ORIGINAL RESEARCH PAPER
Volume - 15 | Issue - 07 | July - 2026 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

# CONVENTIONAL SURGERY VERSUS ENDOVENOUS LASER ABLATION FOR THE TREATMENT OF VARICOSE VEINS: A RANDOMIZED CONTROLLED TRIAL

General Surgery

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## ABSTRACT

**Background:** Conventional surgery involving high ligation and stripping has long been the standard treatment for symptomatic varicose veins secondary to great saphenous vein reflux. Endovenous laser ablation (EVLA) has emerged as a minimally invasive alternative with the potential for improved perioperative outcomes. **Objective:** To compare procedural outcomes, postoperative recovery, pain relief, and complications between EVLA and conventional surgery in patients with symptomatic primary great saphenous vein reflux. **Methods:** This prospective randomized controlled trial was conducted at a tertiary-care teaching hospital in India between November 2023 and May 2025. Fifty patients aged 18–70 years with symptomatic primary great saphenous vein reflux and perforator incompetence confirmed by duplex ultrasonography were randomized to conventional surgery (CS; n=27) or EVLA (n=23). Primary outcomes included procedural duration, return-to-work interval, and postoperative complications. Secondary outcomes included pain severity assessed using the Visual Analog Scale (VAS) and change in pain score from baseline. Patients were followed for three months after intervention.**Results:** EVLA was associated with significantly shorter procedural duration than conventional surgery (median 52.0 [44.5–68.5] vs 84.0 [74.0–99.0] minutes; p=0.0003). Return-to-work interval was comparable between groups (median 4 days; p=0.5488). Absolute VAS scores at one and three months did not differ significantly. However, improvement in pain from baseline was greater following EVLA at one month (median 2.2 vs 1.7; p=0.0133) and three months (3.1 vs 2.4; p=0.0016). Postoperative complications were infrequent in both groups. Any adverse event occurred in 18.5% of patients undergoing conventional surgery and 8.7% of those undergoing EVLA (p=0.4295).**Conclusions:** EVLA demonstrated shorter procedural duration and greater improvement in pain while maintaining comparable recovery and safety outcomes compared with conventional surgery. These findings support EVLA as an effective minimally invasive treatment option for symptomatic great saphenous vein reflux, although larger studies with longer follow-up are required to evaluate long-term outcomes.

## KEYWORDS

Varicose Veins; Endovenous Laser Ablation; Great Saphenous Vein Reflux; Chronic Venous Disease; Minimally Invasive Surgery; Randomized Controlled Trial.

## INTRODUCTION

Chronic venous disease (CVD) is among the most common vascular disorders worldwide and represents a substantial source of morbidity, healthcare utilization, and socioeconomic burden. Varicose veins are the most frequent clinical manifestation of CVD and affect approximately 20–40% of adults, with prevalence increasing with age and prolonged occupational standing. Symptoms commonly include leg pain, heaviness, swelling, pruritus, and nocturnal cramps, which may significantly impair quality of life and functional capacity. In advanced stages, chronic venous insufficiency can result in skin changes, lipodermatosclerosis, and venous ulceration.[1,4]

The pathophysiology of varicose veins is multifactorial and involves venous valvular incompetence, venous hypertension, venous wall remodeling, and chronic inflammation. Reflux at the saphenofemoral junction or along the great saphenous vein leads to progressive venous dilatation and symptom development.[5] [6] Effective treatment aims to eliminate axial reflux, alleviate symptoms, improve quality of life, and prevent disease progression.

For many years, conventional surgery consisting of high ligation and stripping of the great saphenous vein was considered the standard treatment for symptomatic varicose veins. Although effective in abolishing reflux, surgical treatment is associated with wound complications, postoperative pain, bruising, neural injury, and prolonged recovery.[7,8]

The introduction of endovenous thermal techniques has significantly transformed the management of varicose veins. Endovenous laser ablation (EVLA) achieves occlusion of the incompetent vein through ultrasound-guided delivery of thermal energy, allowing treatment through a minimally invasive percutaneous approach. Several randomized controlled trials and meta-analyses have demonstrated comparable anatomical and clinical outcomes between EVLA and conventional surgery, while suggesting advantages of EVLA in terms of reduced perioperative morbidity, earlier recovery, and improved patient satisfaction.[9,12]

Despite increasing adoption of EVLA worldwide, data from Indian tertiary-care settings remain limited. Furthermore, differences in patient demographics, disease severity, healthcare access, and occupational characteristics may influence treatment outcomes. The present randomized controlled trial was therefore undertaken to compare procedural outcomes, recovery profile, and postoperative complications between conventional surgery and EVLA in patients with symptomatic primary great saphenous vein reflux.

