patients had CEAP2-3 GSV reflux. Vein diameter ranged between 4.5 and 6mm and length between 35 and 40cm. Six patients had bilateral EVLA. While 37 limbs had EVLA in continuous mode, 29 had in pulsed mode with LEED of 60-90 j/cm with 8-10 Watts. All patients had operative tumescent analgesia and post-procedure limb compression for 3weeks. Closure rate was 100%, 97% and 94% after one, six and twelve months respectively ($P\text{-value} < 0.02$). Two patients had Class Endovenous Heat Induced Thrombosis (EHIT) with thrombus less than 50% protrusion into CFV with no DVT, identified in 48-Hr-duplex ($P\text{-Value of } 0.01$). Rivaroxaban 20mg/day and weekly duplex U/S till resolution (within 3-4 weeks) then Clopidogrel 75mg/day or Rivaroxaban 10mg/day for additional three months were used in these patients. No patients developed DVT during the follow up period. Eleven limbs had moderate ecchymosis resolved with conservative management within 3-4 weeks, 11 patients (18%, $P\text{-value of } 0.3$) had annoying Saphenous neuropathy resolved spontaneously with expectant management, otherwise no patients had skin burn or infection.

***CAC:** We had 60 limbs in 60 patients, 37 females and 23 males with a mean age of 34 years (± 20) and BMI of 21-30. The patients had CEAP2-3 GSV reflux. Vein diameter ranged between 3.5 and 5mm and length between 50 and 60cm. No patient had bilateral CAC. 37 limbs had the whole GSV treatment. No patient had neither tumescent analgesia nor post-procedure limb compression. Closure rates were 100%, 100% and 96% after one, six and twelve months respectively ($P\text{-value} < 0.01$). One patient had Class Endovenous Glue Induced Thrombosis (EGIT) with thrombus less than 50% protrusion into CFV with no DVT, identified in 48-Hr-duplex ($P\text{-Value} < 0.01$). Rivaroxaban 20mg/day and weekly duplex U/S till resolution (within 3-4 weeks) then Clopidogrel 75mg/day or Rivaroxaban 10mg/day for additional three months were used to treat these patients. No patients had DVT during the follow up period. 17 patients (28%, $p\text{-Value of } 0.6$) had allergic-like reaction to Cyanoacrylate with mild soreness, itching and redness, 3-7 days after the procedure, resolved with warm compresses, topical and oral anti-inflammatory, anti-histaminic, short course of oral corticosteroids (3-5 days) was reserved for resistant cases, this condition was resolved within 2-4 weeks, otherwise no patients had skin burn, ecchymosis, saphenous neuralgia or infection.

Comparisons of the results: We had 60 patients in each group, 60 limbs had had CAC and 66 limbs had had EVLA (6 patients had bilateral Laser treatment). *Demographic criteria* were comparable with predominance of the female gender in both groups, and higher BMI in EVLA patients, CAC-patients were a little bit younger. *Vein diameters* were larger in EVLA (mean diameter 5.25 mm. ± 0.75 mm) in comparison to CAC-patients (mean diameter 4.25 mm ± 0.75 mm). In EVLA, only above the knee segments (35-40 cm) were treated to avoid saphenous

neuropathy, in comparison to CAC-patients (50-60cm). All patients with EVLA had to wear elastic stocking for 3-4 weeks post procedure and none of CAC-patients had to. Ecchymosis (sites of tumescent injection or possible vein perforations) was prevalent in EVLA-patients (17%) and none of the CAC-patients had significant ecchymosis, however 28% of CAC-patients had transient skin reaction (redness and mild itch and discomfort) resolved within one month of conservative treatment. 18% of Group-L developed annoying Saphenous neuropathy, resolved within 6 months with expectant management and none of CAC-patients developed neuropathy. *Vein closure rates* were 100% in 1-month period in both groups. 100% and 97% in 6-month period in CAC-patients and EVLA-patients respectively, but dropped to 97% in CAC-patients and 94% in EVLA-patients in the 12-month follow up period. ($P\text{-value} < 0.01$ and 0.02 respectively). The difference in the rates was statistically insignificant. 3% of EVLA-patients and 2% of CAC-patients had thrombus extending less than 50% into CFV and thrombus at SFJ ($P\text{-Value} < 0.02, 0.01$). Nevertheless, none developed acute DVT during follow up period. The patients of either modality did not have major adverse events (stroke or death)

