"TREATMENT OF VENOUS ULCER OF THE LOWER LIMB BY ENDOVENOUS LASER ABLATION: ONE YEAR LONGITUDINAL STUDY"

By

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ACCEPTANCE LETTER

The softcopy of thesis entitled: **"TREATMENT OF VENOUS ULCER OF LOWER LIMB BY ENDOVENOUS LASER ABLATION: ONE YEAR LONGITUDINAL STUDY, KAHER, FROM JANUARY 2019- DECEMBER 2019."** has been submitted for Anti-Plagiarism check through Turnitin software. The scan has been carried out and the scanned output reveals a match percentage of **04%** which is within the acceptable limits of **10%** as per the guidelines given by UGC.

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LIST OF ABBREVIATIONS USED

SFJ	Saphenofemoral junction
SPJ	Saphenopopliteal junction
IC	Incompetent
USG	Ultrasonography
VCSS	Venous Clinical Severity Scoring
DVT	Deep Vein Thrombosis
CEAP	Clinical-Etiology-Anatomy-Pathophysiology
EVLA	Endovenous laser ablation
EVLT	Endovenous laser therapy
RFA	Radiofrequency ablation
GSV	Great saphenous vein

ABSTRACT

AIM AND OBJECTIVES - To study the treatment of venous ulcers of lower leg by endovenous laser ablation

BACKGROUND –Venous ulcer is the most advanced stage of chronic venous insufficiency (CVI). Active venous ulcers affect 0.3% of the adult population in developed countries. Superficial venous reflux (varicose veins) is usually present in patients with venous leg ulcers. Conservative therapy of venous ulcers and the prevention of new ulcers includes control of edema and venous hypertension by adequate compression therapy, wound cleaning or surgical debridement and systemic antibiotic therapy. Studies with compression bandaging have demonstrated successful healing of venous leg ulcers, but recurrence rates have been high. Traditionally, surgery for venous disease involves removing the veins from the leg. The blood is then diverted through the remaining healthy veins. This reduces the pressure in the veins and helps prevent ulcers that have healed from coming backbut needs hospital admission and anesthesia. EVLA treatment that may be particularly appropriate for the elderly population with venous ulcers of lower limb . In our study we included 30 patients with non healing venous ulcer who underwent EVLA as treatment option. We assessed the healing rate of venous ulcer post procedure and associated complications.

KEYWORDS – venous ulcer, Endovenous laser ablation

INTRODUCTION -The veins of lower limb are designed to return blood from the leg upwards towards the heart. Blood is under the force of gravity and, left to itself, would flow downwards. Valves within the veins normally prevent blood from flowing downwards (i.e. backwards), however, if these valves become leaky, pressure within the veins increases.This high pressure causes swelling, thickening and damage to skin,

which may break down to form ulcers. Venous leg ulcers are associated with pain and mobility restrictions that affect quality of life¨Compression therapy which is used most commonly is not popular due to discomfort and non compliance. In addition healing time is prolonged and recurrence rate is high. Surgery needs general anesthesia which may not be appropriate for high risk and elderly population. The principle mechanism of EVLA therapy is ablation and photocoagulation of the vein, done as day care procedure under local anaesthesia.

The purpose of this review is to evaluate the effectiveness of such newer, minimally invasive surgical techniques for the management of venous leg ulcers

INTERPRETATION AND CONCLUSION-Ulcer healing was compared with baseline ulcer size at 1 month and at 6 months, which showed significant healing with p value <0.001.Even those patients who had not achieved complete healing of their wounds by the end of study had a significant reduction in wound size at a similar rate. At 1 year follow up, there was no evidence of recanalization, DVT or recurrence of venous ulcer. Incorporating EVLA into our practice has increased patient satisfaction significantly when compared to traditional surgery. Hence we can conclude from our study that EVLA is one of the best options for the elderly and high risk population promising superior cosmetic results and faster return to daily routine activities.

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INTRODUCTION

Varicose veins and chronic venous insufficiency (CVI) is a major cause of morbidity and decreased quality of life .Varicose veins are dilated, tortuous, subcutaneous veins more than three mm in diameter measured in the upright position with demonstrable reflux [1,2].

Chronic venous insufficiency (CVI) affects around 10–20% of the Western population and 5% of Indians [5]. Some reports suggest that isolated superficial venous reflux may be the chief cause of venous ulcers in over 50% of the patients with CVI[6]. Prevalence of CVI additionally vary, from <1% to 17% in men and < 1% to 40% in women[2]. Varicose veins occurs more commonly in obese females ranging from 1% to 73% [2].There is strong evidence supporting increased incidence of venous disease with age, due to increased pressure on weakened vessel wall and weakened calf muscles [2].The occurrence of skin changes range from 3% and 13%. CVI is a very frequent explanation for venous leg ulcers, these ulcers are slow to heal with high recurrence rate [8].Venous ulcer is the final stage of CVI. Currently over 500,000 people suffer from venous stasis ulcers. The occurrence of dynamic and healed ulcers is around 1% to 2.7% [7]. Active venous ulcers affect around 0.3% of the adult population in the developed nations. The scarcity of powerful remedies and additionally the recurrent nature results in heavy burden in the health care system [7].

The pathophysiology causing varicosities maybe associated with changes in the vein wall resulting in venous dilatation and secondary valve incompetence Varicose veins develop secondary to venous hypertension resulting in reflux in the

veins of saphenous system and its tributaries leading to ambulatory venous hypertension.

Established chance elements consist of older age, female gender, pregnancy, history of venous disease in the family, obesity, and occupations precipitating orthostasis [(2).] Symptoms include heaviness, ankle swelling, ulcers, itching. Signs include dilated tortuous veins, Telangiectasia, Reticular veins, pigmentation, eczema, dependent pitting edema, lipodermatosclerosis, ulcers. Complications include bleeding, eczema, superficial thrombophlebitis, ulceration and lipodermatosclerosis.

Duplex ultrasound imaging is the mainstay investigation of varicose veins. Duplex imaging can evaluate valve incompetency, extent of reflux, thrombosis, and the number, location; diameter of incompetent perforators. Venous reflux is said to be present when the retrograde flow lasts for more than 1/2 second [(17).]

Several techniques exist to deal with varicose veins and lower extremity skin ulcers which has no proper topical, medical, or surgical remedy [(1).]Traditional open surgical technique involves high ligation and stripping. Newer techniques include foam sclerotherapy, endovenous ablation of varicose veins either by radio-frequency ablation (RFA) or laser ablation, MOCA therapy, endovenous glue injection.

Endovenous laser therapy (EVLT) was first described by Carlos Bone in 1998. It is a minimally invasive procedure done under local anaesthesia with ultrasound guidance. The success rates are similar in RFA and EVLT, but when used with radial fibre 1470 nm, results are much better in EVLT. Besides being less invasive, it is cosmetically superior with immediate return to routine activities.

NEED FOR STUDY

Varicose veins causes serious morbidity and results in reduction in quality of life, EVLT being a minimally invasive procedure with minimal complications is associated with improved quality of life. This study is geared towards assessing this modality of treatment of venous ulcers, its healing post procedure and complications.

AIM & OBJECTIVES

Dedicated to assess the role of EVLA in the management of venous ulcer, its healing process and complications associated with the procedure.

REVIEW OF LITERATURE

"Varicose veins are dilated, tortuous superficial veins of lower extremities of the body". Main cause of varicose veins being incompetent superficial / deep venous system / perforators, resulting in reflux of blood and increase in venous pressure leading to ulceration. Considered primarily a cosmetic problem, it is given less clinical importance. Neglected venous ulcers results in psychologic impact, Commonly reported with fear, self isolation, anger, depression, and negative self-image.[9].

EPIDEMIOLOGY-

Common in obese females and incidence increases with advancing age and occupation demanding prolonged standing. It affects 10-20% of population within the Western world and 5 % of Indian population[5]. The prevalence of skin changes varies between 3 % and 13 % within the population. The incidence of active and healed ulcers various among 1% and 2.7 % [7].

In Terence Kiat Beng Teo study, he concluded that it affects 4 % of the population aged more than sixty five years, with a female-to-male ratio of 3:1, with a average age of 62.9 years [10]. Similar to our study, Robert J. Min, included 423 patients in his study showed a common age was 42 years [12]. The Bonn Vein which enrolled 3072 participants (1722 female and 1350 male), age ranging from 18 to 79, located signs of CVD in 49.1% of males and in 62.1% of females[1].

ETIO-PATHOGENESIS-

Common etiological factors for varicose veins include Prolonged standing, Pregnancy, Pelvic obstruction, Chronic straining, Obesity, Heredity. venous ulcer is defined as loss of epidermis with a part of dermis, most common causes are CVI (45-60%), Arterial insufficiency (10-20%),Diabetes (15-25),Vasculitis, Haemorrhagic diseases, Infections, Trauma, Skin conditions- pyoderma gangrenosum, necrobiosis lipoidica ,Malignancies, Genetic- Klinefelter's syndrome.

The pathophysiology of chronic venous insufficiency is either because of backflow of blood or block in venous blood flow. This results in venous hypertension. Two venous systems in the lower extremity are deep and superficial. Deep venous system ultimately leads back to IVC and to the heart. The principle superficial veins are the Great Saphenous Vein (GSV) and Short Saphenous Vein(SSV) [(1)] ,There is posterior and anterior accessory saphenous vein within the calf and the thigh [(1).] .The deep veins within the calf muscle join to form the popliteal vein, which continues as the femoral vein, then as the common iliac vein, which finally drains into the inferior vena cava. The greater saphenous vein empties into the common femoral vein and the short saphenous vein empties into the popliteal vein. The superficial compartment is a low pressure compartment while the deep compartment is a high pressure compartment. Perforator veins pierce the muscle fascia and connect the deep venous system to the superficial venous system. [(2)]

Superficial vein incompetence is because of weakened valves. Deep venous system is affected due to past DVT, inflammatory changes, scarring of valves and decreased calibre of vessels. The resting pressure within the vein is based on

impedence to outflow, capillary inflow, valve function and muscle pump function [14].