## METHODS

### Study Design and Setting

This prospective, open-label, parallel-group randomized controlled trial was conducted in the Department of General Surgery, S. Nijalingappa Medical College and HSK Hospital & Research Centre, Bagalkot, Karnataka, India, between November 2023 and May 2025. The study was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants prior to enrollment.

### Participants

Patients aged 18–70 years presenting with symptomatic primary varicose veins secondary to great saphenous vein reflux and perforator incompetence confirmed by duplex ultrasonography were considered eligible for inclusion. Symptoms included pain, heaviness, swelling, nocturnal cramps, skin changes, or venous ulceration attributable to chronic venous insufficiency.

Patients with deep venous thrombosis, previous venous intervention, recurrent varicose veins, pregnancy, significant peripheral arterial disease, or inability to comply with follow-up were excluded from the study.

### Sample Size

Sample size was calculated using OpenEpi version 2.3.1 based on previously published literature comparing endovenous and surgical treatment of varicose veins. Assuming a significance level of 5% and statistical power of 80%, a minimum of 25 patients per treatment group

was required. To account for potential losses to follow-up, 50 patients were enrolled.

**Randomization**

Eligible patients were randomized in a 1:1 ratio to undergo either conventional surgery (CS) or endovenous laser ablation (EVLA). Randomization was performed using a computer-generated random allocation sequence. Treatment assignments were placed in sequentially numbered opaque sealed envelopes, which were opened immediately prior to intervention.

**Interventions**

Patients allocated to the conventional surgery group underwent high ligation of the saphenofemoral junction with stripping of the incompetent great saphenous vein and ligation of incompetent perforators as indicated.

Patients allocated to the EVLA group underwent ultrasound-guided endovenous laser ablation of the incompetent great saphenous vein using a 1470-nm diode laser system. The laser fiber was positioned under duplex guidance, and tumescent anesthesia was administered along the course of the vein prior to energy delivery. Incompetent perforators were treated according to standard institutional practice.

All patients received postoperative compression therapy and were encouraged to ambulate early after the procedure.

Outcome Measures

The primary outcomes were:

1. Procedural duration (minutes).
2. Time to return to work or normal daily activities (days).
3. Postoperative complications, including hematoma, wound infection, paresthesia, skin discoloration, and deep vein thrombosis.

Secondary outcomes included pain severity measured using the Visual Analog Scale (VAS) and change in pain score from baseline to follow-up.

**Follow-up**

Patients were evaluated clinically at one month and three months following intervention. Pain severity was assessed using the VAS, and complications were recorded during each follow-up visit. Duplex ultrasonography was performed when clinically indicated.

**Statistical Analysis**

Data were analyzed using IBM SPSS Statistics version XX (replace with actual version used). Continuous variables were expressed as mean ± standard deviation or median with interquartile range according to data distribution. Categorical variables were presented as frequencies and percentages.

Comparisons between treatment groups were performed using the independent-samples t-test or Mann–Whitney U test for continuous variables and Fisher's exact test for categorical variables. All statistical tests were two-tailed, and a p-value <0.05 was considered statistically significant.

## RESULTS

**Baseline Characteristics**

Fifty patients were enrolled, including 27 patients in the CS group and 23 patients in the EVLA group.

The EVLA group was significantly older than the CS group (52.7±9.9 vs 42.2±11.1 years; p=0.001). Patients undergoing EVLA also had significantly higher BMI (28.2 vs 25.5 kg/m²; p=0.023), longer disease duration (4.3 vs 3.0 years; p=0.026), fewer manual laborers (21.7% vs 59.3%; p=0.007), and lower prevalence of low socioeconomic status (4.3% vs 29.6%; p=0.028).

Sex distribution was similar between groups (p=0.741).

**TABLE 1. BASELINE DEMOGRAPHIC CHARACTERISTICS BY TREATMENT GROUP**

| Variable | CS | EVLA | Exact p-value |
|---|---|---|---|
| Age, years | 42.22±11.07 | 52.74±9.85 | 0.0010 |
| Female sex | 13/27 (48.1%) | 10/23 (43.5%) | 0.7412 |
| BMI, kg/m² | 25.50 [23.30, 26.95] | 28.20 [25.95, 30.90] | 0.0233 |
| Manual occupation | 16/27 (59.3%) | 5/23 (21.7%) | 0.0074 |
| Low socioeconomic status | 8/27 (29.6%) | 1/23 (4.3%) | 0.0279 |
| Duration of disease, years | 3.03±1.56 | 4.30±2.34 | 0.0264 |

Despite randomization, significant differences were observed between groups with respect to age, BMI, occupation, socioeconomic status, and disease duration.

