

# Comparison Of The Safety And Efficacy Of Endovenous Laser Ablation Under Ultrasound Guided Regional Nerve Blocks With Cyanoacrylate Glue Ablation (Venaseal) In The Treatment Of Lower Limb Varicose Veins

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#### **ABSTRACT**

**Background:** In India, varicose veins often go untreated until complications develop. Treatment options include surgery and endovenous ablation techniques, which can be thermal or non-thermal. While Western guidelines usually favor thermal ablation, non-thermal methods, such as cyanoacrylate glue ablation (CGA, VenaSeal), provide alternatives without the discomfort of tumescent anaesthesia.

Aims and Objectives: This study compared Endovenous Laser Ablation (EVLA), under regional anaesthesia with VenaSeal for the treatment of lower limb varicose veins. The assessment looked at occlusion rates, pain levels during and after the procedure, changes in r-VCSS and AVVQ scores, complications, time to return to activities, and ulcer healing rates.

Materials and Methods: After obtaining ethical approval, the study was conducted from January 2024 to February 2025, with a six-month follow-up period. Out of 194 patients enrolled, 170 were included, with 85 in the EVLA group and 85 in the VenaSeal group. Medical histories, exams, and ultrasound evaluations were done, and baseline VCSS and AVVQ scores were noted. Pain was assessed during and after the procedures. Patients were checked one week, one month, three months, and six months after the procedure. Follow-ups evaluated occlusion rate, VCSS and AVVQ scores, ulcer size, complications, return to activities, and reflux.

Results and Observation: Both EVLA and VenaSeal achieved complete vein occlusion in all patients. VenaSeal showed lower AVVQ scores and rVCSS compared to EVLA. Ulcer healing rates were similar at six months. EVLA experienced more complications (27.1%), primarily bruising, while VenaSeal's main issue was phlebitis. Using regional anaesthesia during EVLA reduced periprocedural pain, but 62% of patients had severe motor block. There was no difference in post-procedure pain between the two interventions. Patients treated with VenaSeal returned to activities and work sooner than those treated with EVLA.

**Conclusion:** VenaSeal, a non-thermal technique, is more effective than EVLA with regional anaesthesia. It offers a better quality of life, fewer complications, and quicker recovery

**KEYWORDS**: Varicose veins, Endovenous laser ablation, Cyanoacrylate glue ablation, VenaSeal, Regional anaesthesia, Venous ulcer

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# **INTRODUCTION**

Chronic venous disorders (CVDs), including chronic venous insufficiency (CVI), are progressive conditions characterized by venous reflux and increased venous pressure. Varicose veins are dilated superficial veins (≥3 mm) associated with reflux and represent a common manifestation of CVD [1]. The prevalence of varicose veins ranges from 10–20% in Western populations and about 5% in India, with Indian cases showing a male predominance of 64–70% [2–5]. Risk factors include age, gender, genetic predisposition, obesity, pregnancy, thrombosis, and immobility, contributing to venous hypertension through dysregulated expression of matrix metalloproteinases [6-9]. Patients often present with heaviness, pain, fatigue, edema, pigmentation, eczema, lipodermatosclerosis, and ulcers. Assessment tools such as the Revised Venous Clinical Severity Score (rVCSS), and Aberdeen Varicose Vein Questionnaire (AVVQ) help quantify disease severity and impact on quality of life, respectively [10].

Management of CVD includes conservative approaches compression therapy, limb elevation, exercise, and venoactive medications like micronized purified flavonoid fraction (MPFF), ruscus extracts, calcium dobesilate, horse chestnut extract, hydroxyethylrutosides, red vine leaf extract and sulodexide [10] as well as interventional techniques. Endovenous thermal ablation (EVLA, RFA) is considered first-line treatment in Western guidelines [1,10,11], although it requires tumescent anaesthesia, which may cause discomfort due to multiple perivascular injections [12-13]. Ultrasound-guided regional nerve blocks offer an alternative approach to reduce procedural pain during EVLA [14-15].

Cyanoacrylate glue ablation (CGA), commercially available as VenaSeal, is a non-thermal, non-tumescent technique that achieves high closure rates (94–98%) with fewer complications and rapid return to activity [16-23]. However, drawbacks include higher cost, glue migration, and hypersensitivity reactions.