The clinical complications of Varicose Veins are:

1. Bleeding,
2. Eczema,
3. dermatitis,
4. Lipodermatosclerosis,
5. Venous ulcer
6. Deep vein thrombosis,
7. Thrombophlebitis,
8. Calcification of vein,
9. Periostitis,
10. Talipes equino varus.

TYPES OF VARICOSE VEINS –

1. **Primary trunk varicose vein** is due to valvular insufficiency of superficial veins, most typically at sapheno-femoral junction(SFJ)

   Theories -

Primary valve failure- primary degenerative changes within the valvular annulus and leaflets

Secondary valve failure-developmental weakness within the vein wall that leads to secondary widening of the valve commisure and incompetence .

Symptoms of primary venous insufficiency are often undiagnosed. Characteristic leg complaints related to varicose veins include aching pain, night cramps, fatigue, heaviness, or restlessness. These symptoms arise from pressure on somatic nerves by the dilated veins and are typically worsened with prolonged standing. [12].

2. **Secondary trunk varicose vein** is due to deep vein thrombosis that results in chronic deep venous obstruction or valvular insufficiency.

Pregnancy induced and progesterone induced valve weakness, Trauma, Congenital (venous malformations , eg: Klippel-Trenaunay variants).

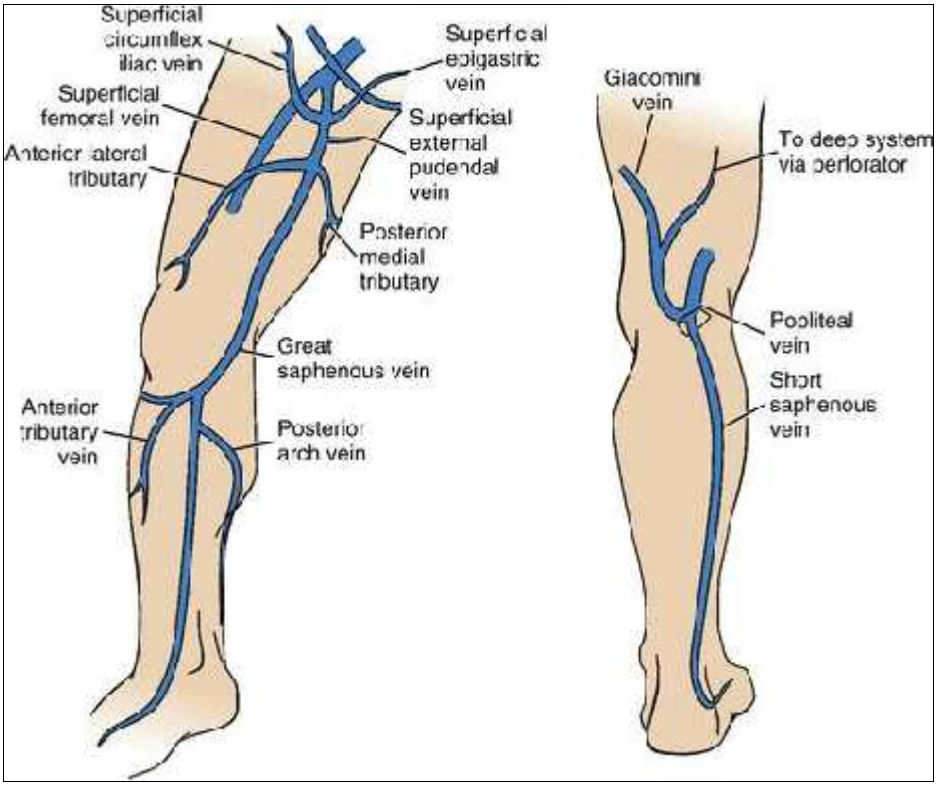


Figure 1: Venous anatomy of Lower Limb

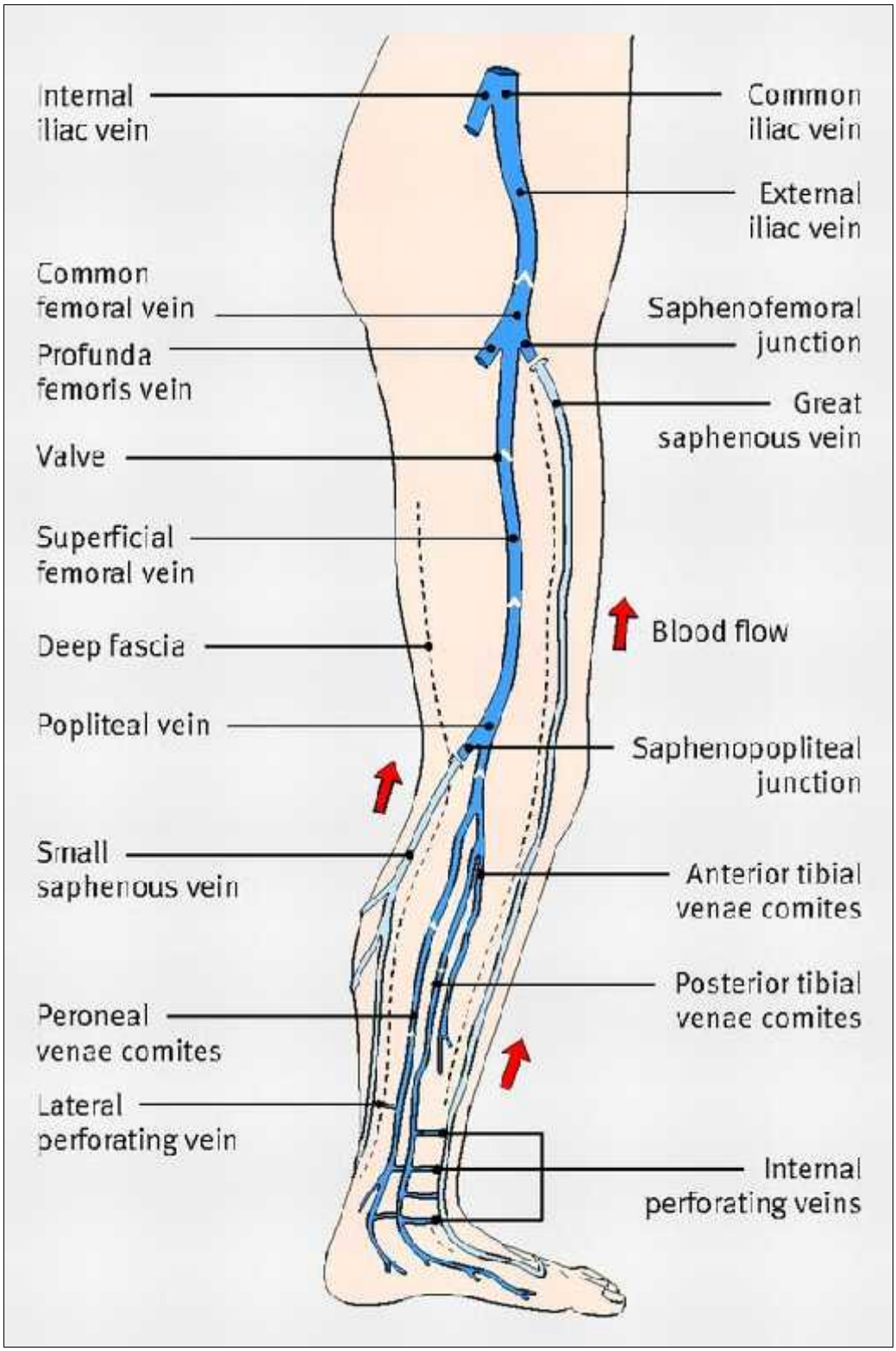


Figure 2: Picture showing Venous Return of Lower Limb

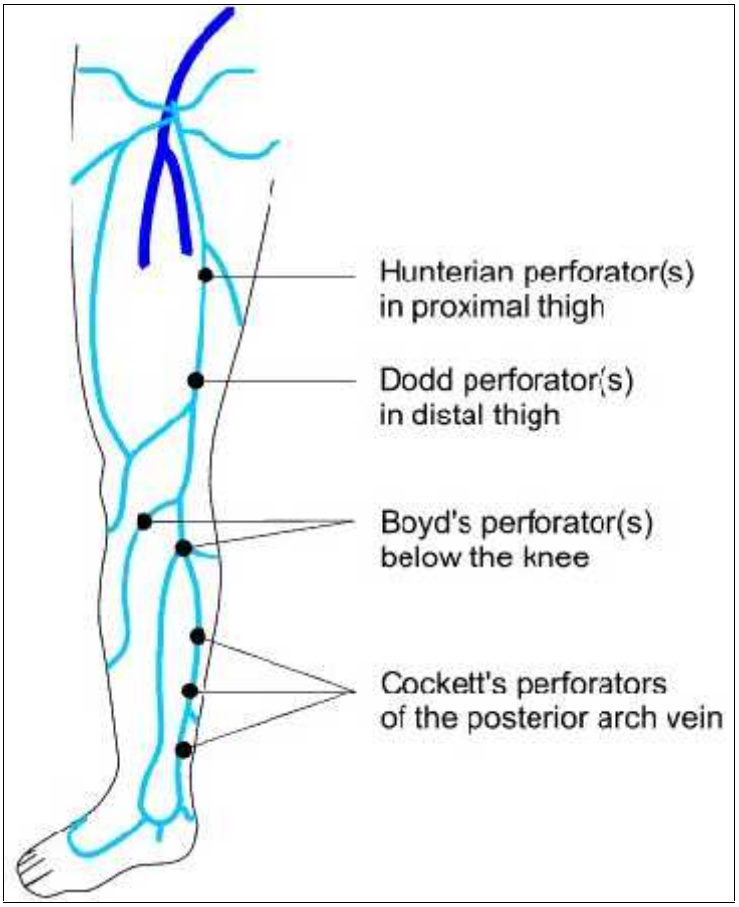


Figure 3: Named perforators

Leg ulcers are divided in three, based on their aetiologies

1. Venous ulcers occur most commonly occur above the medial or lateral malleolus

2. Arterial ulcers often occur over toes, shin or over pressure points

3. Neuropathic ulcers tend to occur on the sole of the foot or over pressure points

VENOUS ULCER – Venous leg ulcers constitute the final result of persistent venous disease. Affecting round 3% of elderly population, considerably impairing their quality of life [(15)]. The primary risk factors are over-weight, obesity, previous leg injuries, deep vein thrombosis, phlebitis. Venous ulcers are often recurrent and active ulcers persist from weeks to many years.