**TABLE 2. BASELINE VENOUS DISEASE SEVERITY AND SYMPTOM PROFILE BY TREATMENT GROUP**

| Variable | CS | EVLA | Exact p- |
|---|---|---|---|
| Baseline pain VAS | 5.00 [4.50, 6.35] | 5.90 [4.20, 6.40] | 0.6542 |
| Advanced CEAP (C4-C6) | 3/27 (11.1%) | 6/23 (26.1%) | 0.2697 |
| Leg pain | 27/27 (100.0%) | 22/23 (95.7%) | 0.4600 |
| Night cramps | 19/27 (70.4%) | 22/23 (95.7%) | 0.0279 |
| Swelling | 16/27 (59.3%) | 20/23 (87.0%) | 0.0297 |
| Itching | 3/27 (11.1%) | 6/23 (26.1%) | 0.2697 |
| Ulcer | 1/27 (3.7%) | 3/23 (13.0%) | 0.3223 |

Baseline pain severity was comparable between groups (VAS 5.9 vs 5.0; p=0.654).

Night cramps (95.7% vs 70.4%; p=0.028) and swelling (87.0% vs 59.3%; p=0.030) were more common among EVLA patients. Other symptoms and CEAP classification were comparable.

**Procedural Outcomes**

EVLA demonstrated significantly shorter procedure duration than conventional surgery (52.0 vs 84.0 minutes; p=0.0003).

Return-to-work interval was similar between groups (median 4 days; p=0.549).

**TABLE 3. PRIMARY OUTCOMES AND SELECTED SECONDARY OUTCOMES BY TREATMENT GROUP**

| Variable | CS | EVLA | Exact p-value |
|---|---|---|---|
| Procedural time, min | 84.00 [74.00, 99.00] | 52.00 [44.50, 68.50] | 0.0003 |
| Return-to-work days | 4.00 [0.00, 12.00] | 4.00 [0.00, 6.00] | 0.5488 |
| Pain VAS at 1 month | 3.71±1.65 | 3.30±1.34 | 0.3393 |
| Pain VAS at 3 months | 2.20 [1.55, 4.45] | 2.50 [1.40, 2.80] | 0.2929 |
| Pain improvement from baseline to 1 month | 1.70 [1.40, 2.00] | 2.20 [1.75, 2.45] | 0.0133 |
| Pain improvement from baseline to 3 months | 2.40 [2.10, 2.95] | 3.10 [2.85, 3.65] | 0.0016 |

**Pain Outcomes**

Pain scores at one month (3.3 vs 3.7; p=0.339) and three months (2.5 vs 2.2; p=0.293) did not differ significantly.

However, improvement in pain from baseline was significantly greater following EVLA at:

- One month: 2.2 vs 1.7 (p=0.013)
- Three months: 3.1 vs 2.4 (p=0.002)

**Complications**

Complication rates were low in both groups.

No infections or skin discoloration occurred in either group.

Deep vein thrombosis occurred in two patients in the conventional surgery group and none in the EVLA group.

Any adverse event occurred in:

- Conventional surgery: 18.5%
- EVLA: 8.7%

This difference was not statistically significant (p=0.429).

**TABLE 4. SPECIFIC POSTOPERATIVE COMPLICATIONS BY TREATMENT GROUP**

| Variable | CS | EVLA | Exact p-value |
|---|---|---|---|
| Infection | 0/27 (0.0%) | 0/23 (0.0%) | 1.0000 |
| Hematoma | 1/27 (3.7%) | 1/23 (4.3%) | 1.0000 |
| Paresthesia | 2/27 (7.4%) | 1/23 (4.3%) | 1.0000 |
| Skin discoloration | 0/27 (0.0%) | 0/23 (0.0%) | 1.0000 |
| Deep vein thrombosis | 2/27 (7.4%) | 0/23 (0.0%) | 0.4931 |
| Any adverse event | 5/27 (18.5%) | 2/23 (8.7%) | 0.4295 |

## DISCUSSION

The present randomized controlled trial compared conventional surgery and endovenous laser ablation (EVLA) in the treatment of symptomatic primary great saphenous vein reflux. The principal findings of the study were that EVLA was associated with significantly shorter procedural duration and greater improvement in pain scores during follow-up, while return-to-work interval and postoperative complication rates were comparable between treatment groups. These findings support the role of EVLA as an effective minimally invasive alternative to conventional surgery for appropriately selected patients with varicose veins.