To our knowledge, no studies have directly compared EVLA with regional anaesthesia versus CGA, and studies comparing thermal and non-thermal ablations in cases involving anterior saphenous veins (ASV) and perforators are limited. This study aimed to compare the efficacy and safety of EVLA with ultrasound-guided nerve blocks against VenaSeal in managing lower-limb varicose veins, including ulcer outcomes, pain, complications, and quality-of-life scores.

# Aims and Objectives

The primary objectives of this study were to compare the occlusion rate and periprocedural and postprocedural pain, measured using the visual analog scale (VAS), between EVLA under ultrasound-guided nerve blocks and CGA (VenaSeal). Secondary objectives included comparing the rVCSS and AVVQ scores, assessing complications, evaluating return to activity and work, and analysing the ulcer healing rate between the interventions.

# MATERIALS AND METHODS

The Institutional Ethics Committee approved this study. Patients with CVD symptoms at the Interventional Radiology Outpatient Department of KLES Dr. Prabhakar Kore Hospital, Belagavi, who met the selection criteria were included.

Inclusion criteria:

- Age  $\geq$  18 years
- Superficial vein diameter ≤ 12 mm
- Reflux in superficial veins > 500 msec and perforators > 350 msec
- CEAP classification C2-C6

Exclusion criteria:

- $\bullet$  Peripheral arterial disease with an Ankle Brachial Index (ABI)  $\leq 0.8$
- Acute DVT
- Pregnancy/lactation
- Superficial thrombophlebitis
- · Sensitivity to cyanoacrylate
- Malignancy
- Sepsis
- Prior varicose vein intervention in the affected limb.

# **Study Design and Patient Allocation**

In this prospective interventional observational study, a total of 194 patients were screened; 170 patients meeting eligibility criteria were enrolled and allocated into two groups, based on their choices:

**Group 1**: EVLA under ultrasound-guided regional nerve blocks (n = 85)

**Group 2**: Cyanoacrylate glue ablation (VenaSeal) (n = 85)

Baseline evaluation included medical history, physical examination, CEAP staging, rVCSS, AVVQ scores, and duplex ultrasonography of the affected limbs. Ultrasound assessments were performed in standing positions using Mindray DC-60 Exp or Resona I9 with linear and curvilinear transducers to assess vein diameters, reflux patterns, and thrombosis.

#### **Procedures**

**VenaSeal Procedure**: Performed under local anaesthesia using a 7F radial sheath and cyanoacrylate catheter system. The catheter tip was positioned 5 cm distal to the saphenofemoral or saphenopopliteal junction. Applying proximal compression, two 0.10 ml adhesive injections were given at 5 and 6 cm distal to the junctions, followed by catheter retraction for 3 cm. After waiting for 3 minutes, adhesive (0.10 mL) was continously injected every 3 cm accompanied by proximal compression, with waiting period of 30 sec between injections. Perforator veins were treated with adhesive via an 18G cannula.

**EVLA Procedure**: Conducted with femoral and/or sciatic nerve blocks using 0.2% Ropivacaine (15 mL). Access was obtained with 6F radial sheath. A 1470 nm diode laser fibre (neoLaser) was inserted 3 cm distal to junctions. Tumescent anaesthesia (0.9 % normal saline, 2 % lignocaine and sodium bicarbonate) was infiltrated perivascularly. The laser fibre was retracted by 1 cm after each ablation. Power settings varied by segment. Perforators were treated using an 18G cannula and radial laser microfiber.

Periprocedural pain was recorded immediately on procedure completion and the post procedure pain next day using VAS (primary outcome). Motor block (in EVLA group) was graded as severe, moderate, or mild based on functional testing. Compression stockings (Class 2) were worn for 6 months in EVLA patients and for 1 month or until edema resolved for Venaseal patients. Patients were told to mobilize for two hours immediately after both procedures or after motor block resolution in EVLA patients.

### Follow-up and Outcome Measures

Patients were followed at 1 week, 1 month, 3 months, and 6 months. Evaluations included:

Primary outcomes: Vein occlusion (ultrasound)

Secondary outcomes: AVVQ, rVCSS, ulcer size, return to routine activities, return to work, complications, and recurrence

Ultrasound assessments evaluated vein patency, DVT, endovenous glue-induced thrombosis (EGIT), endothermal heat-induced thrombosis (EHIT), venous reflux, incompetent perforators, and varicosities.

#### **Statistical Analysis**

Data were analysed using Python 3.11.6 and Microsoft Excel.