Three main theories of venous ulceration are: [41]

1. Fibrin cuff theory – fibrinogen leaks from dilated capillaries of the epidermis forming a pericapillary fibrin cuff. This is responsible for reduced diffusion of oxygenated blood to the tissues resulting in Ulceration.

2. Leukocyte entrapment theory- Venous hypertension reduces the Pressure gradient between the arteriolar and venular end of capillaries. This results in sluggish moment of blood within these capillaries and increases the adherence of blood cells to the endothelium, inflammatory mediators(ICAM-1,VCAM-1) and reactive oxygen species release resulting in obliteration of capillaries thereby aggravating ischemia and results in Ulceration

3. Microangiopathy Theory- Some of the capillaries in patients with venous ulcers are obliterated with microthrombi or exhibit long intracapillary stasis. This inturn reduces the oxygenation to skin, predisposing to Ulceration.

The mainstay of remedy for venous leg ulcers is compression therapy, which has been proven to improve ulcer recovery rates but is associated with high recurrence rate [15].Surgical alternatives have become obsolete with increasing popularity of newer minimally invasive techniques. These newer ablative procedures fasten the ulcer healing with less / no recurrence. [16]

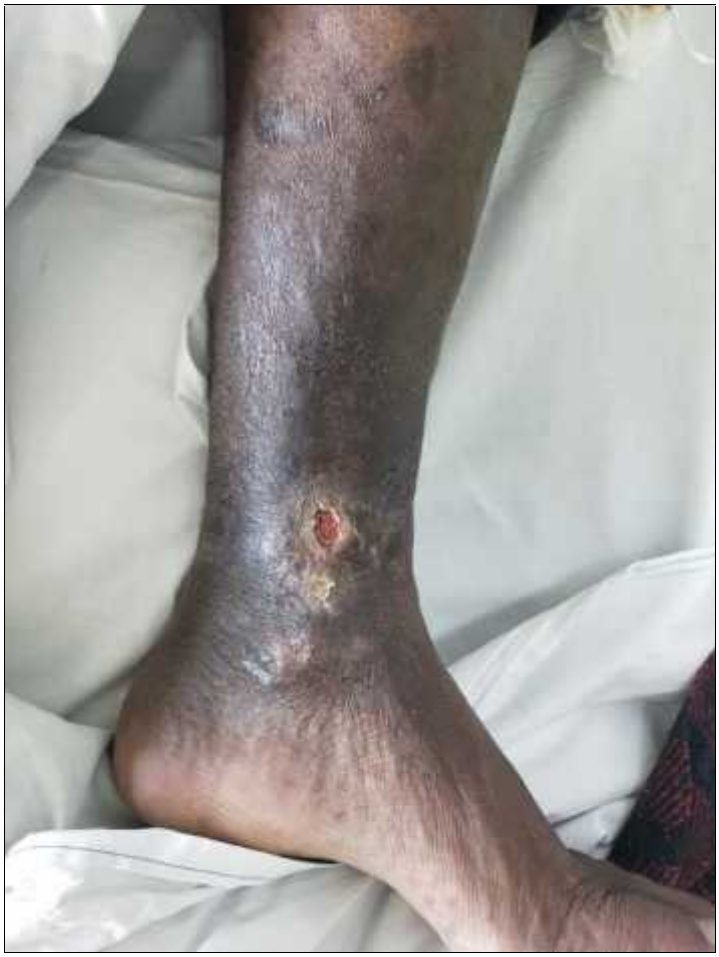


Figure 2: Venous Ulcer in the Gaiter of Left Lower Limb

THE CEAP CLASSIFICATION device became advanced evaluation for comparison of outcomes across clinical studies. Most recently, the Venous Severity Scoring (VSS) system was introduced in a trial to switch the CEAP assessment.

The VSS system consists of three components,

VCSS (venous clinical severity score),

VSDS (venous segmental disease score),

VDS (venous disability score) [(2)]

DIAGNOSTIC EVALUATION-

Clinical examination-

History-

A thorough case history is important in the patient's evaluation and will establish the diagnosis of primary, secondary, or congenital varicosities [(1)]

Which includes, Past history of DVT, Known thrombophilia, Medical history of intake of contraceptive pills/HRT, smoking, pregnancies, family history of varicosity or thrombotic disorders [(1)]

Physical examination-

Examination of lower limb- Haemosiderin staining, Thickening and fibrosis, Dilated veins, Crusty, dry and hyperkeratotic skin, Eczematous , Itchy skin, presence of peripheral pulsations, Normal capillary refill, Limb edema, ulceration at gaiter area, most commonly over medial aspect.

Ulcer characteristics: [(41)]

- Shallow with flat margins,
- Pale granulation tissue +/- slough

Look for ankle mobility and mass per abdomen [(1).]

Corona phlebectasia is a fan-shaped pattern of small intradermal veins located round the ankle /the dorsum of the foot. This is considered an early sign of advanced venous disease [(1)]

THE CEAP CLASSIFICATION- CEAP underwent its first official review and revision by a world panel under the auspices of the AVF in 2004.

Table 1 CEAP Classification of Varicose Veins

CEAP	DESCRIPTION
1.CLINICAL CLASSIFICATION	No visible or palpable signs of venous Disease
C0	Telangiectases or reticular veins
C1	Varicose veins
C2	Edema
C3	Pigmentation and/or eczema
C4a	Lipodermatosclerosis and/or atrophie blanche
C4b	Healed venous ulcer
C5	Active venous ulcer
C6	Symptoms, including ache, pain, tightness,
Cs	skin irritation, heaviness, muscle cramps, as well as other complaints attributable
CA	to venous dysfunction Asymptomatic
2.ETIOLOGICAL CLASSIFICATION	
Ec	Congenital
Ep	Primary
Es	Secondary (postthrombotic)
En	No venous etiology identified
3.ANATOMICAL CLASSIFICATION	
As	Superficial veins
Ap	Perforator veins
Ad	Deep veins
An	No venous location identified
4.PATHOPHYSIOLOGICAL CLASSIFICATION	
Pr	Reflux
Po	Obstruction
Pr,o	Reflux and obstruction
Pn	No venous pathology identified

THE DUPLEX ULTRASOUND EXAMINATION - Venous duplex ultrasound plays a vital role in the management. Report should contain information on patency of deep venous system, location of normal and refluxing axial veins, and presence of duplicate or accessory refluxing vein segment.

The following data needs to be established: [17]

1. Saphenous junction incompetency, their locations and diameters.
2. The reflux status of saphenous veins of the thighs and legs and their diameters.
3. The number, location, diameter and function of incompetent perforating veins.
4. Other veins that show reflux.
5. The state of the deep venous system competence of valves and evidence of previous phlebothrombosis.

TREATMENT –

Non operative management includes the use of graded compression stocking with 20-30mmhg which is contraindicated in patients with concomitant arterial insufficiency. Conservative remedy of venous ulcers and its prevention consists of control of edema and lowering venous pressure via compression therapy / local debridement.

COMPRESSION STOCKINGS -

Compression therapy plays a vital role for treatment of patients with venous leg ulcers [18]. The consistent pressure applied to the veins ends up in decrease in vessel diameter and reduced transmural pressure. Pressure values as low as 15 mmHg are sufficient to constrict superficial and deep veins, which subsequently results in an acceleration in blood flow. To attain this while standing up, significantly higher

pressure (60–90 mmHg) is required [18]. The wearing of Grade 1 compression stockings till knee level (10 to 15 mmHg at the ankle) has resulted in significant improvement in symptomatology and quality-of-life in patients. [18]

ULCER STOCKING SYSTEMS -

Ulcer stocking systems usually incorporates two components, an understocking and a compression stocking. The understocking already exerts a therapeutically effective resting pressure; additionally, the underlying wound dressing is protected and held in situ. In mobile patients with venous ulcers, these stocking systems could also be an inexpensive alternative to compression bandages following initial decongestion. [18]

Conservative management includes lower limb elevation/ frequent ambulation / ankle pump exercise / local dressing .Common practice was to attempt to to philosopher's wool paste dressing with graded triple layer compression dressing. Patients with refractory symptoms to conservative therapy, recurrence, non-healing venous ulcers require interventional treatment.

SURGICAL MANAGEMENT –

TYPES-

Saphenous vein ligation

Saphenous vein stripping +/- ligation

Flush SFJ ligation, stripping of GSV with excision of tributaries

Stab avulsion technique (ambulatory phlebectomy)

Extrafascial ligation of perforators

Subfascial ligation of perforators

Table 2: Indications and Contraindications of Surgical management of Varicose veins

INDICATIONS –	**CONTRAINDICATIONS-**
• GSV/SSV incompetency • Perforating vein incompetency	• DVT • Pregnancy • Thrombophlebitis • PVD

ENDOVENOUS ABLATION – Endovenous thermal ablative techniques have increased in popularity since 1998. EVLT was first described by Carlos Bone´ in 1999. FDA approval for EVLT using an 810nm device was granted in January of 2002 [12, 19]. These minimally invasive procedures involve the use of duplex-guided, catheter-directed thermal energy into the incompetent superficial veins, causing their permanent occlusion.[15,19,22]

There are three types of therapies:

Radiofrequency ablation,

Laser ablation,

Foam sclerotherapy.

Patients on anticoagulation regimen should remain on their standard regimen, with INR is < 3.

