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A Case Series on an Innovative Multimodal Approach for the Management of Venous Ulcers: Endovenous Laser Ablation, Four-Layer Compression Therapy, and Medicinal Leech Therapy

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ABSTRACT

Venousulcersareoftenrecurrent,andopenulceration can last from weeks to years. Chronic venous disease (CVD) is a condition characterized by abnormal venous function and structure, often leading to symptoms and complications. Venous ulcers, the most severe manifestation of CVD, are open sores on the legs caused by chronic venous insufficiency (CVI) and venous hypertension, leading to inflammation, microcirculatory dysfunction, and impaired wound healing. This study evaluates the effectiveness of Endovenous Laser Therapy (EVLT), 4-layer bandaging (4-LB), and leech therapy (MLT) in promoting venous ulcer healing and reducing recurrence. 20 patients with lower limb venous ulcers underwent comprehensive clinical examination, laboratory investigations, and treatment combining these modalities. EVLT involved laser ablation of the great saphenous vein, complemented by foam sclerotherapy. The 4-layer bandage technique provided graduated compression to enhance venous return and manage oedema. Leech therapy, inspired by Ayurvedic principles, utilized bioactive compounds in leech saliva to promote anticoagulation, vasodilation, and anti-inflammatory effects, supporting wound healing.Results demonstrated significant clinical improvement, with 95% of patients achieving complete ulcer healing. Pre-treatment symptoms, assessed via the Venous Clinical Severity Score (VCSS), showed marked reduction in pain, edema, pigmentation, inflammation, induration, ulcer size, and duration post-treatment.This study highlights the synergistic potential of combining modern and traditional therapies, offering a promising, integrative approach to managing chronic venous ulcers. Further research with larger sample sizes and longer follow-up is warranted to validate these findings and optimize treatment protocols..

Keywords: Venous Ulcer,Chronic venous disease (CVD), Endovenous Laser Therapy (EVLT), Four-Layer Compression Therapy, Leech therapy

1. INTRODUCTION

Venousulcersareoftenrecurrent,andopenulceration can last from weeks to years.[i]Chronic venous disease (CVD) is a condition characterized by abnormal venous function and structure, often leading to symptoms and complications. Venous ulcers, the most severe manifestation of CVD, are open sores on the legs caused by chronic venous insufficiency (CVI) and venous hypertension.[ii] It occurs due to abnormally functioning venous system caused by venous valvular incompetence, impairs blood flow in the legs, leading to increased pressure and tissue damage, ultimately resulting in venous ulcers , affecting the lower limbs, with a higher prevalence in women (35%) compared to men (15%).[iii,iv,v]The pathophysiology behind venous ulcer is venous reflux or outflow obstruction results in venous hypertension. Elevated ambulatory venous pressure induces a chronic inflammatory state, leading to microcirculatory dysfunction. Clinically, this manifests as edema, dermal fibrosis, mast cell degranulation with pruritus, fibroblast differentiation into myofibroblasts contributing to venous ulceration, and impaired wound healing. The constellation of symptoms characteristic of CVI includes pain, aching, edema, pruritus, hyperpigmentation, dermal fibrosis, and venous ulceration[vi,vii].

The pathogenesis of varicose veins is multifactorial, involving genetic predisposition, female sex, pregnancies, age,

prolonged periods of standing, trauma, and obesity. While certain risk factors can be managed through lifestyle modifications such as increased physical activity, weight control, and smoking cessation, others are non-modifiable. Consequently, the development of CVD is inevitable for a significant proportion of the population.[viii] Other etiologies of lower extremity ulcerations encompass arterial insufficiency, prolonged pressure-related injuries, diabetic neuropathy, and systemic conditions such as rheumatoid arthritis, vasculitis, osteomyelitis, and cutaneous malignancies.[ix]

Treatment options for varicose veins include compression therapy, minimally invasive procedures like sclerotherapy, endovenous laser therapy (EVLT), radiofrequency ablation (RFA), and VenaSeal, along with surgical methods such as phlebectomy and high ligation with vein stripping. Venous ulcers are managed through compression therapy, wound care, antibiotics for infections, and in severe cases, skin grafts or hyperbaric oxygen therapy to support healing.[x]

Recent Ayurvedic clinical research and review articles have established a bridge between traditional Ayurvedic medicine and modern science in treating non-healing ulcers. These studies demonstrate the potential of Ayurveda in preventing complications and improving quality of life (QoL) for patients with chronic wounds. Compiling and reviewing this research would benefit future investigators by providing a centralized source of evidence[xi].