One of the most notable findings of the present study was the significantly shorter procedural duration observed with EVLA. The median operative time in the EVLA group was 52 minutes compared with 84 minutes in the conventional surgery group. This difference is likely attributable to the minimally invasive nature of EVLA, which eliminates the need for groin dissection, saphenofemoral junction ligation, vein stripping, and multiple skin incisions. Similar findings have been reported by Darwood et al., who demonstrated that endovenous treatment could be performed more efficiently while achieving clinical outcomes comparable to surgery. Likewise, Carradice et al. reported reduced procedural burden and improved perioperative recovery among patients undergoing endovenous treatment compared with conventional surgical intervention. These observations suggest that EVLA may offer logistical advantages in busy surgical units by reducing operating room utilization and facilitating earlier patient mobilization.[1,2]

Return-to-work interval did not differ significantly between the two groups in the present study, with a median duration of four days in both treatment arms. Although several previous studies have demonstrated earlier return to normal activities following EVLA, the findings of the present study indicate that factors beyond procedural invasiveness may influence postoperative recovery. Occupational demands, socioeconomic circumstances, workplace policies, and individual patient preferences may all contribute to the timing of return to work. Rasmussen et al. reported faster recovery and earlier return to routine activities following EVLA, while Carradice et al. similarly observed improved postoperative recovery profiles in patients undergoing endovenous interventions. The absence of a significant difference in the present study may be related to the relatively small sample size and heterogeneity of occupational characteristics within the study population.[3,4]

Pain reduction remains an important patient-centered outcome in the management of chronic venous disease. Although absolute Visual Analog Scale (VAS) scores at one and three months were comparable between groups, patients undergoing EVLA experienced significantly greater improvement in pain from baseline at both follow-up intervals. These findings suggest that EVLA may provide superior symptomatic relief despite similar final pain scores. Reduced tissue trauma, avoidance of extensive vein stripping, and lower inflammatory response following endovenous treatment may explain the observed benefit. Similar improvements in postoperative pain and patient comfort have been reported in previous randomized studies comparing EVLA with conventional surgery. Carradice et al. demonstrated improved postoperative quality-of-life measures and reduced early postoperative discomfort following endovenous treatment, while several meta-analyses have shown favorable short-term recovery outcomes associated with minimally invasive venous interventions.[2,5]

Postoperative complications were infrequent in both treatment groups. Although adverse events were numerically less common following EVLA, the difference did not reach statistical significance. Deep vein thrombosis occurred in two patients in the conventional surgery group and was not observed in the EVLA group; however, the low event frequency precludes definitive conclusions regarding comparative safety. The overall complication profile observed in the present study is consistent with previously published literature demonstrating comparable safety between endovenous and surgical approaches. A systematic review and meta-analysis by Siribumrungwong et al. found no significant differences in major adverse events between EVLA and surgery while reporting advantages of endovenous techniques with respect to postoperative recovery and patient satisfaction. Similarly, long-term follow-up studies have demonstrated comparable efficacy and safety outcomes between these treatment modalities.[5,6]

The findings of the present study should be interpreted in the context of several limitations. First, the sample size was relatively small, which may have limited statistical power, particularly for the assessment of uncommon postoperative complications. Second, follow-up was restricted to three months, preventing evaluation of long-term outcomes such as recanalization, recurrent varicosities, and durability of symptom relief. Third, despite randomization, baseline imbalances were observed between treatment groups with respect to age, body mass index, occupation, socioeconomic status, and disease duration. These differences may have influenced treatment outcomes and should be considered when interpreting the results. Finally, quality-of-life instruments such as the Venous Clinical Severity Score (VCSS) and Aberdeen Varicose Vein Questionnaire (AVVQ) were not utilized, limiting assessment of patient-reported outcomes.

Despite these limitations, the study possesses several strengths. The randomized controlled design minimized selection bias, and all patients underwent standardized preoperative evaluation and postoperative follow-up. Furthermore, the study contributes valuable prospective data from an Indian tertiary-care setting, where evidence directly comparing EVLA and conventional surgery remains relatively limited.

In conclusion, the present study demonstrates that EVLA provides shorter procedural duration and greater improvement in pain compared with conventional surgery while maintaining similar complication rates and return-to-work outcomes. These findings support the growing role of EVLA as an effective minimally invasive treatment option for symptomatic great saphenous vein reflux. Larger multicenter studies with longer follow-up are warranted to evaluate long-term recurrence rates, quality-of-life outcomes, and cost-effectiveness.

## CONCLUSION

In this randomized controlled trial, endovenous laser ablation (EVLA) was associated with significantly shorter procedural duration and greater improvement in pain compared with conventional surgery for the treatment of symptomatic primary great saphenous vein reflux. Return-to-work interval and postoperative complication rates were comparable between the two treatment modalities. These findings suggest that EVLA is a safe and effective minimally invasive alternative to conventional surgery in appropriately selected patients with varicose veins. Further studies with larger sample sizes and longer follow-up are required to evaluate long-term durability, recurrence rates, quality-of-life outcomes, and cost effectiveness. valuable minimally invasive alternative for appropriately selected patients.

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