Variables in EVLA treatments include the power setting, laser wavelength, laser output (pulsed or continuous wave), pullback speed, fibre tip design and total energy delivered [20]

Shorter wavelength lasers - (810, 940, 980 nm) [20]

Longer laser wavelengths - (1320, 1470 and 1510 nm) [20]

Up to 100% closure rates at 6 and 12 months are reported with longer laser wavelengths Nd: YAG laser using a LEED of only 50–62 J/cm [20]

Lasers of 1320, 1470 and 1510 nm appear to give as good efficacy whilst minimising side effects, allowing the LEED to decrease to a variety of >50 J/cm and <80 J/cm [20]

ENDOVENOUS LASER ABLATION- A minimally invasive technique, done under ultrasound guidance for treatment of varicose veins. Under tumescent local anaesthesia a catheter with a laser probe in inserted in the targeted vein, till saphenofemoral junction or saphenopopliteal junction. Then, the laser fibre is slowly withdrawn with applied energy. Laser ablation delivers energy to blood itself and coagulation occurs after completion of laser energy. Laser energy catheters are available in different wavelength starting from 810nm-1470nm. Investigations have demonstrated that higher the wavelength fibres appear to be related to less post procedural discomfort.

RADIOFREQUENCY ABLATION- This is similar to EVLT, but in this technique we use radiofrequency catheter instead of laser probe. Radiofrequency ablation delivers heat at a temperature of 120 degrees/C, which damages the vein wall endothelium, leading to collagen contracture and thrombosis of treated vein. Radiofrequency catheters length varies but not in temperature delivered.

FOAM SCLEROTHERAPY- In this foamed sclerosant is injected into the targeted vein under ultrasound guidance. This can be used even for small veins located under the venous ulcer.

SUBFASCIAL ENDOSCOPIC PERFORATOR SURGERY- this is used for treating incompetent perforator veins. Using endoscopic technique the perforators are clipped or divided.

Table 3: Indications and Contraindications of Subfascial Endoscopic Perforator Surgery

INDICATIONS-	**CONTRAINDICATIONS-**
• Varicosities below knee and caused by perforators • Recurrent • Large venous telangiectasia • Dilated branch vein around the knee following early GSV incompetence • Refusal for surgery	• DVT • SFJ incompetence • Veins in lower 1/3rd of leg • Veins on foot • Immobile patients • Post thrombotic syndrome • Extensive eczema

COMPLICATIONS OF ABLATIVE PROCEDURES –

Anaphylaxis & sensitivity

Pigmentation & ulceration

Superficial & deep thrombophlebitis

Arterial injection & nerve damage

CONTAINDICATIONS FOR TREATMENT-

1. DVT, since they're the only bypass pathways.
2. Pregnancy (may regress spontaneously post delivery)

FACTORS ASSOCIATED WITH RECURRENCE OF VARICOSE VEINS AFTER THERMAL ABLATION: [44]

1. Perforators
2. Neovascularity
3. Recurrent Saphenous insufficiency.

TECHNIQUE-

Under local anaesthesia and ultrasound guidance , using Seldinger's technique the great saphenous vein was accessed antegradely at the ankle joint and 6F vascular radial sheaths were placed [19,21]. A radial firing 1470nm diode laser fibre from Neolaser is passed through the venous accesses within the GSV antegradely from ankle up to 2cm before the saphenofemoral junction [1, 13, 19, and 21]. Using USG guidance, the tumescent fluid was injected extraluminally round the venous wall right along its length [19].Endovenous laser ablation of entire great saphenous vein from groin region up to ankle was done. The laser is activated and slowly pulled again. Pull back speed 2 mm / sec [13, 19]

Vascular sheath was discarded at the end of procedure and haemostasis achieved at the puncture site by digital compression.

It is important to treat incompetent perforators also, to enhance ulcer healing and to prevent recurrence. So patients with incompetent perforators underwent laser ablation using microfiber Laser.

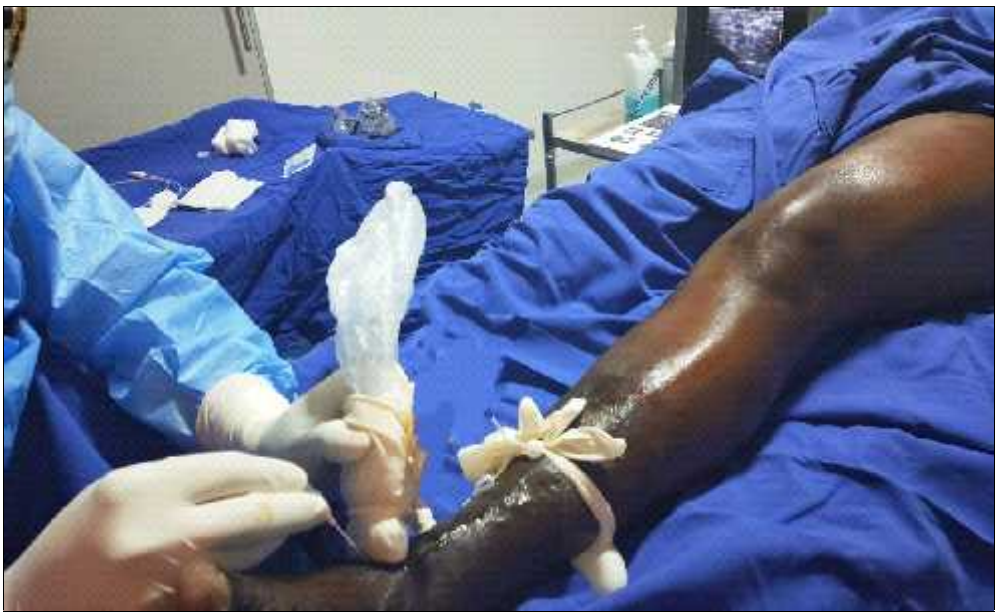


Figure 3: Figure Showing Antegrade Access at the ankle joint

Figure 4: Neo Laser machine

When the procedure is completed, the laser access site is covered with a steri-strip and a transparent dressing. At the completion of the procedure, the SFJ and SPJ are inspected with duplex ultrasound to make sure there's no thrombus extending into the common femoral or popliteal veins [(19)]

Care should be taken to ensure superficial venous ablation won't compromise the venous outflow of post-thrombotic limb .Compression stockings were applied immediately and patient was advised to mobilize continuously for two hours. Compression stockings to be continued for six months .

Endovenous laser ablation of direct perforators was done using laser microfiber. [31,39]

When compared to EVLA with traditional surgical high ligation and stripping, The technique of EVLT was being developed and manufacturers recommended that ablation be performed within the above-knee portion of the GSV only. This recommendation was driven by concerns about saphenous and sural nerve injury [19,27,40]

KEY MECHANISM OF EVLA –

The mechanism of action of laser ablation is to cause a non thrombotic occlusion of the vein by delivery of laser energy (heat) endoluminally. The endothelium is destroyed leading to contraction of contracts and fibrosis. [12, 13, 15, 19]

Involves transmission of laser energy down an optical fibre placed within the vein . This energy is absorbed by haemoglobin, or water, present inside the vessel and its wall, creating heat.[15]. Thermal energy causes collagen to contract and endothelium to be denuded; occlusion of the vein is caused by thickening of the vein wall, contraction of the lumen and fibrosis of the vein. [15]. The 1470nm diode laser is safe and highly effective for endovenous laser treatment of varicose veins within the great saphenous vein. Evidence from systemic review suggest that recanalization or

persistence of reflux at six weeks and one year are less common in EVLA compared to traditional surgery.

ADVANTAGES OF EVLA-

Compared with conventional open surgery, RFA may be performed in outpatient setting without the requirement for hospital admission or anaesthesia. [4].

Generally safe and fewer complications,

Day care procedure,

Requires one small incision,

Less invasive,

Absence of scars,

Early resumption of normal day to day activities

DISADVANTAGES OF EVLA- [37]

Skin burns,

Induration,

Swelling,

Paraesthesia,

DVT,

Recanalization

COMPLICATIONS-

Saphenous neuralgia,

Nerve injury,

Bruising and soreness,

Hyperpigmentation alongside the direction of the dealt with vein,

Pulmonary emboli are rare,

Hematoma [2,4].

According to Robert J min, in his study he noted temporary paraesthesia's (thigh, 9%; leg, 51%), skin burns (3%), deep vein thrombosis (3%), and one pulmonary embolus [12]. Drain the vein adequately for tumescent anesthesia from the skin with adequate compression. This can further lower the threat of hyperpigmentation [19,33].

ULCER HEALING –

Early intervention of incompetent venous system has helped in ulcer healing process. Intervening incompetent direct perforators along with the main venous system plays a pivotal role in ulcer healing, since most of the ulcers occur commonly due to incompetent perforators locally. [31,35,36]

MATERIALS AND METHOD

TREATMENT OF VENOUS ULCER OF LOWER LIMB BY ENDOVENOUS LASER ABLATION: ONE YEAR LONGITUDINAL STUDY" KAHER,

FROM JANUARY 2019- DECEMBER 2019 .

SOURCE - Patients admitted under Department of General Surgery / Interventional Radiology, who had undergone endovenous laser ablation at KAHER,on OPD/IPD basis diagnosed with lower limb venous ulcer.

STUDY POPULATION- Patients getting admitted for lower limb venous ulcers under department of General Surgery / Interventional Radiology at KAHER.

STUDY DESIGN- A longitudinal study

STUDY SETTING- KAHER, Belgaum.

STUDY PERIOD- January 2019 – December 2019.

STUDY DURATION- 1 year

SAMPLE SIZE- 30

SAMPLE SIZE FORMULA-

The minimum sample size formula based on prevalence rate is

$$n = \frac{z_\alpha{}^2 P(1-P)}{d^2}$$

Where P - percentage of prevalence

d - Percentage likely difference in the prevalence.

zα is associated with the level of significance.

For 5% level of the significance zα = 1.96.

Ref: [2]

With P = 73% and d = 25% of P = 18.35%, the sample size is 23

To make the study more confirmative, the sample size will be raised to 30.

SELECTION CRITERIA- All patients who fulfilled the inclusion criteria were included in the study.

INCLUSION CRITERIA-

Patients presenting to OPD and admitted in KAHER Hospital, Belgaum and those who give written and informed consent for participation

Male/Female patients

Age more than 18 years of age

CEAP classification C3-C6

Ankle–brachial index of more than 0.8 in affected limb

Primary or recurrent superficial venous reflux .