Wound healing is a critical aspect of surgical care. Historically, wound infections have been a significant concern, potentially leading to severe complications. Non-healing wounds, such as diabetic ulcers, venous stasis ulcers, arterial ulcers, and pressure ulcers, are chronic wounds that exhibit delayed healing. These wounds significantly impact patients. Conventional surgical treatments for chronic wounds often involve antibiotics and antiseptic dressings, which may have limitations and adverse effects[xii].

Medicinal leech therapy (MLT), also known as hirudotherapy, is a complementary and integrative treatment modality that utilizes the blood-sucking properties of leeches for therapeutic purposes. This ancient practice involves attaching one or more leeches to the affected area, allowing them to feed and secrete saliva that contains bioactive compounds with potential therapeutic benefits.[xiii],[xiv]

Acharya Sushruta's treatise on wound management[xv], as outlined in the Shashthi Upakrama, includes a detailed description of Rakta-Visravana, or bloodletting, via leech therapy. This non-invasive technique involves the application of leeches to remove impure blood from the affected area, thereby facilitating blood purification. Leech therapy, also known as Raktamokshana or Jalaukavacharana, is indicated for various conditions, including Raktaja Roga (diseases caused by impure blood), Pitta dushita Rakta disease, dermatological disorders, and inflammatory conditions. This unique and effective method of bloodletting is considered a valuable treatment modality in Ayurvedic medicine.

Substance in Leech saliva[xvi]-

Leech saliva contains a variety of bioactive substances that contribute to its therapeutic effects. Hirudin acts as a potent anticoagulant by binding to thrombin, while calin (saratin) inhibits blood coagulation by blocking the binding of von Willebrand factor to collagen and preventing collagen-mediated platelet aggregation. Destabilase exhibits monomerizing activity, dissolves fibrin, and has thrombolytic properties. Hirustasin, a serine proteinase inhibitor, blocks the activity of kallikrein, trypsin, chymotrypsin, and neutrophilic cathepsin G. Bdellins provide anti-inflammatory effects by inhibiting trypsin, plasmin, and acrosin. Hyaluronidase, known as the "spreading factor," increases interstitial permeability, facilitating the dispersion of other active compounds, and possesses mild antibiotic properties. Leech-derived tryptase inhibitor (LDTI) blocks proteolytic enzymes from host mast cells, contributing to anti-inflammatory actions. Eglins further support anti-inflammatory effects by inhibiting α-chymotrypsin, chymase, subtilisin, elastase, and cathepsin G. Additionally, the factor Xa inhibitor disrupts the coagulation cascade by forming equimolar complexes with factor Xa, while complement inhibitors may substitute for natural complement inhibitors in cases of deficiency. Carboxypeptidase A inhibitors enhance blood inflow to the bite site. Suspected components of leech saliva include histamine-like substances and acetylcholine, both acting as vasodilators to increase local blood flow, while an unidentified anesthetic substance numbs the bite site, ensuring a painless feeding process[xvii,xviii].

Table no. 1- Substance in Leech saliva-

Substance	Effect on the host
Hirudin	Inhibits blood coagulation by binding to thrombin
Calin (saratin)	Inhibits blood coagulation by blocking the binding of von Willebrand factor to collagen Inhibits collagen-mediated platelet aggregation
Destabilase	Monomerizing activity Dissolves fibrin

	Thrombolytic effects
Hirustasin	(Serine proteinase) Inhibits kallikrein, trypsin, chymotrypsin, and neutrophilic cathepsin G
Bdellins	Anti-infla this layer provides the higher level of compression (sub-bandage pressure approximately 23mmHg) and must not be over-extended.mmatory Inhibits trypsin, plasmin, and acrosin
Hyaluronidase	("Spreading factor") Increases interstitial viscosity Antibiotic
Leech-derived tryptase inhibitor (LDTI)	(Tryptase inhibitor) Inhibits proteolytic enzymes of host mast cells
Eglins	Anti-inflammatory Inhibit the activity of α-chymotrypsin, chymase, subtilisin, elastase, and cathepsin G
Factor Xa inhibitor	Inhibits the activity of coagulation factor Xa by forming equimolar complexes
Complement inhibitors	May possibly replace natural complement inhibitors if they are deficient
Carboxypeptidase A inhibitors	Increases the inflow of blood at the bite site
Suspected saliva components:	Effect on the host
Histaminelike substances	Vasodilator. Increases the inflow of blood at the bite site
Acetylcholine	Vasodilator
Anesthetic substance	Anesthetic

The aim of the study is evaluating the effectiveness of Leech therapy, 4-Layer bandaging and EVLT (Endovenous Laser therapy) to promote wound healing in venous ulcer and minimize the recurrence.

Clinical Examination for Varicose Veins:

Inspection: The examiner observed dilated, tortuous, and bulging veins, particularly in the lower limbs. Skin changes such as hyperpigmentation, eczema, or ulceration were carefully noted, along with the presence of edema, especially around the ankles.