Comparative statistics: Welch's t-test, Mann-Whitney U test, ANCOVA with adjusted mean difference

Effect size: Hedges' g, probability of superiority(PS)

Categorical comparisons: Fisher's exact test, Chi-square test

Significance was set at p < 0.05.

#### RESULTS

The mean age of the study population was  $47.04 \pm 13.35$  years (median 47 years). EVLA patients had a mean age of 45.69 years, while VenaSeal patients averaged 48.38 years. Participants were categorised into three age groups: 18-39 years (young), 40-59 years (middle-aged), and >59 years (elderly), with middle-aged individuals comprising 50% of the cohort [Figure 1(a)].

The overall mean BMI was  $27.95 \pm 5.58$  kg/m² (median 27.44 kg/m²). EVLA and VenaSeal groups had comparable mean BMIs of 27.85 and 28.04 kg/m², respectively. Based on WHO-Asian BMI criteria, 67.06% of participants were classified as obese ( $\geq 25$  kg/m²) [Figure 1(b)].

Out of 170 patients, 124 (72.94%) were male and 46 (27.06%) female [Figure 1(c)].

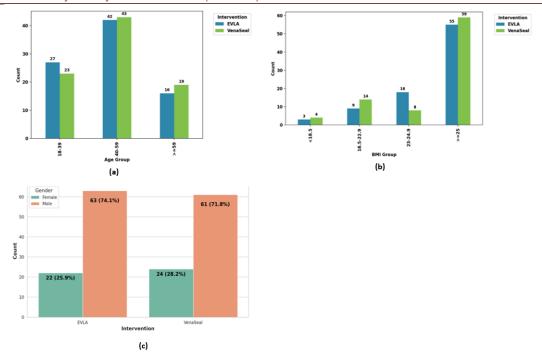


Figure 1: Bar charts showing (a) age group, (b) BMI group, and (c) gender distributions of the study population.

Healthcare workers, clerks, managers, shopkeepers, homemakers, engineers, police, army personnel, and drivers comprised 80% of the study population [Figure 2(a)]. VenaSeal was more commonly chosen by clerks, healthcare workers, and homemakers, while EVLA was preferred by managers and shopkeepers [Figure 2(b)].

Comorbidities were present in 31.2% of patients, with hypertension (64.2%) and diabetes (43.4%) being most common, followed by ischaemic heart disease and hypothyroidism (7.5% each). Two patients (3.8%) had a history of left lower-limb DVT [Figure 2(c)].

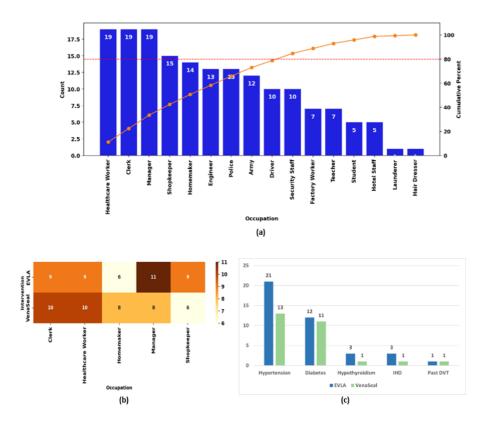


Figure 2: (a) Pareto chart showing the frequency of occupations (b) Heat map showing the distribution of interventions in the top five occupations (c) Bar Chart showing the distribution of interventions in the top five comorbidities.

Active ulcers were present in 33 patients (18.33%), with three having bilateral ulcers and two having multiple ulcers on one leg, totalling 38 ulcers. The medial distal leg was the most affected site (21 cases; 55.26%) [Figure 3(a)]. Security personnel and police accounted for the highest number of ulcer cases (five each; 30.3%) [Figure 3(b)]. Of these, 25 patients underwent EVLA and 8 received VenaSeal treatment.

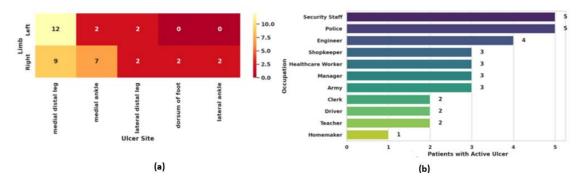


Figure 3: (a) Heat map showing distribution of sites of active ulcer. (b) Occupational distribution of active ulcer

All 85 EVLA patients received nerve blocks per protocol [Figure 4(a)]; all but one developed motor block, with 62% experiencing severe block resolving within 6–8 hours. Among 222 treated lower limbs, 117 (52.7%) underwent VenaSeal and 105 (47.3%) received EVLA. The right and left limbs were treated in 106 and 116 cases, respectively [Figure 4(b)].