EXCLUSION CRITERIA-

Patients who refused to provide consent

Suspected / proven malignancy

Hypercoaguable state

Deep vein thrombosis

Pregnancy

Peripheral arterial disease

Lymphedema

Allergy to the sclerosant or lidocaine or antibiotics

Non-venous leg ulcers.

ETHICAL CLARANCE- The Ethical Clearance was obtained from the Institutional Ethics Committee, KAHER, Belagavi prior to the commencement.

INFORMED CONSENT (ANNEXURE I)- Those patients who fulfilled selection criteria were briefed about the nature of study and the endovenous laser ablation procedure and follow up pattern.

METHOD OF COLLECTION OF DATA- Patients satisfying the choice standards have been interviewed and the demographic facts inclusive of age and sex, chief complaints have been noted. The patients underwent clinical and systemic examination and the findings were recorded on a predesigned and pretested proforma (Annexure II).

The subjects have been enrolled in the study after written and informed consent. A detailed history was taken and all subjects were subjected for

1. Preoperative Doppler evaluation
2. CEAP classification of chronic venous disease.

ULCER MANAGEMENT- All patients were managed conservatively for atleast 5 weeks, which included wound culture, topical antibiotics, debridement when

appropriate, topical wound recovery agents, and three or four layer semi inflexible compression till knee. [16]

Protocol utilized in our study is,

Antibiotics- oral / local as per wound culture and sensitivity

Analgesics, cap.becosules, tab.Limcee

Diabetic management

Regular dressings.

For non-healing big ulcers AG-Fix foam dressing was done.

Stockings – Grade 1 till below knee and Grade 2 over that till groin is worn for six months.

Postoperatively repeat Doppler was done on day 1 and at 1 month to ensure complete occlusion of vein. Assessment of ulcer healing was done on 1 month, 3 months and 6 months.

OUTCOME VARIABLES-

Ulcer healing rate

Mean age of study population

Laterality

Perforator incompetence

Skin pigmentation

Short saphenous vein involvement

RESULT

This longitudinal study consisted of 30 patients, who have been admitted under Department of Surgery and Interventional Radiology with venous ulcer and who had undergone endogenous laser ablation at KLES PrabhakarKore Hospital and MRC, Belgaum from January 2019- December 2019

In this study we studied on venous ulcer healing at 1 month, 3 months and at 6 months and incidence of complications associated with the procedure

All quantitative variables were checked for normal distribution within each category.

The change in the quantitative parameters, before and after the intervention was assessed by paired student t-test

"P value of <0.05 is significant".

1. DESCRIPTIVE ANALYSIS OF AGE IN STUDY GROUP-

Table 4:Descriptive analysis of age in study population

	MEAN	**S.D.**	**MINIMUM**	**MAXIMUM**
AGE	43.03	14.50	23	67

In our study population mean age was 43. Minimum age was 23 years and maximum was 67 years

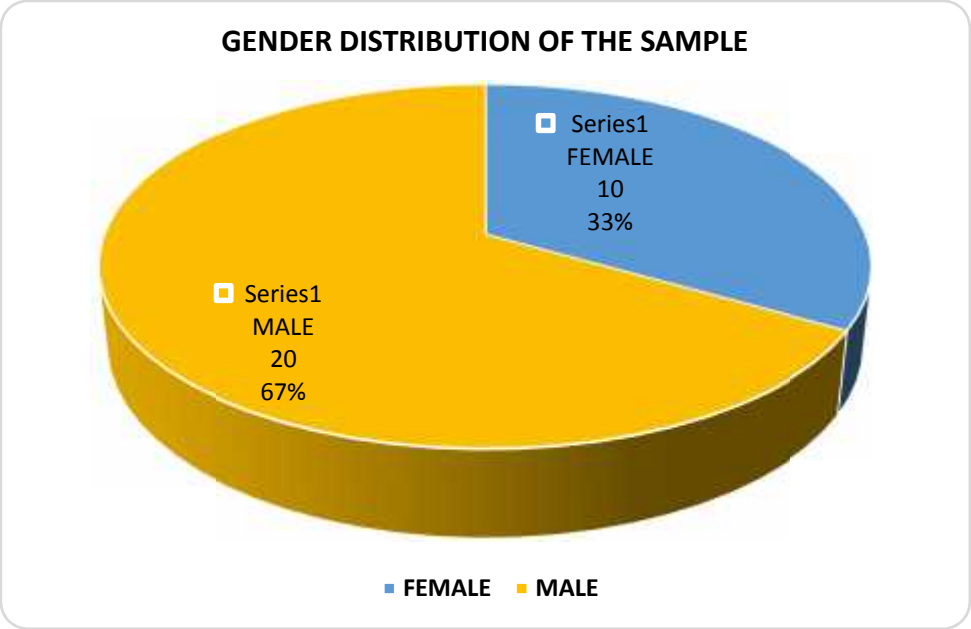
2. DESCRIPTIVE ANALYSIS OF GENDER IN STUDY GROUP-

Among the study population, 20 (66.6%) were male participants and remaining 10 (33.3%) participants were female

Table 5: Descriptive analysis of gender in study population

GENDER	NUMBER	PERCENTAGE
FEMALE	10	33.33
MALE	20	66.67
TOTAL	30	100.00

Graph 1 Pie Chart Showing Gender Distribution



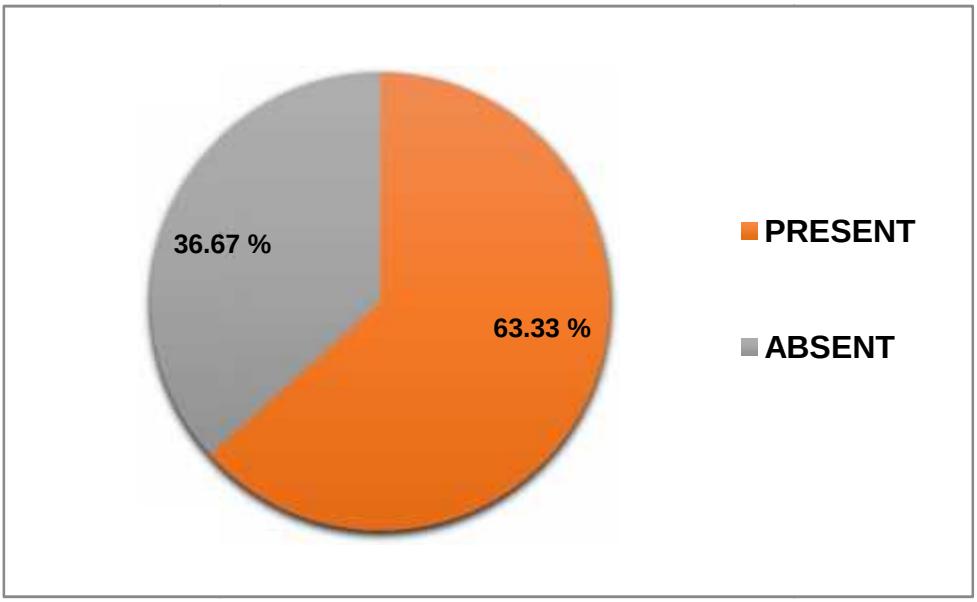
3. DESCRIPTIVE ANALYSIS OF INCOMPETENT PERFORATORS IN STUDY GROUP

In our study 19 patients (63.3%) had incompetent perforators and underwent laser ablation using microfiber Laser for the same, and 11 patients (36.6%) incompetent perforators were not present

Table 6: Descriptive analysis of number of IC perforators in study population

PERFORATORS	NUMBER	PERCENTAGE
PRESENT	19	63.33
ABSENT	11	36.67
TOTAL	30	100.00

Graph 2: Pie chart showing Incompetent perforators in study group



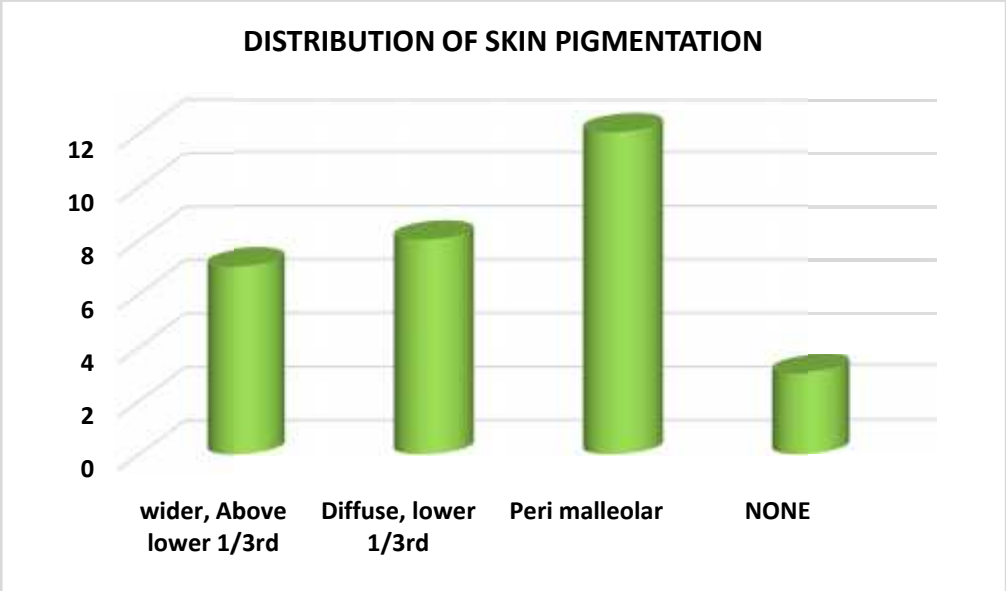
4. DESCRIPTIVE ANALYSIS OF SKIN PIGMENTATION IN STUDY GROUP

Among 30 patients in our study group, 7 patients (23.3%) had wider, above lower 1/3 calf pigmentation, 8 patients (26.6%) had diffuse, lower 1/3 calf pigmentation and 12 patients (40.0%) had perimalleolar pigmentation. 3 (10.0%) patients had no skin pigmentation

Table 7: Descriptive analysis of Skin pigmentation is each limb in study population

SKIN PIGMENTATION	NUMBER	PERCENTAGE
Wider, Above lower 1/3rd	7	23.33
Diffuse, lower 1/3rd	8	26.67
Perimalleolar	12	40.00
NONE	3	10.00
TOTAL	30	100

Graph 3: Bar graph showing distribution of Skin Pigmentation



5. DESCRIPTIVE ANALYSIS OF SSV INVOLVEMENT IN STUDY GROUP-

In our study group 9 patients (30%) had short saphenous vein involvement and in 21 patients (70%) it was not involved.

