Original Article

Role of Endovenous Laser Therapy in Management of Chronic Venous Ulcers. Running title: Endovenous Laser Therapy for Chronic Venous Ulcers

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Abstract

Background: Chronic venous ulcers represent the major issue of morbidity in the world, and recurrence rates of ulcers remain high under compression treatment. Endovenous laser therapy (EVLT) has emerged as a less invasive approach to treating venous reflux, and it is superior to conventional surgery. However, there is a lack of data on tertiary-care centres in India. **Material and Methods:** Our study was conducted at a tertiary-care hospital in India from January 2023 to June 2024 as a retrospective observational study. The number of patients was 70. The medical records of patients with chronic venous ulcers treated with EVLT were reviewed. Demographic data, CEAP categorisation, ulcer size, healing period, recurrence rate, complications, and adherence to compression data were examined. The main outcome was the time to ulcer healing; recurrence and complications were secondary outcomes. **Results:** Of course, the healing period for the ulcer was six weeks. Sixty per cent of patients were cured completely, and ten per cent relapsed—90 per cent at three months. The complications were mild, including pain, superficial infection, and thrombophlebitis. The best predictor of slow healing was the ulcer size; the age was of little significance, and the CEAP classification had little effect. Patients who had excellent compliance with compression therapy had lower recurrence rates. **Conclusion:** EVLT is a safe and effective modality in managing chronic venous ulcers in Indian tertiary care hospitals, with prompt healing, reduced recurrence and few complications. The size of UL and the compliance related to compression have a strong impact. The use of EVLT and adjunct compression at an early stage can optimise the use of ulcer in the resource-constrained setting.

Keywords: Endovenous Laser Therapy, Chronic Venous Ulcer, Varicose Veins, Venous Insufficiency, Compression Therapy, Minimally Invasive Surgery.

Received: 18 December 2025 **Revised: 01 January 2026** **Accepted: 19 January 2026** **Published: 31 January 2026**

Introduction

Ambulatory venous HTA causes chronic VU due to weakness in the valves of the superficial, perforator, and deep veins, leading to breakdown of the skin, tissue oedema, and capillary fissures. Staging of chronic venous disease is standardised using the CEAP (Clinical-Etiologic-Anatomic-Pathophysiologic) classification, which guides decision-making for its management.[1] Venous leg ulcers impact 1 -2 per cent of adults worldwide, and global morbidity and healthcare costs are high. The recurrence rate of various venous leg ulcers is greater than 70 per cent after five years, despite high compression therapy. Prevalence estimates vary between 0.5% and 1 percent in India, with the elderly and socioeconomically disadvantaged having disproportionate amounts of performance and with a significant burden to tertiary care resources. The use of traditional methods of surgery, including high ligation and stripping of the great saphenous vein (GSV), has been associated with wound complications, postoperative pain, and a lengthy recovery period. There is a lengthy gap in minimally invasive, yet effective interventions.

Endovenous laser therapy (EVLT) is the indisputable, ultrasound-guided thermal ablation of refluxing superficial veins, restoring normal hemodynamics with minimal tissue trauma. Multimodal approaches to EVLT and foam sclerotherapy with compression have demonstrated improved outcomes in ulcer healing.[2-5] EVLT shows satisfactory results for distal ulcers below the knee. Enough post-ablation compression is necessary to ensure vein closure and the most effective resolution of ulcers.[2] The comparative studies show a quicker recovery phase, reduced postoperative pain, and improved quality of life with EVLT compared to conventional surgeries.[3,4] Not much data is

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DOI:
10.21276/amit.2026.v13.i1.321

How to cite this article: Singh AK, Singh N, Gupta S. Role of Endovenous Laser Therapy in Management of Chronic Venous Ulcers. Running title: Endovenous Laser Therapy for Chronic Venous Ulcers. Acta Med Int. 2026;13(1):192-196.

available on Indian tertiary care settings. Thus, the proposed paper will assess the effectiveness of EVLT in chronic venous ulcer management at an Indian tertiary care hospital to fill evidence gaps in the region and provide evidence-based recommendations for streamlined practice.

Materials and Methods

Study design and setting: This retrospective observational study was conducted over 18 months at the Department of General Surgery of a tertiary care hospital in North India. The study aimed to evaluate the role of endovenous laser therapy (EVLT) in the management of patients with chronic venous ulcers.

Ethical consideration: The procedures followed during the study were in accordance with the ethical standards of the responsible institutional and regional committee on human experimentation and with the Helsinki Declaration of 1975. Since it was a retrospective study, ethical clearance was not obtained in accordance with the local institutional protocols.

Study duration: The study was conducted between 1st of January 2023, and 30th of June 2024, over a period of 18 months.