In single-limb procedures, 65 patients underwent EVLA and 53 received VenaSeal. Among bilateral cases, 32 received VenaSeal and 20 underwent EVLA. Ablated veins included GSV (217), SSV (144), ASV (31), calf perforators (407), and thigh perforators (14) [Figure 4(c), (d)]. Most veins were ablated on the left side, except thigh perforators, which were predominantly on the right.

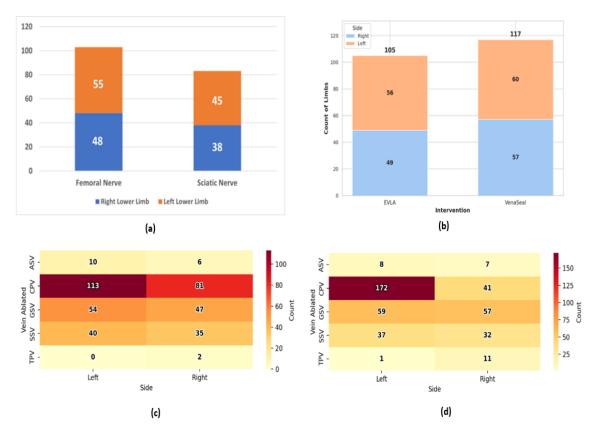


Figure 4: Stacked Bar charts showing (a) the types and frequency of nerve blocks in both limbs and (b) the distribution of treated lower limbs. (c) Heat map of veins ablated by EVLA. (d) Heat map of veins ablated by Venaseal.

Technical and anatomical success was 100% for both EVLA and VenaSeal, with complete vein occlusion maintained at six months. However, six patients who underwent bilateral GSV EVLA developed new reflux in both SSVs by three months, associated with incompetent calf perforators and varicosities. Additionally, two patients developed new calf varicosities due to emerging incompetent perforators during follow-up.

Table 1 summarises the mean AVVQ scores (single and bilateral limbs), mean rVCSS, and ulcer size at baseline, 1 week, 1 month, 3 months, and 6 months for both interventions.

Timepoint	Baseline	One Week	One Month	Three Months	Six Months
AVVQ EVLA (single limb)	39.06	44.05	28.44	17.37	10.91
AVVQ VenaSeal (single limb)	35.92	39.25	27.17	12.85	5.67
AVVQ EVLA (both limbs)	43.23	53.19	36.73	28.03	26.85
AVVQ VenaSeal (both limbs)	42.66	44.44	29	10.19	5.79
rVCSS EVLA	10.53	12.23	10.24	7.23	5.2
rVCSS VenaSeal	9.72	10.38	9.28	4.05	0.89
Ulcer Size (cm) EVLA	3.42	2.78	1.44	0.26	0.04
Ulcer Size (cm) VenaSeal	3.71	3.13	1.49	0	0

Table 1: Mean AVVQ (single and both treated lower limbs), mean rVCSS, and mean ulcer size for both interventions at baseline, one week, one month, three months, and six months follow-ups.

In patients treated for a single lower limb, both EVLA and VenaSeal showed increased AVVQ scores at one week, with no significant difference. By one month, scores declined in both groups without substantial variation. At three months, VenaSeal showed greater improvement, though not statistically significant. However, by six months, VenaSeal demonstrated a significant advantage (Welch's *t*-test p = 0.021; Mann–Whitney Up = 0.022; ANCOVA p = 0.021), with an effect size of  $g \approx -0.39$  and an adjusted mean difference of -5.5 AVVQ points, suggesting clinical benefit [Figure 5(a)].

In **bilateral treated lower limbs**, EVLA showed a significant increase in AVVQ at one week, while VenaSeal showed minimal change. At one month, both groups improved, with a greater reduction in VenaSeal (Welch's t-test p = 0.015; U = 0.021; ANCOVA p = 0.00011; g = 0.88; mean difference  $\approx 7.5$  points). By three months, differences were more pronounced (Welch's t-test p = 4.6e-05; U = 2.2e-05; ANCOVA p < 1e-9; g = 1.53; mean difference  $\approx 17.74$ ). This significant improvement with VenaSeal persisted at six months (p = 1.1e-04 across tests; g = 1.50; mean difference  $\approx 21$  points) [Figure 5(b)].