Table 8: Descriptive analysis of SSV involvement in each limb

	SSV	
	PRESENT	**ABSENT**
TOTAL	9	21
PERCENTAGE	30	70

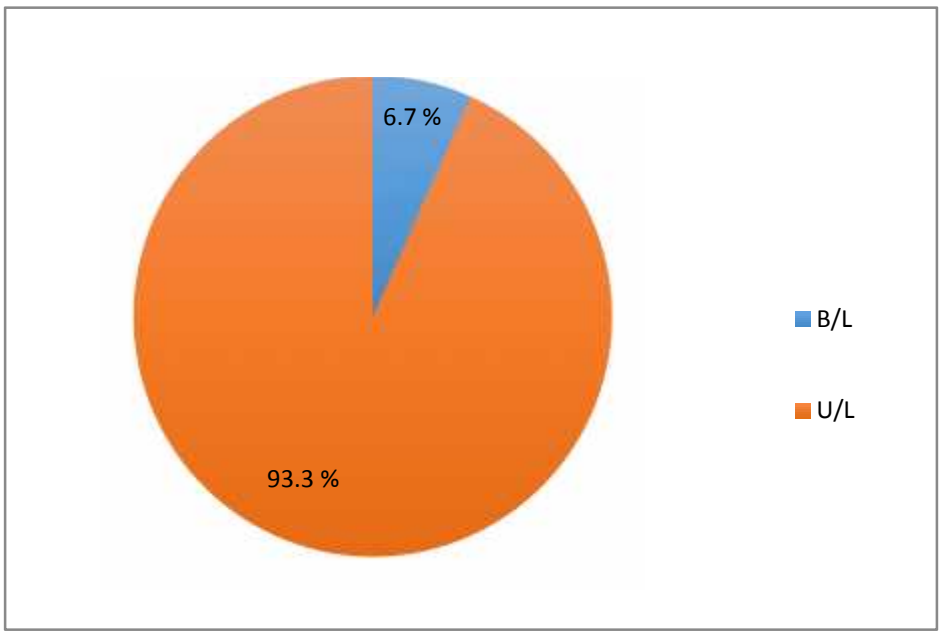
6. DESCRIPTIVE ANALYSIS OF LATERALITY IN STUDY GROUP-

In our study population 2 patients (6.66%) underwent EVLT for B/L lower limbs and 28 patients (93.3%) underwent for single limb.

Table 9: Descriptive analysis of Laterality in Study population

	LATERALITY	
	FREQUENCY	**PERCENTAGE**
B/L	2	6.66
U/L	28	93.3

Graph 4: Pie chart showing distribution of laterality in study group



7. DESCRIPTIVE ANALYSIS OF ULCER HEALING IN STUDY GROUP AT 1 MONTH & 6 MONTHS INTERVAL –

Among 30 patients in our study population, all patients had non healing venous ulcer who underwent EVLA. Post procedure healing rates were assessed at 1 month and 6 months. Baseline minimum ulcer size was 2sq.cm and maximum was 8. At 1 month maximum size was 4 sq.cm, there was significant reduction in ulcer size with P Value of <0.0001.12 patients had complete healing of ulcer. At 6 months maximum ulcer size was 2 sq.cm, with P value of <0.0001.

When ulcer healing was compared between 1 month and 6 months, significant healing in ulcer size was present with P value <0.0001 .

After 6 months 2 patients had residual ulcer with initial ulcer size being 7 and 8 sq.cm, post procedure with regular dressings ulcer healed to 2 sq.cm.

These residual ulcers were treated with AG Foam dressing, which was changed once in 4 days. Grade 1 Compression stockings Grade 1 was applied till below knee level over the dressing and Grade 2 stockings was applied over Grade 1 stockings till groin.

None of the patients in study group underwent skin grafting for ulcer post EVLA.

Table 10: Descriptive analysis of Ulcer healing at 1 month

	BASE LINE				AFTER ONE MONTH					
	MEAN	**S.D.**	**MINI**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
ULCERSIZE	3.47	1.87	2	8	1.40	1.43	0	4	< 0.0001	HS

Table 11: Descriptive analysis of Ulcer healing at 3 months

	BASELINE				**AFTER THREE MONTHS**				
	MEAN	SD	MIN	MAX	MEAN	SD	MIN	MAX	P value
ULCER SIZE	3.47	1.87	2	8	0.23	0.72	0	3	<0.0001

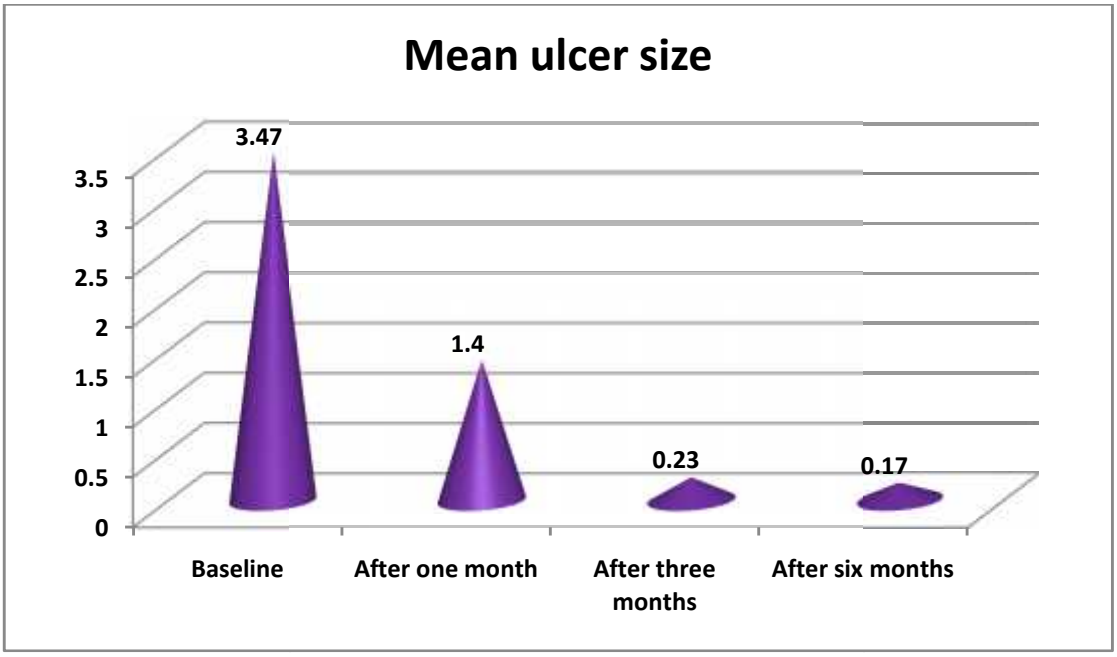
Table 12: Descriptive analysis of Ulcer healing at 6 months

	BASE LINE				AFTER SIX MONTHS					
	MEAN	**S.D**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
ULCER SIZE	3.47	1.87	2	8	0.17	0.53	0	2	< 0.0001	HS

Table 13: Descriptive analysis of Ulcer healing compared with 1 month and at 6 months.

	AFTER ONE MONTH				AFTER SIX MONTHS					
	MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MINI**	**MAX**	**p VALUE**	**INFERENCE**
ULCER SIZE	1.40	1.43	0	4	0.17	0.53	0	2	< 0.0001	HS

Graph 5: Bar graph showing mean Ulcer size comparison



At 1, 3, 6 months follow-up Doppler showed no evidence of residual incompetent perforators/ recanalization of GSV/SSV/ evidence of DVT.

Focal varicosities were present but were non-functioning.

All patients had complete absence or reduction in visible large varicosities.

DISCUSSION

Varicose veins and chronic venous insufficiency (CVI) are major causes of morbidity and decreased quality of life in our population. Venous ulcer is the most advanced stage of CVI. Traditionally practiced surgical high ligation and stripping results in complications such as neovascularization, saphenous nerve injury, delayed wound healing, surgical site infection and morbidity in up to 30% of patients. Carradice et al reported that EVLA had a significantly lesser recurrence rate when compared to surgery, 4.0 versus 20.4% respectively[(43)].Success rate post EVLA is increased because of ablation of direct perforators along with the superficial venous system. Other concerns with traditional surgery included requirement of general anesthesia, longer time to return to routine daily activities and surgical scar. These limitations have led to development of minimally invasive endovenous laser procedures. EVLA is a relatively newer method for treating varicose veins, which is less invasive in comparison with conventional stripping surgical procedure.[(22).]