Palpation: Tenderness along the affected veins was assessed. The skin's temperature and texture were evaluated — induration was noted as a possible sign of chronic venous insufficiency. Pitting edema was also checked for and recorded.

Trendelenburg Test: This test was performed to assess valve incompetence by elevating the leg and applying a tourniquet. Venous filling was then observed upon standing to evaluate valve function, revealing saphenofemoral junction (SFJ) incompetence in all 20 patients.

Perthes Test: The patients were asked to walk with a tourniquet applied. This test was performed to evaluate the patency of the deep veins by observing whether the superficial veins collapsed or remained distended, and it was negative for all patients.

Cough Impulse Test: A hand was placed over the saphenofemoral junction while the patient was instructed to cough. A palpable impulse, indicating saphenofemoral junction incompetence, was observed in all patients.

Brodie-Trendelenburg Test: This test was conducted to differentiate between saphenofemoral junction and perforator vein incompetence. The leg was elevated, a tourniquet applied, and the patient was asked to stand. Rapid venous filling before

releasing the tourniquet suggested perforator vein incompetence, while rapid filling after releasing it indicated saphenofemoral junction incompetence.

Clinical Examination for Venous Ulcers:

Inspection: The ulcer's location was assessed, commonly found near the medial malleolus. The size, shape, depth, and any exudate from the ulcer were noted. The surrounding skin was examined for changes such as hemosiderin staining, lipodermatosclerosis, or dermatitis.

Palpation: Skin temperature, tenderness, and texture were evaluated. Peripheral pulses were palpated to rule out arterial involvement. The severity of edema was assessed, distinguishing between pitting and non-pitting types.

Case Series Report: The present study was carried out in the OPD/IPD of Department of Shalya tantra/General Surgery, Sir Sundar Lal hospital, IMS, BHU, Varanasi, Uttar pradesh between 2022, 2023 and 2024. A total of 20 patients with unilateral or bilateral lower limb venous ulcers were included in the study. The study was initiated after obtaining the voluntary written informed consent from the patients. Complete and Thorough Physical Examination and investigation Performed in All Patients. Along with this laboratory investigation such as CBC, coagulation Profile (PT, INR), fasting blood sugar (FBS), postprandial blood sugar (PPBS), hba1c, renal function test (RFT), liver function test (LFT), viral markers (Hepatitis B, Hepatitis C, HIV), blood grouping and cross-matching and diagnostic investigation (colour Doppler of B/L or U/L lower limb) was done for each patient. They were treated with EVLT, 4-LB andLeech Therapy in OPD/IPD of Department of Shalya tantra/ general surgery. The operative procedures have been explained in detail below.

EVLT- For Bilateral/ unilateral lower limb.

The patient was shifted to the operation theater after **color doppler marking of lower limb (unilateral or bilateral as per procedure planned)**. Under spinal anaesthesia, after aseptic painting and draping from the umbilicus to the foot, a 1 cm horizontal incision was made 2 cm below and medial to the tibial tuberosity over the USG-guided marked course of the great saphenous vein (GSV). The GSV was identified, dissected, and lifted. The proximal and distal ends of the GSV were secured with a loose tie on both sides. A venotomy was performed, and a radial laser probe (IMDSL Medical Diode Laser device) was inserted into the GSV towards the saphenofemoral junction (SFJ). Using a marker, the course of the GSV was marked up to the SFJ. Tumescent anaesthesia (500 mg lidocaine, 1 mg of epinephrine, and 12.5 mEq sodium bicarbonate added to a 1 litre solution of 0.9% normal saline.) was administered along the marked course of the GSV.

The probe was activated, and 70 joules of energy were selected for each cycle. The probe was withdrawn 1 cm after each cycle, with simultaneous compression applied over the vein. Subsequently, the venous ends were tied with Vicryl 2-0 CRB. A cannula was inserted into the distal end, and foam sclerosant (Two ml of Sodium Tetradecyl Sulphate were mixed with four times the volume of air (8 ml) to produce 10 ml foam) was injected. The venous ends were then tied with Vicryl 2-0 CRB. Compression dressing was applied, and postoperatively, all patients were transferred to the recovery room in stable condition.

4- LAYER BANDAGE- Here are the methods of application for 4-layer dressing Preparation of the Wound Area- The wound area was cleaned and dried thoroughly to ensure proper application. Any debris or exudate was carefully removed to maintain a sterile environment. Primary a Dressing of non-adherent wound contact layer was placed directly over the wound to protect it and promote healing while preventing it from sticking to the wound.

Padding Layer- A soft padding layer (orthopaedic wool) was applied over the primary dressing to provide cushioning and absorb any excess exudate. This layer was wrapped evenly to avoid pressure points.