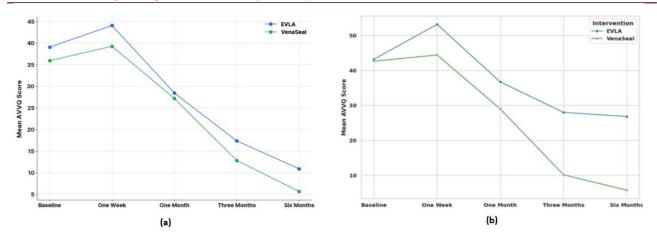


Figure 5: Linear plots of mean AVVQ scores at baseline and subsequent follow-ups for (a) single and (b) both lower limb treated patients

**rVCSS Comparison:** At one week post-procedure, EVLA patients had significantly higher mean rVCSS than those treated with VenaSeal (p < 0.001; g = 0.73; PS = 0.72; adjusted mean difference = 0.9 points). By one month, both groups showed similar rVCSS reductions, with no significant difference. At three months, a statistically significant difference emerged in favour of VenaSeal (Welch's *t*-test p = 0.003; U test and ANCOVA p < 0.001; g = 0.47; PS = 0.66; adjusted mean difference = 2.2 points higher for EVLA). This persisted at six months (p < 0.001; g = 0.93; PS = 0.74; adjusted difference = 3.3 points), indicating a sustained clinical benefit with VenaSeal [Figure 6(a)].

**Ulcer Healing Comparison:** Initially, ulcers in the VenaSeal group were slightly larger, though this was not statistically significant. At one week, EVLA showed a marginal, non-significant advantage. One-month healing rates were similar. By three months, VenaSeal achieved earlier complete healing, with significance in Welch's t-test (p = 0.005; g = +0.68), though borderline in U test (p = 0.057) and ANCOVA (p = 0.060). At six months, both groups showed full healing, with no significant difference after adjusting for age, BMI, limb involvement, and comorbidities. The ulcer subgroup included 25 EVLA and 8 VenaSeal patients [Figure 6(b)].

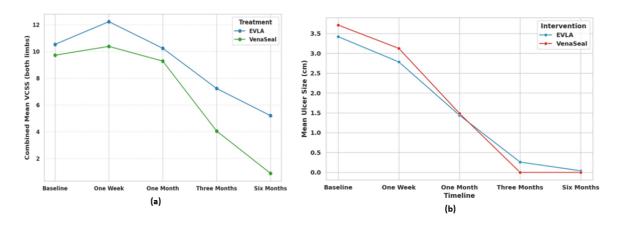


Figure 6: Linear plots of (a) mean rVCSS and (b) mean active ulcer size at baseline and subsequent follow-ups for both interventions

Postprocedural complications occurred in 34 patients (20%), with 23 (63.65%) following EVLA. Bruising was the most common EVLA-related issue (56.52%), while phlebitis was most frequent with VenaSeal (33.33%) [Figure [7]. The overall complication rate was significantly higher with EVLA (27.1%) compared to VenaSeal (12.9%) ( $p \approx 0.034$ , Fisher's exact test;  $p \approx 0.021$ , Chi-Square test). EVLA carried a 2.09 times higher risk of complications than VenaSeal.

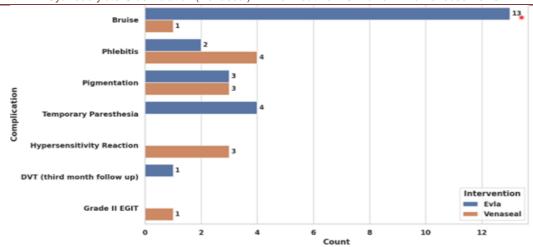


Figure 7: Horizontal bar chart showing complications in both interventions, with a red asterisk indicating the overall most common complication in the study population.

The mean **periprocedural pain score** (VAS) was significantly lower for EVLA  $(0.86 \pm 0.84)$  compared to VenaSeal  $(2.83 \pm 0.51)$ . Median [IQR] scores were 1 [0.00-1.00] for EVLA and 3.00 [2.50-3.00] for VenaSeal. This difference was statistically significant (p < 0.0001), Welch's *t*-test and Mann–Whitney U test), with EVLA patients reporting pain levels 2 points lower. [Figure 8 (a)]

**Postprocedural pain scores** were similar for both groups (median = 4). VenaSeal had a mean of 4.72 and EVLA 4.46. While Welch's t-test showed significance (p = 0.22), the Mann–Whitney U test did not (p = 0.06), indicating a minor, clinically insignificant difference in distribution.