In our study 30 subjects with proven CVI having non healing venous ulcers were included. As a part of diagnostic work up all subjects had preoperative clinical evaluation, colour Doppler evaluation and underwent endovenous laser ablation of varicose veins (GSV, SSV, direct perforators) as the standard treatment; these patients were included in the study. Following the procedure, patients were assessed for ulcer healing at 1 month, 3 months and at 6 months. Supportive treatment options for all patients included class 2 Compression stockings, which prevents backflow of blood and regular care by use of silver dressings. Compression is unpopular due to discomfort/ longer healing time, and recurrence. EVLA has overcome these

inconsistencies, by being less invasive and more definitive and has become the preferred choice, especially for the elderly and for those with cosmetic concerns. [15]

All the 30 patients underwent EVLA of superficial venous system as a standard treatment option for non-healing venous ulcer along with laser ablation of direct perforators using laser microfiber. Of the 30, 20 were male (66.6%), with mean age group of 43 years.Nwaejike in his five years prospective study, he also noted similar mean age of 45 years[45].Post procedure all patients had check Doppler on POD-1 to confirm complete occlusion of the treated vein and to rule out DVT. Post procedure ulcer healing rates were assessed at 1 month, 3 months and at 6 months. Baseline minimum ulcer size was 2sq.cm and maximum was 8sq.cm. At 1 month maximum size was 4 sq.cm, there was significant reduction in ulcer size with P Value of <0.0001. 12 Patients showed complete healing of the ulcer at 1 month post procedure. At 3 months 16 more patients had their ulcers healed completely and At 6 months , 2 patients had persistent but significant decreased in ulcer size , with the maximum ulcer size being 2 sq.cm, with P value of <0.0001.When ulcer healing was compared between 1 month, 3 months and at 6 months, significant healing in ulcer size was present with P value <0.0001.

Similar to our study, two persistent ulcer at 6 months with decrease in ulcer size, Andrej SikovecAvelana, studied 23 unhealed persistent ulcers treated with EVLA of related perforating and truncal incompetent veins. 21 patients among 23 (91.3%) showed adequate healing of the ulcer. With the commencing of the brand new approach of endovascular ablation of the perforating veins, the remedy for peripheral venous stasis ulcers has become much less invasive with earlier restoration (31).

These residual ulcers were treated with AG Foam dressing, which was changed once in 4 days. Grade 1 Compression stockings was applied till below knee level over the dressing and Grade 2 stockings was applied over Grade 1 stockings till groin.

Incompetent Perforator veins are the most important cause of CVI, leading to recurrent Ulceration. Interventions of these incompetent perforators are proven to heal ulcers and prevent recurrence.[39]. In our study 19 patients had incompetent perforators and underwent laser ablation with microfiber laser for the same. This improved the healing of chronic non-healing ulcers and also showed no recurrence with 18 months follow-up.

Similar to our study 100% occlusion rates were reported by F Pannier, his study with 50 limbs treated with EVLA had complete occlusion, no recurrence or DVT at 6 months follow-up.[42]

NedzadRustempasic, showed return to daily routine life in EVLA was on the first day after intervention, while it was on 12th day in surgical intervention with p value <0.05 [34]. Deanne Leopardi, in his study comparing EVLT vs surgical stripping of veins, ended in a median reflux abolition of 96.3% out of 750 limbs while Surgery had a median reflux abolition of 87.1%, followed up for a maximum of 17 months [27].

L.Yang, X.P. Wang, studied 112 limbs, undergoing EVLA, postoperative recuperation time of the ulcer was earlier in EVLA group than in stripping group with p value < .01. In the EVLA group, complete closure was noted in 116/122 limbs (95.1%) after 1 month [35].Manjit S. Gohel, M.D., studied, A Randomized Trial on EVLA in Venous Ulceration Among the 389 subjects, Early endovenous ablation of

superficial venous reflux resulted in faster recuperation of venous leg ulcers. The median time to ulcer recuperation changed into fifty six days within the early-intervention group [(36)]. Tania Phillips, in her study on the effect of leg ulcers in the quality of life, said that in patients with leg ulcers and Edema, reduction of Swelling was perhaps critical in improving quality of life, which is adequately achieved with EVLA[(37).]

F.Pannier also confirmed return to routine activities in 1.6 days. Regarding analgesic use, 50% didn't take analgesics at any time after the procedure. Twenty-seven patients had slight postoperative pain with a mean value of 0.6. Similar to our study he additionally cited using a 1470 nm diode laser and a radial fibre EVLA which showed high occlusion rates after six months and was also more secure and a good remedy option.New Laser with wavelengths 1470 nm have a better absorption in water and cause less pain and bruising post procedure[(42)].

NedzardRustemoasicalso concluded there is less pain and appreciably less chances of hematoma formation in EVLA group when compared to surgical group[(34)]

No patients in our study group had procedure related complications at 1 year follow-up. One non-randomized comparative study determined the time required to go back to work was less in patients receiving EVLT, both unilaterally and bilaterally, in comparison with patients receiving stripping ($p< 0.001$). Patients who underwent EVLT had reduced postoperative pain, reduced analgesic usage, decreased hematoma and oedema occurrence, and bruising. Similarly Kaushal P, Shen XS studied Forty subjects with unilateral varicose veins treated with EVLA, and concluded that EVLA appears to be a secure and powerful minimally invasive remedy with high quality final results in regards to decreased postoperative pain, early return to routine

activities and less complications [32]. Luis Navarro, in his study had no hematoma, infection, etc., in addition to no heat related complications like skin burns, paresthesias, cellulitis, etc. And none of the patients had thrombophlebitis of the GSV/DVT/pulmonary emboli with 100% closure rate [33].

From our study we observed 100% closure rate, with no evidence of DVT/recurrence. None of the patients had procedure related complications. All patients were discharged 36 hours post procedure.

EVLT is a safe and effective modality of treatment for varicose veins, with minor complications such as burns, recurrence, phlebitis and pain which is mostly due to incorrect procedure. As the knowledge of this technique among Indian surgeons is limited, it is not popular here. EVLT has made the treatment of venous ulcers highly efficient & effective by not only being minimally invasive but by also providing patients with faster recovery and minimal complications and thereby an improved quality of life.[33]

CONCLUSION

- A prospective observational study carried out in a tertiary care centre with 30 participants, who underwent enodvenous laser ablation for non healing venous ulcer.
- In our study the average age is 43 years with 66.6% being male.
- 93.3% of study population underwent EVLT for single lower limb and 6.66% underwent for bilateral lower limbs.
- In 70% of subjects short saphenous vein was also involved and underwent procedure.
- 63% of subjects had incompetent perforators and underwent treatment for the same.

- Among 30 patients in our study group, 7 patients (23.3%) had wider, above lower 1/3 calf pigmentation, 8 patients (26.6%) had diffuse, lower 1/3 calf pigmentation and 12 patients (40.0%) had perimalleolar pigmentation. 3 (10.0%) patients had no skin pigmentation

- Ulcer healing was compared with baseline ulcer size at 1 month , 3 months and at 6 months, which showed significant healing with p value <0.0001.
- Among 30 patients, at 3 months post procedure , 28 patients had their ulcers healed completely with P value being <0.0001
- Even patients who had no longer done recovery in their wounds had a significant reduction in wound size.

- Patients with residual ulcer post procedure were treated with AG Foam dressing, none of the patients underwent surgical management for ulcer healing such as skin grafting
- There was no evidence of recanalization or DVT or recurrence of venous ulcer. None of the patients in our study group had complications associated laser therapy such as ecchymosis, skin pigmentation, hematoma etc.

SUMMARY

- The study was a prospective observational study.
- Patients attending to the department of General Surgery and Interventional Radiology with venous ulcer was advised endovenous laser ablation.
- 30 patients were included in the study after observing the inclusion and exclusion criteria.
- Preoperative Doppler scan of the lower limbs was done to assess the superficial & deep veins and sapheno-femoral junction competence and perforator incompetence.
- Preoperative ulcer management was done before procedure.
- 28 patients underwent EVLT for single lower limb and 2 patients underwent for bilateral lower limbs.
- Doppler scan was performed immediately after the procedure and at the end 6 months and 1 year to check for recurrences.
- Following the operative procedure they were again subjected for regular ulcer size measurements.
- No patient in our study had developed Deep vein thrombosis or recanalization of superficial veins during follow-up period.
- 63% of patients underwent ablation for incompetent perforators also, which had enhanced early ulcer healing and also prevented recurrence.

- Ulcer healing was compared with baseline ulcer size at 1 month, 3 months and at 6 months, which showed significant healing with p value <0.0001. Significant reduction in wound size was noted even in patients with residual ulcer at the end of 6 months.

Advances in imaging and catheter generation has made EVLT possible. EVLT is a short outpatient procedure. It isn't always safe or durable [2,5] but prevents the development of chronic venous leg ulcers in sufferers with isolated GSV incompetence. [8]

Incorporating EVLT has improved patient delight and has helped us cater to a much broader variety of patients more correctly compared to traditional techniques.[2,5]

It is established that venous leg ulcers are more common in elderly population. To treat such chronic non healing venous ulcers a multi-disciplinary approach is required. EVLA treatment that will be particularly appropriate for these elderly population with venous leg ulcers, may improve ulcer healing .Studies with compression bandaging have demonstrated successful healing of venous leg ulcers, but recurrence rates are high. Because of better patient satisfaction and shorter restoration time, endovenous laser ablation grow to be the remedy of desire for varicose.

So we can conclude from our study that EVLT can be offered to elderly patients who are unfit for anaesthesia and young patients looking for superior cosmetic results.

LIMITATIONS AND RECOMMENDATIONS

This study has a few limitations. It was only a prospective observational study with a small sample size. Our follow up period was not long enough to see for recurrence, neo-vascularization and other complaints due to practical difficulties.

This study highlights the effectiveness of EVLA in treatment of venous insufficiency. Besides being less invasive, it is devoid of scars and normal day to day activities can be resumed immediately. Hence, EVLT can be an effective treatment for varicose veins which requires further RCTs to substantiate the evidence

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ANNEXURE I – CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr/Mrs. _____ we are requesting you to enroll yourself in study titled **"TREATMENT OF VENOUS ULCER OF THE LOWER LIMB BY ENDOVENOUS LASER ABLATION: ONE YEAR LONGITUDINAL STUDY**"AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTER BELAGAVI**"** conducted by _____, Post Graduate in M.S. GENERAL SURGERY under the guidance of _____ Department of General Surgery, Jawaharlal Nehru Medical College, Belagavi. And Co-Guide _____, dept. of Interventional Radiology, Jawaharlal Nehru Medical College, Belagavi.

The purpose of research study is to know the beneficial effects of endovenous laser ablation in the treatment of non healing venous ulcers. I will be the investigator for our study. This study is not being funded.Iam going to give you information about this research project. Before you decide, you can talk to anyone you feel comfortable with about the research.