Light Compression Layer- A light compression bandage was wrapped over the padding layer. It was applied with moderate tension to offer gentle support and help manage swelling.

Elastic Compression Layer- Finally, an elastic compression layer was applied as the outermost layer. It was wrapped firmly but comfortably to provide the necessary compression for improved circulation and edema management.(sub-bandage pressure 35-40mmHg at the ankle

Securing the Dressing- The edges of the dressing were secured with adhesive tape or clips to ensure it stayed in place during movement. this layer provides the higher level of compression (sub-bandage pressure approximately 23mmHg) and must not be over-extended. These steps ensured effective application of the 4-layer dressing in the past.

LEECH THERAPY- Equipment Used- Aquarium, small glass jars, small glass bowls, disposable bottle of sterile water, turmeric powder.

The leeches were first detoxify by placing them in turmeric mixed water for 30 minutes. Then The site of application was cleaned with sterile water or normal saline. The leeches were applied to the margin of ulcer. Further A square gauze piece with a hole in the middle was dampened and placed over the application site to form a barrier, preventing the leeches from wandering. The head of the leech was attached to the margin of the ulcer, and it quickly adhered to the site. If the head of the leech did not attach, a small needle prick was made over the site, producing a blood drop that the leech sucked to help it

attach. Once the leech was attached, it remained safely in place until fully distended and then detached itself (approximately after 30-35 minutes). The gauze piece was kept wet throughout the process.

Dealing with the Leeches After Use: The used leeches were detoxified by placing them in turmeric mixed water. Later cleaned with sterile water and kept separately in glass jar for further use in future and to avoid contamination.

Post-Bite Care of Wound: The wound was cleaned with normal saline, Yashtimadhu powder (Glycyrrhiza glabra.) was applied over the wound and covered with sterile gauze pieces. This procedure is done in all patients weekly once for 6 weeks.

Result: The collected data is observed and analysed by as mentioned below

Table no. 2- Demographic presentation-

S. NO.	CATEGORY	SUBCATEGORY	FREQUENCY (N)	PERCENTAGE (%)
1	Age (years)	Minimum	-	28
		Maximum	-	75
		Mean ± SD	-	44.35 ± 12.55
2	Sex	Male	18	90
		Female	2	10
3	Religion	Hindu	17	85
		Muslim	3	15
4	Occupation	Ex-Army Man	1	5
		Ex-Police Man	1	5
		Farmer	5	25
		Govt Worker	2	10
		Housewife	2	10
		Private Practitioner	4	20
		Teacher	5	25
5	Education	Graduated	10	50
		Intermediate	4	20
		Matriculated	5	25
		Post-Graduated	1	5
6	Socioeconomic Status (WHO)	Lower Class	3	15
		Lower Middle Class	11	55
		Upper Middle Class	6	30

Demographic presentation-

The study included participants aged between 28 and 75 years, with a mean age of 44.35 ± 12.55 years. Among the participants, 90% were male (n=18) and 10% were female (n=2). In terms of religion, 85% were Hindu (n=17), while 15% were Muslim (n=3). Regarding occupation, 5% were ex-army men (n=1), 5% were ex-police men (n=1), 25% were farmers (n=5), 10% were government workers (n=2), 10% were housewives (n=2), 20% were private practitioners (n=4), and 25% were teachers (n=5). Educationally, 50% of the participants were graduates (n=10), 20% had completed intermediate education (n=4), 25% were matriculated (n=5), and 5% were postgraduates (n=1). Socioeconomic status, as per WHO classification, indicated that 15% of the participants belonged to the lower class (n=3), 55% to the lower middle class (n=11),

and 30% to the upper middle class (n=6).

Table no. 3- Limb involvement before and after treatment:

B/L OR UNI/L LOWER LIMB BT		B/L OR UNI/L LOWER LIMB AT		Total
		0 (Cured)	1 (Uni/L)	
1(Unilateral)	Count	15	0	15
	% within B/L OR UNI/L LOWER LIMB BT	100.0%	0.0%	100.0%
2 (Bilateral)	Count	4	1	5
	% within B/L OR UNI/L LOWER LIMB BT	80.0%	20.0%	100.0%
Total	Count	19	1	20
	% within B/L OR UNI/L LOWER LIMB BT	95.0%	5.0%	100.0%

Limb involvement before and after treatment:

Before treatment, 15 participants had unilateral lower limb involvement, while 5 had bilateral lower limb involvement. After treatment, all 15 participants (100%) with unilateral lower limb involvement were cured. Among those with bilateral lower limb involvement, 4 participants (80%) were cured, while 1 participant (20%) continued to have unilateral lower limb involvement. Overall, 19 participants (95.0%) were cured, while 1 participant (5.0%) had unilateral lower limb involvement after treatment.