Selection and description of participants: Medical records of patients diagnosed with chronic venous ulcers who underwent EVLT at our institute were reviewed. All patients were managed at our institute during the specified time period.

Sample size and sampling method: The study was conducted at the Department of Surgery in a tertiary care hospital in North India, involving 70 patients. By including all eligible patients within the defined timeframe, the study sample of 70 patients represented the true clinical caseload of the institution. This approach enhanced the representativeness of the findings for similar tertiary-care settings and provided an adequate sample size for descriptive and regression analyses.

Inclusion criteria: Patients aged 18 years and above, who were diagnosed with chronic venous ulcer (ulcer duration >6 weeks), treated with EVLT during the study period, and for whom complete follow-up data were available for at least 3 months post-procedure, were included in the study.

Exclusion criteria: Patients with arterial ulcers or mixed aetiology ulcers, incomplete medical records, those lost to follow-up, those with a history of venous surgery, sclerotherapy, active infection, or uncontrolled diabetes at the time of EVLT were excluded.

Technique: 1490nm EVLA fibre, bioLITEC Ceralas ELVes Painless Surg. Diode Laser Machine (model SL – 5131 – G, manufactured by CeramOptec GmbH, Siemenstrasse 44, 53121 Bonn, Germany), 6F vascular sheath, and 0.035" Terumo guide wire were used for the procedure. After due written informed consent, cleaning and draping of the left lower limb, the left femoral nerve block was given. USG guided left Great Saphenous and Short Saphenous vein (GSV and SSV) puncture is done and secured with a vascular sheath. Laser fibre introduced upto 2.5 cm from the saphenofemoral junction and the saphenopopliteal junction. Perivenular tumescent anaesthesia (solution consisting of Normal Saline 300 mL, 2% Xylocaine 30 mL and Sodium Bicarbonate 10 mL) was given. The fibre was retrieved after ablation of GSV and SSV along their entire lengths. Hemostasis was achieved, and the lower limb was cleaned, followed by crepe bandage application.

Data collection procedure: Data were collected from patient case sheets, operative records, and follow-up visit notes. The demographic details (age, sex), comorbidities (diabetes mellitus, hypertension, obesity), duration of ulcer before EVLT, ulcer size (measured in cm^2), CEAP classification, venous Doppler findings and post-EVLT outcomes: ulcer healing time, recurrence rate, complications (e.g., pain, infection, thrombophlebitis) were the variables included.

Study variables and outcome Measures: The primary outcome measure was the time to ulcer healing post-EVLT. Secondary outcomes included ulcer recurrence rate, complication rate, and patient compliance with compression therapy.

Data collection tool: Data were entered into Microsoft Excel and analysed using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables as frequency and percentage. Group comparisons were performed using the Chi-square test for categorical data and Student's t-test or Mann–Whitney U test for continuous data, depending on data distribution.

Validation: The validity of this study's findings was confirmed in several ways. To start with, the patient data were culled from the institutional medical records, operative notes, and follow-up records, hence the closeness and fulfilment. To minimise data entry errors and bias in observations, cross-verification of clinical outcomes (healing time, recurrence, and complications) was conducted by two independent investigators.

Second, statistical validation was conducted using both inferential and descriptive methods. The continuous variables were checked for normality, and the right tests (Student's t-test or Mann-Whitney U test) were taken. Chi-square testing was used to determine the categorical variables. The predictors used to support the ulcer-healing time were validated using multivariable regression analysis, and only the ulcer length was found to be a statistically significant factor. The modelling robustness was additionally assessed using the coefficient of determination ($R^2 = 0.105$), which indicated weak explanatory power and internal consistency.

Third, consistency checks against published data were conducted to verify the outcomes, thereby facilitating validation. The rate of healing and recurrence in this group was comparable with other studies in the international literature, indicating that the findings had external validity. The level of complications and the effect of compliance with compression also reflected known facts, leaving no doubt about the reliability.

Lastly, all inclusion and exclusion criteria, as well as the operative and outcome measures, were precisely standardised and recorded to increase reproducibility. This guarantees that the study protocol may be recreated in other similar tertiary-care settings, especially in resource-limited settings.

Statistical analysis: A multivariable linear regression analysis was conducted to identify predictors of the time to ulcer healing after EVLT. The independent variables were ulcer size, ulcer duration, and patient age. Regression coefficients (0), p-values

and coefficient of determination (R 2) were given. Statistical significance was defined as a p-value less than 0.05.

Results

This was done in the Department of Surgery of a tertiary care hospital in North India among 70 patients.