-Cyano-Acrylate showed better *closure rates* than EVLA, but these rates were statistically insignificant, but the *ecchymosis, neuropathy and pain rates* were higher in EVLA-patients. EVLA superseded Cyanoacrylate closure in freedom from allergic skin reaction (0% to 27%). Both modalities had no significant venous thrombosis that would harm the patients. In both groups, CEAP and VCSS were improved, CEAP from C2-3 to C0-1 and VCSS from 3-6 to 1-3.

DISCUSSION

Primary varicose veins is a common venous disorder. 10% of males and 20% of females suffer from one aspect or more of varicose veins with symptoms varying from mild ache to resistant chronic leg ulceration. Great saphenous veins reflux represents 60% of the affected truncal veins [2-4]. Surgery once was the standard practice for treatment, but the advent of endovenous modalities with the concept of treating the veins from inside surpassed the surgery. Endovenous intimal injury followed with luminal obliteration and wall fibrosis currently is the gold standard of the treatment for truncal vein reflux [5].

Endovenous *Laser Ablation* EVLA (introduced in 1990's), with endoluminal ablation by laser fiber heat generated. The laser fiber generates temperature that reaches 200°C, this extreme temperature results in not only of vein wall ablation but overly collateral tissue damage [5]. Risk of thermal damage is common in thin patients with little body fat, or when treating the below knee GSV segment where the saphenous vein is not deep enough and in close contact with the saphenous nerve. Old laser generators with lower wave length (810nm) and bare-tipped laser fiber had more thermal damage than the new ones

with higher wave lengths (1320,1470nm) [6,7]. To lessen this damage, endothelium-specific laser wave length and instillation of cool saline (*Tumescent fluid*) around the treated vein are utilized. Also, adjusting the generators to lower Watts (10-12W) to generate Linear Endovenous Energy Density 60-90 J/cm instead of 90-120 J/cm. Post-procedure *limb bandaging and wearing elastic stocking* for few weeks is a must, it decreases post-operative swelling and ecchymosis. Moreover, it keeps the wall abutted together, leading to wall fibrosis without undue thrombosis. Thrombosis subsequently dissolute and could re-canalize later on.

Cyanoacrylate, its medical N-Butyl-2-Cyanoacrylate NBCA derivative was introduced for varicose veins treatment in 2011 and gained FDA approval in 2015 [8]. It exhibited comparable closure rates without generating high temperature that leads to in-wanted thermal damage to surrounding tissues with no need for tumescence or compression [8]. It relies on immediate polymerization and solidification once it gets in contact with negatively charged surfaces. It rapidly sticks and damages the vein wall. Transient manual compression to oppose vein wall together obliterating the lumen and enabling the glue to act, is needed only during the procedure. It has its peculiar tissue reaction that in some patients followed with self-limited allergic reaction, it is in the form of soreness and redness along the GSV few days following the intervention and usually goes away (spontaneously or with mild anti-inflammatory drugs) within 2-4 weeks [8,9].

Vein closure rates, which is the absence of antegrade or retrograde blood flow within the treated vein segment (the whole treated length or less than 5cm) with vein fibrosis and obliteration. In both modalities, the rates are higher than 90% after a year in most of the series [10].