**Return to routine activities** was faster with VenaSeal (mean  $1.31 \pm 0.51$  days; median 1.0 [1.0-2.0]) versus EVLA (mean  $2.07 \pm 1.17$  days; median 2.0 [1.0-3.0]). The difference was statistically significant (p < 0.000001), with VenaSeal patients resuming activities 0.76 days earlier (95% CI: 0.49-1.04) [Figure 8(b)].

**Return to work** was also earlier in the VenaSeal group (mean 3.49 days; median 3; range 2–4) compared to EVLA (mean 6.65 days; median 6; range 4–8). The difference was significant in both tests (p < 0.000001), with VenaSeal patients returning to work approximately 3 days earlier [Figure 8(c)].

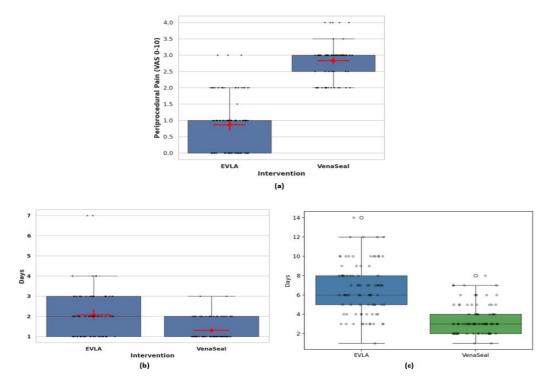


Figure 8: Box and whisker plots of (a) periprocedural pain, (b) return to routine activity, and (c) work for EVLA and VenaSeal patients.

# **DISCUSSION**

This prospective study compared the safety, efficacy, and recovery outcomes of CGA (VenaSeal) and EVLA under ultrasound-guided regional anaesthesia for treating lower-limb varicose veins. The majority of patients were obese males aged 40–59 years. Obesity raises venous pressure and inflammation, contributing to the development of varicose veins. [24]. The 72.94% prevalence in males matches Indian studies, which show a range of 64-70% in males [4,5]. Age group 40-59 represents a working population where early intervention improves productivity and quality of life. [25] Occupational patterns, especially prolonged standing and sitting, were key contributors to disease progression, reflecting well-established risk factors. [3]

In our study, 31.2% of the patients had comorbidities. Hypertension often accompanies venous insufficiency and influences ulcer healing through inflammation and endothelial dysfunction [26,27]. Diabetes affects vascular health through microangiopathy and inflammation, increasing the risk of ulcer infections [28]. Ischemic heart disease shares risk factors with varicose veins, with advanced CEAP stages being associated with cardiovascular disease [29]. Two patients with a history of left lower limb DVT had procedures after confirming resolution. These cases require care from multiple specialties.

Both EVLA and VenaSeal achieved 100% occlusion rate at six months, with successful closure of great saphenous, small saphenous, and incompetent perforator veins. These results are consistent with the literature, which reports short- to mid-term closure rates of 94–100% for both EVLA and CGA [16,20,21,23,30]. Although EVLA may offer greater long-term durability, our data support the clinical equivalence of CGA for short-term treatment success, including in less commonly studied segments such as the ASV and calf perforators [31-33]. However, the occurrence of new reflux in some patients emphasises the progressive nature of venous disease and the importance of ongoing monitoring.

rVCSS and AVVQ scores improved significantly in both groups, with greater reduction in rVCSS and AVVQ scores (bilateral limb) for VenaSeal group at 3 and 6 months. For AVVQ (single limb) there was significant reduction for VenaSeal group at 6 months. Studies confirm that both treatments improve disease severity and quality of life scores [16-18,20,21,23,34]. Ay et al. reported better improvement in CIVIQ-14 scores and VCSS with radiofrequency ablation than cyanoacrylate embolization [35]. Calik et al. noted significant reductions in VCSS & CIVIQ scores, with no differences between CGA and EVLA [36]. Eroglu et al. reported less pain, and lower VCSS scores for CGA as compared to RFA and EVLA [37]. The initial increase in rVCSS and AVVQ scores likely came from the addition of stockings. Literature review found no sources on the different responses of the single and both treated lower limbs in AVVQ score improvement. This study is the first to compare AVVQ scores between VenaSeal and EVLA, showing a significant reduction in the VenaSeal group.