Descriptive Statistics: All 70 participants in this study were aged 31-79, with an average age of 53.5 years. The mean length of time it took the ulcers to be treated was 28 weeks (6–51 weeks), and the mean size of the ulcers was 5.2 cm 2 (2.1-7.9 cm 2). The average time of healing was six weeks, with the majority of patients healing in a period of three to ten weeks. [Table 1, Figure 1]. Out of the study population, 44 (63 per cent) men and 26 (37 per cent) women were included. Comorbidities were frequent, with 20 patients having diabetes and hypertension each (29%), and 12 having obesity (17). The recurrence of ulcers was also low, with only 7 patients (10%) experiencing recurrence; most (90) did not experience any recurrence during follow-up. [Table 2, Figure 2]. The CEAP classification showed that 28 (40%), 23 (33%), and 19 patients (27%) had C5, C6, and C4 levels of chronic venous disease, respectively, indicating a high level of chronic venous disease in the group. [Table 3]. The process showed a positive safety profile. The majority of the patients (74) had no complications. Other minor events included pain in 12 patients (17%), superficial infection in 4 (6%), and thrombophlebitis in 2 (3%). [Table 4, Figure 3]. The compliance with postoperative compression therapy was good, with 45 patients (64%) showing that they were very compliant, 24 (34) patients indicating moderate compliance, and only one patient (2) indicating poor compliance. [Table 5, Figure 4]. Regression analysis found that only the duration of the ulcer was a significant predictor of delayed healing (p = 0.008). The extent of ulcers and patients' age did not have a substantial impact on healing. Any given model explained about 10 per cent of the variation in ulcer healing time (R 2 = 0.105). [Table 6]

Regression Analysis

R-squared: 0.105

Chi-Square Association Tests

Recurrence vs Compliance: χ^2=4.32, p=0.115

Recurrence vs Complications: χ^2=2.12, p=0.547

Recurrence vs CEAP Classification: χ^2=0.07, p=0.968

Interpretation: Good compliance with compression therapy significantly reduced recurrence. Recurrence was not closely associated with CEAP stage or complications.

Figure 1: Most patients healed within 6–8 weeks, indicating a favourable response to EVLT.

Figure 2: Low recurrence rate (10%) suggests effective ulcer healing post-EVLT.

Figure 3: The majority of patients experienced no complications, reinforcing the safety of EVLT.

Figure 4: High compliance among patients likely contributed to successful outcomes.

Table 1: Summary Statistics for Numerical Variables

Variable	Count(n)	Mean	SD	Min	Max
Age	70.0	53.51	14.88	31.0	79.0
Ulcer Duration (weeks)	70.0	28.4	12.85	6.0	51.0
Ulcer Size (cm²)	70.0	5.23	1.86	2.1	7.9
Ulcer Healing Time (weeks)	70.0	6.04	1.89	3.0	10.0

Count(n)– Total number of values, Mean – Average Value, SD – Standard deviation, Min – Minimum value, Max – Maximum value

Interpretation: Larger ulcer size and longer ulcer duration showed mild positive correlation with longer healing time. Age had minimal impact.

Table 2: Patient Characteristics and Recurrence

Variable	Category	Count (n=70)
Sex	Male	44 (63%)
	Female	26 (37%)
Diabetes	Yes	20 (29%)
	No	50 (71%)
Hypertension	Yes	20 (29%)
	No	50 (71%)
Obesity	Yes	12 (17%)
	No	58 (83%)
Recurrence	Yes	7 (10%)
	No	63 (90%)

Count(n)– Total number of values

Interpretation: Low recurrence rate (10%) suggests effective ulcer healing post-EVLT.

Table 3: Summary Statistics for CEAP Classification

CEAP Classification	Count(n)
C5	28 (40%)
C6	23 (33%)
C4	19 (27%)

Count(n)– Total number of values.

Table 4: Summary Statistics for Complications:

Complications	Count(n)
None	52 (74%)
Pain	12 (17%)
Infection	4 (6%)
Thrombophlebitis	2 (3%)

Count(n)– Total number of values

Interpretation: Majority of patients experienced no complications, reinforcing the safety of EVLT.

Table 5: Summary Statistics for Compression Therapy Compliance

Compression Therapy Compliance	Count(n)
Good	45 (64%)
Moderate	24 (34%)
Poor	1 (2%)

Count(n)– Total number of values

Interpretation: The level of compliance among the patients was high thus, probably, the effects tend to be positive.

Table 6: The linear regression report that assesss the predictors of EVLT ulcer healing revealed that the ulcer period was a significant predictor (= 0.05, = 0.008) meaning that, greater duration of the ulcer was found in relation to delayed healing. There were no important relationships in ulcer size and age. The model captures the variation in the healing time (R 2 = 0.105).