Clinical features as per VCSS before and after treatment.

Table no. 4- VCSS data summary

CF	**Treatment**	**0 (Absent)**	**1 (Mild)**	**2 (Moderate)**	**3 (Severe)**	**Total**
Pain	Before	0	3	11	6	20
	After	19	1	0	0	20
Varicose Vein	Before	0	1	14	5	20
	After	19	1	0	0	20
Venous Edema	Before	0	02	11	7	20
	After	15	5	0	0	20
Skin Pigmentation	Before	0	1	10	9	20
	After	1	16	3	0	20
Inflammation	Before	0	7	10	3	20
	After	16	3	1	0	20
Induration	Before	0	8	10	2	20
	After	16	3	1	0	20

Number of Active Ulcer (Before)			(less than 2 cm)	(two ulcer)	(more than two)	
	Before	0	13	5	2	20
	After	18	2	0	0	20
Active Ulcer Size (Before)			(less than 2 cm)	(2-6 cm)	(more than 6 cm)	
	Before	0	6	10	4	20
	After	18	2	0	0	20
Ulcer Duration (Before)			(< 3 months)	(>3 months but < 1 year)	(> 1 year)	
	Before	0	5	7	8	20
	After	18	1	1	0	20
Compression Therapy		Not used	1(inter mittent use of stockin g)	2 (stocking use most days)	3 (full complianc e with stocking)	
	Before	0	0	0	20	20 (100%)
	After	0	15 (75.0%)	5 (25.0%)	0	20 (100%)

VCSS data summary-

Before treatment, pain severity among participants was reported as mild in 3 cases, moderate in 11 cases, and severe in 6 cases. After treatment, 19 participants experienced an absence of pain, while only 1 reported mild pain. Regarding varicose veins, 1 participant had mild symptoms, 14 had moderate symptoms, and 5 had severe symptoms before treatment. After treatment, 19 participants had no varicose veins, while only 1 had mild symptoms. Venous edema was mild in 2 cases, moderate in 11 cases, and severe in 7 cases before treatment. After treatment, 15 participants had no edema, while 5 had mild symptoms.

Skin pigmentation was mild in 1 case, moderate in 10 cases, and severe in 9 cases before treatment. After treatment, 1 participant had no pigmentation, 16 had mild pigmentation, and 3 had moderate pigmentation. Inflammation was mild in 7 cases, moderate in 10 cases, and severe in 3 cases before treatment. After treatment, 16 participants had no inflammation, 3 had mild inflammation, and 1 had moderate inflammation. Induration was mild in 8 cases, moderate in 10 cases, and severe in 2 cases before treatment. After treatment, 16 participants had no induration, 3 had mild induration, and 1 had moderate induration.

Before treatment, 13 participants had one active ulcer of less than 2 cm, 5 had two ulcers, and 2 had more than two ulcers. After treatment, 18 participants had no active ulcers, while 2 had one ulcer of less than 2 cm. Regarding ulcer size before treatment, 6 participants had ulcers of less than 2 cm, 10 had ulcers between 2-6 cm, and 4 had ulcers larger than 6 cm. After treatment, 18 participants had no ulcers, while 2 had ulcers of less than 2 cm.

Ulcer duration before treatment showed that 5 participants had ulcers for less than 3 months, 7 had ulcers for more than 3 months but less than a year, and 8 had ulcers for more than a year. After treatment, 18 participants had no ulcers, 1 had an ulcer for more than 3 months but less than a year, and 1 had an ulcer for more than a year.

Regarding compression therapy, before treatment, all 20 participants (100%) were in full compliance with stocking use. After

treatment, 15 participants (75.0%) reported intermittent use of stockings, while 5 participants (25.0%) used stockings most days, maintaining a 100% adherence rate.