VenaSeal enabled earlier ulcer healing at three months compared to EVLA, although both groups achieved complete healing by six months. These results are consistent with findings by O'Banion et al., who demonstrated significantly faster healing with VenaSeal than RFA (43 vs. 104 days; p = 0.001) [38]. Kiguchi et al. noted that VenaSeal allows for longer treatment lengths, which may affect perforator vein treatment and may further enhance ulcer healing in complex CVD cases [36]. While the ulcer cohort in our study was small and unevenly distributed, these findings support the clinical relevance of CGA in ulcer management. (Figure 9)



EVLA was associated with a higher complication rate (27.1%) primarily bruising and paraesthesia while VenaSeal showed fewer complications (12.9%), with phlebitis and hypersensitivity reactions being most common, which corroborated with the previous studies. One patient developed EGIT Grade II after VenaSeal, and another developed DVT after EVLA. These events are well documented in prior literature, with DVT rates in EVLA ranging from 0.3% to 3% and EGIT risk influenced by technique, glue volume, and vein anatomy [17,19,30,37,40,42,43]. (Figure 10) Chronic inflammation or granulomatous reactions to cyanoacrylate have been described in rare cases showing up later [41].

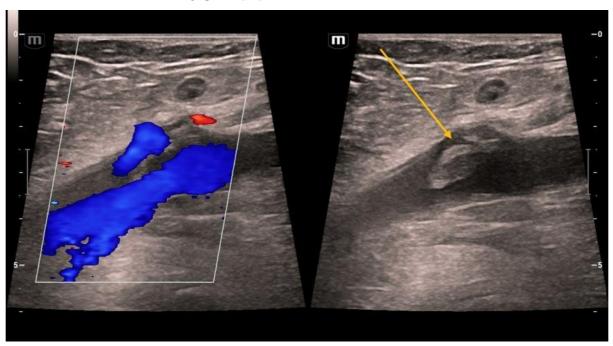


Figure 10: EGIT Grade II with glue cast extending into the common femoral vein

Periprocedural pain was significantly lower with EVLA due to the use of ultrasound-guided regional anaesthesia with 0.2% ropivacaine. However, severe motor block occurred in 62% of EVLA patients, delaying early ambulation. Literature suggests that femoral and sciatic nerve blocks with ropivacaine may cause 6–12 hours of motor impairment [44,45]. In contrast, VenaSeal allowed immediate mobilisation, avoiding the discomfort of tumescent anaesthesia and thermal injury [37,46].

Postprocedural pain scores at 24 hours were comparable in both groups. Although CGA is generally associated with lower pain levels, this convergence may be due to inflammatory responses common to both treatments. Pain levels measured the next day may be similar once the effects of anaesthesia wear off in EVLA patients. This finding contrasts with some prior studies and highlights the need for further evaluation of postprocedural pain dynamics.

Patients treated with VenaSeal returned to routine activities and work significantly earlier than those treated with EVLA. This is attributable to the elimination of tumescent anaesthesia, reduced bruising, and fewer complications. Eroglu et al. also observed quicker recovery and earlier return to work with CGA compared to both EVLA and RFA [37]. In our cohort, EVLA recovery was further delayed due to motor impairment from regional anaesthesia, even though it reduced intraprocedural pain effectively.

**Limitations** The study had several limitations. The six-month follow-up limits conclusions on long-term durability and recurrence. The unequal distribution of ulcer cases (25 EVLA vs 8 VenaSeal) may have affected the ulcer healing comparison. The cost of VenaSeal and variability in compression stockings usage could have influenced patient selection. Finally, limited sample size having 85 patients in each intervention and the single-centre setting may limit generalisability to broader populations.

# **CONCLUSION**

Varicose veins in India often present late, increasing chronic venous disease (CVD) burden. Surgical options are declining due to prolonged recovery and complications. This study compared EVLA under regional anaesthesia and CGA (VenaSeal). Both methods achieved complete vein occlusion. VenaSeal demonstrated superior improvement in AVVQ and rVCSS scores, fewer complications, and quicker return to activity. Ulcer healing was slightly faster for VenaSeal but not statistically significant. EVLA had more complications. Regional blocks reduced EVLA pain but caused motor block. VenaSeal offers better efficacy, safety, and recovery, pending large scale trials with long-term confirmation

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