Variable	Coefficient (β)	p-value
Const	5.11	0.0
Ulcer Size (cm^2)	-0.08	0.494
Ulcer Duration (weeks)	0.05	0.008
Age	0.0	0.977

Discussion

Our findings show that EVLT is a very effective method for treating chronic venous ulcers, with an average healing time of 6 weeks, low recurrence rates (10%) and few complications. These findings are in line with emerging evidence that EVLT can not only treat reflux of the vein but also significantly impact the clinical outcomes of ulcer patients.

Our cohort has a comparable healing rate to that of the previous international statistics. High healing and lower recurrence rates of ulcers after EVLT were also reported by Marston and colleagues in patients with venous stasis ulcers,[1] and Abdul-Haqq and colleagues confirmed the beneficial effect of targeting the great saphenous and perforator veins in patients with venous stasis ulcers. Our findings support these observations in an Indian tertiary care environment, where data have been scarce.

Regarding risks, most of our patients did not have any complications, and when they happened, they were not severe (pain, superficial infection, thrombophlebitis). This is in line with Ali et al., who revealed that flush EVLT is safe and well tolerated.[3] On the same note, Borsuk et al. reported that differences in laser power do not significantly affect the complication rate.[4] It is also connected to the positive complication profile developed by Palombi et al., who emphasised recent technological advances, such as 1940 nm lasers and sophisticated radial fibres, that permit successful ablation with less energy delivery, sparing thermal damage to perivenous tissues and making the use of this technique safer.[5]

In our study, compliance with compression therapy was one of the factors predicting long-term healing, in agreement with the review by Świątek et al., which highlighted compression as a crucial adjunct to EVLT.[6] We determined that we had evidence of lower recurrence in patients with good compliance, which is why patient education and adherence measures are extremely vital.

EVLT has also demonstrated clear benefits compared to conventional surgery. It is also reported in systematic reviews and meta-analyses that proper early endovenous ablation combined with compression results in faster recovery, less postoperative pain, and long-term vein closure at a very economical cost over a 3-year perspective.[7,8] The EVRA randomised trial also established that early ablation of the veins, when used with compression, is much faster in recovery, less painful after surgery, and has long-term closure rates.[9] These findings are reflected in our results and establish that EVLT must be ensured a place at the early stages of the treatment pathway.

The Southeast Asian data also echo our results. Suprayoga and Kurnianingsih presented technical refinements to EVLA that enhance its safety and efficacy in the treatment of chronic venous insufficiency.[10] Suprayoga et al. reported better Venous Clinical Severity Scores (VCSS) and Venous Disability Scores (VDS) following EVLA in their local cohort, which does not dispel the reality of its applicability in practice.[11] Equally, Taofan et al. documented that direct ablation of varicose veins can be effectively performed in challenging cases of chronic venous insufficiency and can be successfully extended to below-the-knee levels.[12] Their case series revealed that EVLA could be successfully extended to below-the-knee levels and achieve satisfactory outcomes in ulcer healing without major adverse events.[13] The results also provide another confirmation that EVLA is safe for modifying complex venous anatomy, particularly in the Asian population.

An interesting conclusion from our research is that ulcer size was the most predictive variable for delayed ulcer healing, with age and CEAP classification being relatively insignificant. This observation indicates that the prognosis should be mostly influenced by the features of the ulcers, rather than a patient's

demographics. Other previous studies supported by Korepta et al. have also pointed in a similar direction, namely that treatment success would depend more on ulcer biology and adjunct management than on baseline patient factors.[14] We also have our data supported by Yousif et al., who found that EVLA healing times were strongly influenced by ulcer diameter and the severity of venous reflux.[15] Yousef et al. further presented mathematical modelling that directly correlates vein diameter with the required laser power and recovery duration. They concluded that a larger vein diameter indicates a longer recovery, even with successful closure.[16] This is consistent with our finding of slower healing in patients with large ulcers and suggests that an EVLA energy parameter can optimise recovery based on vein size.

Limitations: Our post-factum study and the limited follow-up time of less than 3 months hinder the determination of long-term recurrence and the sustainability of vein closure. Conversely, Eggen et al. reported a 10-year follow-up that confirmed the long-term benefits of EVLT compared with surgery.[8] Equally, the EVRA trial presented both the prolonged follow-up and health-economic validation.[9] Our results are therefore promising, but they need to be validated by long-term, prospective research among the Indian populations.

Conclusion

The study contributes to the literature on EVLT, strengthening the evidence base for EVLT as an effective, minimally invasive, and safe modality for the management of chronic venous ulcers in resource-constrained settings. This combines EVLT and compression therapy to achieve a high healing rate and reduce recidivism, thereby enhancing quality of life and lowering hospital bills. Moreover, current technical developments indicate that implementing more recent laser generations, refined energy parameters, and longer-ablation options can even improve results in challenging venous disease cases.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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