Although both modalities are safe, some *rare grave adverse effect* could happen. Venous thrombosis or Cyanoacrylate migration can result in acute DVT, as well as Endovenous *Heat-Induced thrombosis* EHIT for EVLA and *Glue-Induced Thrombosis* EGIT for Cyano-Acrylate. Luckily, these complications are less than 1% and 5%, respectively [11]. Heat and glue induced thrombosis usually settle with anticoagulation, but less than 0.1% could lead to DVT or the need of thrombolysis or open thrombectomy [11]. We elected to give one dose of S.C Heparin as a premedication and to keep the EVLA or Cyano-acrylate catheter 5 cm away from the SFJ and to encourage the patient to walk early and to have follow up venous duplex U/S 48-72 hours after the procedure to check for induced thrombosis or DVT [12]. In rare instance, the patient could develop stroke, when the thrombus or the substance travels to the cerebral circulation through right to left heart shunt (Patent foramen ovale) [13,14].

Our results were comparable to the results of reciprocal equivalent studies and trials. We collected the data between *Jan. 2022 and March 2025*. Of the 120 patients with GSV reflux,

66 limbs in 60 patients had EVLA. *Ceralas E series, Bioletic medical* Laser apparatus with ELVeS radial 1470 nm laser fiber was used for EVLA and *VenaSeal, Medtronic* N-Butyl-2-Cyanoacrylate Catheter was used for CAC. The patients were followed for *12-month period*. They had follow up venous duplex 48/72 hrs, 6 months and 12months after the procedure. Our goal was to investigate *vein closure rate* and *DVT* incidence in both groups. *Vein closure rates* were *100% early*, 100% in CAC-patients and 97% in EVLA-patients in 6-month period and finally 96% in CAC-patients and 94% in EVLA-patients on conclusion of follow up period with no incidence of DVT in both groups. However, two patients developed Grade-II/I junctional Endovenous heat-induced EHIT and one patient had Endovenous glue-induced thrombosis EGIT (0.9%) detected during 48-72 hrs follow up duplex and resolved within a month with anticoagulation with no DVT or grave sequelae (stroke, myocardial infarction or death). We observed 18% saphenous neuropathy rate in EVLA-patients that could be attributed to below knee vein puncture or inadequate tumescence infiltrate.

Serpil Sahin, et al. found 96.9% and 92.6% vein closure rates in Cyano-acrylate and Laser treatment respectively, in a total of 200 adult patients between January 2018 and December 2021 and followed for 6 months after [15]. *Bozkurt et al.* found 12 months vein closure rates of 92.2% for laser ablation and 95.8% for cyanoacrylate ablation groups in 310 patients [16]. *Eroglu et al.* found vein closure rates after 6 months of 95.1% in Laser group and 98.1% in Cyanoacrylate group, in 250 patients [17].

Tural K. et al found 12-month GSV occlusion rate of 97.4% in 77 patients treated with CAC and followed for one year post-procedure [18]. Our results were matching the reciprocal studies.

Limitations: We need larger patient cohort and longer follow up to emphasize our results.

CONCLUSION

Both modalities were effective with no DVT, but Cyanoacrylate vein closure rates were better in 6-month period. All patients had smooth recovery and the minor complications were tolerable.

Cyanoacrylate showed better closure rates than EVLA, these rates were statistically insignificant, but the ecchymosis, neuropathy and pain rates were higher in Group-L. EVLA superseded Cyanoacrylate closure in freedom from allergic skin reaction (0% to 27%). Both modalities had no significant venous thrombosis that would harm the patients. In both groups, CEAP and VCSS were improved, CEAP from C2-3 to C0-1 and VCSS from 3-6 to 1-3

Ethics Committee Approval: We conducted our study according to our Scientific and Ethical committee approval (N-14-2025, of Kasr AlAiny School of Medicine, Cairo University) and complying with the terms of Helsinki Declaration.

Patient Consent for Publication: Not necessary for this manuscript.

Data Sharing Statement: The information in the present research are contained within this published paper.

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