Table no. 5- Colour doppler findings pre and post treatment

Category	No. of Patients	Minimum Diameter in mm	Maximum Diameter in mm	Mean in mm	Std. Deviation
GSV Diameter RT LB (Pre-op)	20	2.5	8	4.78	1.7037
GSV Diameter LT LB (Pre-op)	20	2.5	7.2	4.56	1.3527
SSV Diameter RT LB (Pre-op)	20	2.4	4.7	3.395	0.627
SSV Diameter LT LB (Pre-op)	20	2	5.5	3.2	0.7398
Competency of SFJ,SPJ and perforators		competent	incompetent		
SFJ Reflux RT LB (Pre-op - Incompetent)	20	7 35.0%	13 65.0%	-	-
SFJ Reflux LT LB (Pre-op - Incompetent)	20	8 40.0%	12 (60.0%)	-	-
SPJ Reflux RT LB (Pre-op - Incompetent)	20	19 (95.0%)	1 (5.0%)	-	-
SPJ Reflux LT LB (Pre-op - Incompetent)	20	18 (90.0%)	2 (10.0%)	-	-
Perforator Competency (Pre-op - Incompetent)	20	5 (25.0%)	15 (75.0%)	-	-
GSV Diameter RT LB (Post-op)	20	1.5	8	2.68	1.4292
GSV Diameter LT LB (Post-op)	20	0.45	7.2	2.7275	1.37587
SSV Diameter RT LB (Post-op)	20	2	4.2	2.85	0.6403
SSV Diameter LT LB (Post-op)	20	1.4	3.2	2.38	0.6271
Competency of SFJ,SPJ and perforators		competent	incompetent		
SFJ Reflux (Post-op - Present) of Bilateral LB	20	19 (95.0%)	1 (5.0%)	-	-
SPJ Reflux (Post-op - Present)	20	20 (100.0%)	-	-	-
Perforator Competency (Post-op - Incompetent)	20	15 (75.0%)	5 (25.0%)	-	-

Colour doppler findings pre and post treatment-

Before surgery, the great saphenous vein (GSV) diameter in the right lower limb ranged from 2.5 mm to 8 mm, with a mean of 4.78 mm ± 1.7037. In the left lower limb, the GSV diameter ranged from 2.5 mm to 7.2 mm, with a mean of 4.56 mm ± 1.3527. The small saphenous vein (SSV) diameter in the right lower limb varied between 2.4 mm and 4.7 mm, with a mean of 3.395 mm ± 0.627, whereas in the left lower limb, it ranged from 2 mm to 5.5 mm, with a mean of 3.2 mm ± 0.7398.

Regarding the competency of the saphenofemoral junction (SFJ), saphenopopliteal junction (SPJ), and perforators before surgery, SFJ reflux in the right lower limb was present in 13 participants (65.0%), while 7 (35.0%) had competent SFJ. In

the left lower limb, SFJ reflux was observed in 12 participants (60.0%), with 8 (40.0%) having competent SFJ. SPJ reflux was noted in 19 participants (95.0%) in the right lower limb and 18 participants (90.0%) in the left lower limb. Additionally, 15 participants (75.0%) had incompetent perforators, while 5 (25.0%) had competent perforators preoperatively.

Following surgery, the GSV diameter in the right lower limb decreased, ranging from 1.5 mm to 8 mm, with a mean of 2.68 mm ± 1.4292. The left lower limb GSV diameter reduced to a range of 0.45 mm to 7.2 mm, with a mean of 2.7275 mm ± 1.37587. The SSV diameter in the right lower limb postoperatively ranged from 2 mm to 4.2 mm, with a mean of 2.85 mm ± 0.6403, whereas in the left lower limb, it varied from 1.4 mm to 3.2 mm, with a mean of 2.38 mm ± 0.6271.

Postoperatively, SFJ reflux was absent in 19 participants (95.0%), while 1 (5.0%) had persistent incompetence. SPJ reflux was absent in all participants (100.0%). Perforator competency improved, with 15 participants (75.0%) having competent perforators and only 5 participants (25.0%) remaining incompetent after surgery.

Table no. 6- VAS score for Bilateral lower limb Pre and post treatment after 1 month follow up

VAS Score (Pain Level)	Pre- treatment Right Lower Limb (n=20)	Pre-treatment Left Lower Limb (n=20)	Post-treatment Right Lower Limb (n=20)	Post-treatment Left Lower Limb (n=20)
0 (No Pain)	5 (25.0%)	7 (35.0%)	5 (25.0%)	7 (35.0%)
1 (1-2 Mild Pain)	2 (10.0%)	1 (5.0%)	9 (45.0%)	7 (35.0%)
2 (1-2 Mild Pain)	-	-	6 (30.0%)	5 (25.0%)
3 (1-2 Mild Pain)	-	-	0 (0.0%)	1 (5.0%)
4 (3-6 Moderate Pain)	4 (20.0%)	5 (25.0%)	-	-
5 (3-6 Moderate Pain)	6 (30.0%)	4 (20.0%)	-	-
6 (3-6 Moderate Pain)	3 (15.0%)	2 (10.0%)	-	-
7 (7-9 Severe Pain)	0 (0.0%)	1 (5.0%)	-	-
Total	20 (100.0%)	20 (100.0%)	20 (100.0%)	20 (100.0%)

VAS score for Bilateral lower limb Pre and post treatment after 1 month follow up -

Before treatment, the pain levels in the right lower limb showed that 25% of patients experienced no pain, while 10% had mild pain at level 1. Moderate pain was reported by 65% of the patients, with 20% at level 4, 30% at level 5, and 15% at level 6. No patients reported severe pain. In the left lower limb, 35% had no pain, 5% had mild pain at level 1, and 60% reported moderate pain, distributed as 25% at level 4, 20% at level 5, and 10% at level 6, while 5% of patients experienced severe pain at level 7.

After treatment, the right lower limb pain levels showed that 25% of patients remained pain-free, while the proportion of patients with mild pain increased significantly, with 45% at level 1 and 30% at level 2. No patients reported moderate or severe pain. Similarly, in the left lower limb, 35% remained pain-free, 35% reported mild pain at level 1, 25% had mild pain at level 2, and 5% had mild pain at level 3. No moderate or severe pain was recorded after treatment, indicating a significant reduction in pain levels.

2. DISCUSSION-

The study demonstrated notable improvements across various clinical outcomes on various parameter. Participants ranged in age from 28 to 75 years, with a mean age of 44.35 ± 12.55 years, predominantly consisting of males (90%) and Hindus (85%). The majority were farmers (25%), teachers (25%), and graduates (50%), with most belonging to the lower middle class (55%) according to WHO socioeconomic classification. Clinical features assessed using the Venous Clinical Severity Score (VCSS) exhibited substantial improvement, with pain, varicose veins, venous oedema, inflammation, and induration showing a significant shift from moderate and severe presentations to absent or mild status after treatment. Active ulcers, initially present in 20 participants, majority of the patient having no remaining ulcers after treatment. Only 2 participants

experiencing small residual ulcers. From full compliance with stocking tointermittent use of compression in 75% of patients, reflecting symptomatic relief. Colour Doppler findings showed a marked reduction in the great and small saphenous vein diameters, indicating improved venous function. Preoperatively, a high percentage of participants exhibited incompetence in the saphenofemoral junction (SFJ), saphenopopliteal junction (SPJ), and perforators. Postoperatively, SFJ and SPJ reflux showed a near-complete resolution, with 95% and 100% competency, respectively, while perforator competency improved in 75% of cases. Leech therapy played a vital role in reducing venous congestion, promoting wound healing, and alleviating pain, contributing to the shift from moderate pain (Visual Analog Scale) to predominantly mild or pain-free states. This shift highlights the efficacy of the intervention in alleviating discomfort. The comprehensive analysis underscores that the treatment not only improved physical outcomes like venous function and ulcer healing but also enhanced overall comfort and quality of life. The reduction in severe clinical symptoms and the increased competency of key venous structures suggest that the intervention successfully addressed the underlying venous insufficiency, contributing to both symptomatic relief and functional recovery. Notably, patients who had experienced non-healing ulcers and persistent symptoms despite months of conventional treatments showed drastic improvements with a combined approach of leech therapy.

Additionally, although we did not include patients with DVT related ulcers in this study, but during this study we observed significant improvement in patients with ulcers caused by deep vein thrombosis (DVT). Leech therapy showed remarkable results not only in aiding ulcer healing but also in contributing to DVT resolution, highlighting its potential as a therapeutic option for such challenging cases. The collective improvements across multiple parameters affirm the effectiveness of this comprehensive treatment protocol, demonstrating substantial recovery, improved vascular function, and enhanced patient well-being. This study highlights leech therapy as an effective, adjunctive treatment for chronic venous insufficiency, promoting pain relief, ulcer healing, and venous function restoration. The results advocate for a large-scale study to validate these findings across a broader, more diverse population.

3. CONCLUSION

The study demonstrated significant improvements in clinical outcomes among patients with chronic venous insufficiency by leech therapy 4- layer dressing and EVLT. Leech therapy emerging as a pivotal component in enhancing recovery. Participants showed notable reductions in pain, varicose veins, oedema, inflammation, and induration — shifting from moderate/severe to mild or absent presentations. Active ulcers, initially present in 20 patients, healed in the majority of the patients. the comprehensive improvements in both physical outcomes and overall patient comfort underscore the efficacy of leech therapy as a valuable adjunctive treatment for chronic venous insufficiency. this study supports the need for large-scale trials to further validate the findings and explore the broader application of leech therapy in managing chronic venous disorders.

Here are five reflective questions based on the article, designed to prompt critical thinking and deeper understanding of the treatment outcomes and methodology:

How did the combination of leech therapy, 4-layer dressing, and EVLT contribute to the observed improvements in venous function and ulcer healing, and which component appears to have played the most pivotal role?

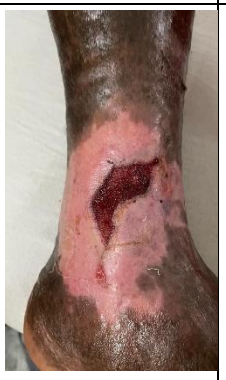
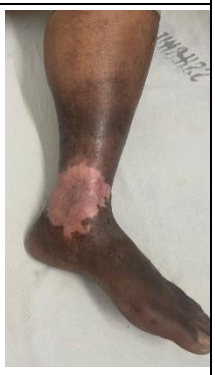
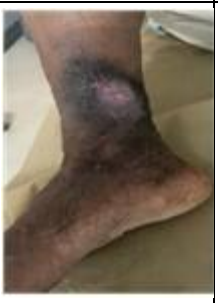
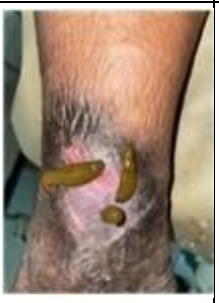
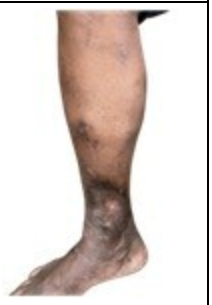
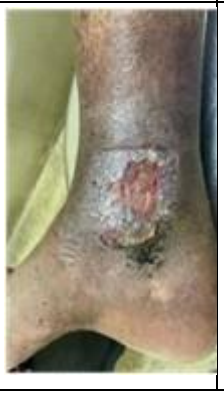
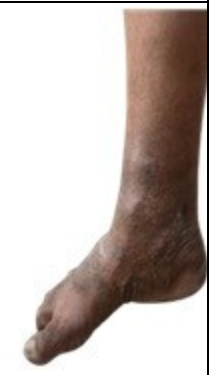
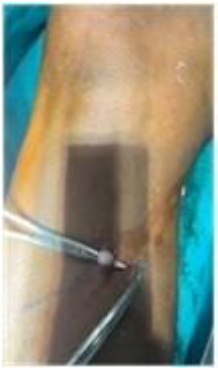
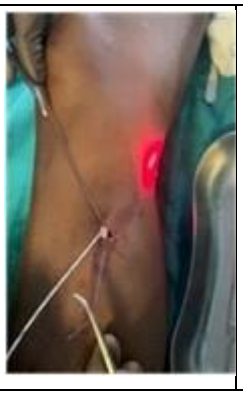
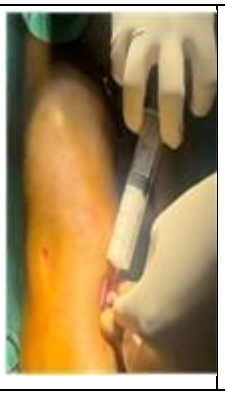
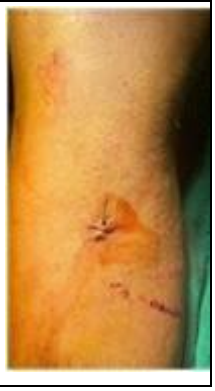
What implications do the results of this study have for the management of chronic venous insufficiency in patients who are unresponsive to conventional treatments?

How does the shift in VCSS scores before and after treatment reflect the efficacy of the multimodal therapeutic approach, and what does this suggest about patient quality of life?

Given the observed improvements in Doppler findings post-treatment, how might leech therapy contribute to physiological changes in venous circulation beyond symptomatic relief?

What challenges or considerations should be addressed in future large-scale studies to validate the use of leech therapy in diverse patient populations with chronic venous insufficiency?

TABLE OF FIGURE

SN	BT	Doppler study BT	Measurement of wound	DT	AT
1					
2					
3					
	EVLT Procedure pictures				
4					

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Informed Consent - Informed consent was taken from all the patients before the treatment and for publishing their details.

Trial Registration No./Date-CTRI/2023/02/050023 and reference number REF/2023/01/062024.

Grant No- Nill

Ethical Statement- Prior to the commencement of the study, approval was obtained from the Institutional Ethics Committee under the reference number ECR/526/Inst/UP2014/RR-20 dated 19.05.2020, as per Dean's letter No. Dean/2022/EC/3559 dated 20/10/22.

Conflicts of interest- The authors declare that they have no conflicts of interest regarding the study design, data collection, analysis, interpretation of data, or publication of this article. There is no financial support, sponsorship, affiliations, or personal relationships influenced the development, conduct, or conclusions of this research.

All phases of the study—including its conception, methodology, clinical execution, statistical analysis, and interpretation—were carried out independently by the authors.

Data Availability Statement-The authors affirm that all original data supporting the findings of this study are readily available and can be provided upon reasonable request. The data have been securely retained by the research team and may be shared for the purpose of verification, clarification, in accordance with institutional and ethical guidelines.

Other Journal specific statement as applicable- This research article has neither been published nor submitted for publication to any other journal.

4. DECLARATION

conflicts of interest-The authors declares that there is no conflicts of interest related to this study. The research was conducted independently, and no financial or personal relationships influenced the outcomes of the work.

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