Purpose of the study-

I have been informed by _____, post graduate in M.S.General Surgery under the guidance of _____, Professor Departement of General Surgery,J.N.Medical College, KLE University, Belgavi and _____ Associate Professor,DEPT. of Interventional Radiology ,J.N.Medical college ,Belgavi is conducting a study , to study the treatment of lower leg

venous ulcers by endovenous laser ablation at KLE'S DR.PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELGAVI.

Venous ulcer is the most advanced stage of chronic venous insufficiency (CVI). Active venous ulcers affect 0.3% of the adult population in developed countries

Superficial venous reflux (varicose veins) is usually present in patients with venous leg ulcers. Endovenous interventions (ultrasound-guided foam sclerotherapy) are effective, minimally invasive procedures that are used for the treatment of varicose veins. The purpose of this study is to determine the treatment of lower leg venous ulcers by endovenous laser ablation.

Study procedure-

Once you have signed the informed consent, necessary personal information and detailed medical history will be taken by the investigator. After you will be planned for the proposed procedure. And follow up be done once in a month for upto 3 months or when the ulcer heals. Healing will be assessed based on reduction in size, healthy granulation.

RISKS AND BENEFITS:

There is no increased risk involved in becoming a part of this study and the complications are those which are normally anticipated, such as hematoma, skin discolouration. This study will help us to estimate the efficacy of endovenous laser ablation in non-healing venous ulcer. The results derived at the end of study will benefit all similar patients admitted in this hospital.

BENEFITS OF TAKING PART IN THE RESEARCH:

The treatment modalities are individualized according to patient factors. So, the chosen treatment modality will ensure the maximum efficacy, minimal side effects, and minimize dosing of the drug. Patient will get the benefit of maximum compliance**.**

No bias will be done to the patients who are not willing to participate in the study from the treatment point of view.

VOLUNTARY PARTICIPATION / WITHDRAWAL FROM THE STUDY:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study and may choose to leave the study anytime in between**.**

ALTERNATIVES:

Your decision regarding participation in study will not change present or future health care services offered to you at KLES Dr. PrabhakarKore Hospital and Medical Research Centre, Belagavi.You would simply be excluded from the study if youwish to, and all your details shall be kept confidential and you will get the routine line of management.

PRIVACY AND CONFIDENTIALITY:

All data collected or disclosed by you during the course of participation of study, will be kept fully confidential. If however during the course it becomes necessary for the progress of the course to disclose the identity, it would be done so only after your informed & written consent.

The only people to know that you are a research subject are members of the research team. No information about you will be disclosed to other without your written permission except:

- In emergency to protect your rights AND welfare.
- If required by law.

AUTHORIZATION TO PUBLISH RESULT:

The results of the study may be used to publish an article. When the results of research published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information obtained in connection with this study and that can be identified with you will remain confidential.

FINANCIAL INCENTIVES FOR PARTICIPATION:

No additional costs shall be incurred upon you for the purpose of this study.

It is purely being done with the idea of research and all the cost of study will be borne by the investigator.

COMPENSATION:

In the event that you become injured as a result of taking part in this study, treatment will be offered to you at KLES Dr. PrabhakarKore Hospital and Medical Research Centre, Belagavi, or you will be given information about where to receive medical care. However, no reimbursement, compensation or free medical care will be given**.**

QUESTIONS/CONTACT DETAILS:

You shall be free to contact the below mentioned name & addresses anytime during the study period for any clarification or help as you may desire for.

In case you need any further information regarding your rights as study participant you may contact:

Dr. ROOPA BELLAD **M D**

Professor of Pediatrics& Chairman,

JNMC Institutional Ethics Committee

on Human Subjects Research,

Jawaharlal Nehru Medical College

Consent statement:

I, _____ voluntarily agree for participating in this study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read form in my own vernacular language, including the risks and the benefits and having all my questions answered.

Participant Name : _____

Signature of the Left Thumb Print of Participant : _____

Investigators Name: _____ Signature: _____

Witness Name : _____ Signature: _____

Date: _____

ANNEXURE-II

PROFORMA

TREATMENT OF VENOUS ULCER OF THE LOWER LIMB BY ENDOVENOUS LASER ABLATION

PROFORMA OF CLINICAL EXAMINATION OF INDIVIDUAL PATIENT

Name	
Age	
Address	
Occupation	
Phone number	
Date of admission	
IP No.	

1.Education : 1-Illiterate ☐

2-Primary (1^{st}-7^{th}std)

3-High school (8^{th}-10^{th}std)

4-Intermediate

5-Degree and above

2.Socio-economic status : 1-Low

2-Middle

3-High

Screening -

3.H/O smoking : 1-Yes 2-No

4.H/O other illness : 1-Yes 2-No

5.If yes : 1.Diabetes mellitus

2. Hypertension

3.Tuberculosis

4.Asthma/COPD

5.HIV/AIDS

6.Others

7.Applicant is willing to give consent :

1-Yes 2-N0

8.Final result

1-Inelgible

2-Elgible but refused

3-Elgible and participating

Data collection instrument :

1. Chief Complaints-

2. Onset-

3. Duration -

4. If ulcer -

Site

Number

Progression

5.Associated symptoms- 1.Fever ☐

2.Pain

3.Discharge

4.Itching

5.Dilated veins

6.Any past h/o treatment for ulcer

1.Yes 2.No ☐

7 .If Yes, type of treatment-

8. Has the ulcer healed before-

9. Past medical history-

10. Past surgical history-

11. H/O immobilization/Hospitalization-

CEAP CLASSIFICATION (C3 — C 6)

C0- NO CLINICAL SIGNS	
C1- SMALL VARICOSE VEINS	
C2- LARGE VARICOSE VEINS	
C3- EDEMA	
C4- SKIN CHANGES WITHOUT ULCERATION	
C5- SKIN CHANGES WITH HEALED ULCER	
C6- SKIN CHANGES WITH ACTIVE ULCERATION	

Examination:

Height	Weight	BMI

Pulse rate	Blood pressure	Temperature	Respiratory Rate

Pallor -

Icterus -

Cyanosis -

Clubbing -

Lymphadenopathy -

Pedal edema -

INSPECTION

1. Attitude of the limb-

2. Wound Observations: Ulcer

- Number -
- Site -
- Size -
- Shape -
- Edge -
- Floor -
- Discharge -
- Surrounding skin -

OTHERS:

PALPATION-

1.ULCER- Tenderness-

Edge-

Base-

Depth-

Bleeding on touch-

2.VARICOSE VEINS-

Tenderness or thickening of veins-

Trendlenbergs test 1-

Trendlenbergs test 2-

Three tourniquet test-

3. LYMPH NODE —

4. PERIPHERAL PULSES-

5.OTHER LIMB —

OTHER SIGNIFICANT FINDING

OTHER SYSTEMS

CARDIO VASCULAR SYSTEM

RESPIRATORY SYSTEM

PER ABDOMEN

Investigations-

Doppler report-

Post Procedure Evaluation-

Check USG and Venous Doppler-

Observation-

	Day-1	1 month	3 months	6 months

ANNEXURE-III-ETHICAL CLEARANCE LETTER

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone: (+ 91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 08 **Date: 24/11/2018**

To.

REG NO: B H 0 1 1 8 0 0 6

J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"TREATMENT OF VENOUS ULCER OF THE LOWER LEG BY ENDOVENOUS LASER ABLATION: ONE YEAR LONGITUDINAL STUDY",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

6

ANNEXURE IV: FIGURES

Figure 7: Varicose veins involving Great Saphenous Vein of Left Lower Limb

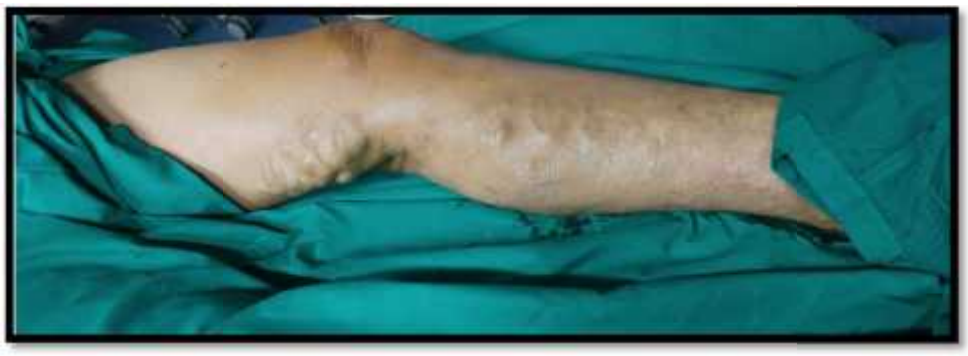


Figure 8: Skin Pigmentation around the ankle

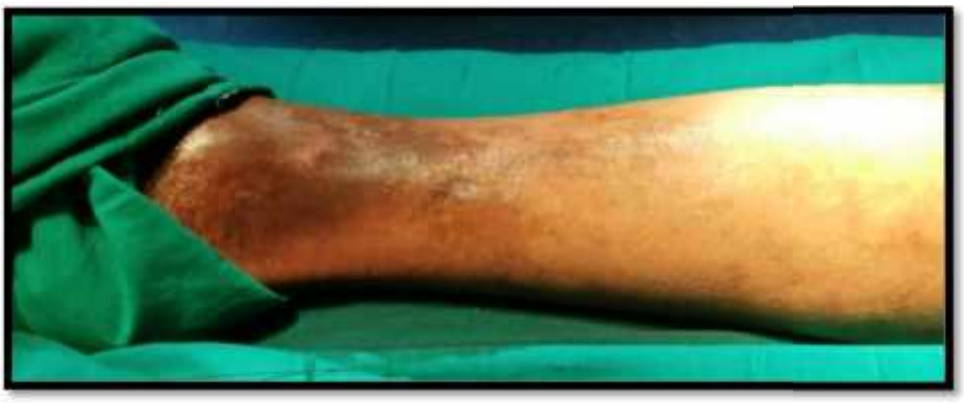


Figure 9: Doppler image showing Sapheno-femoral junction incompetence

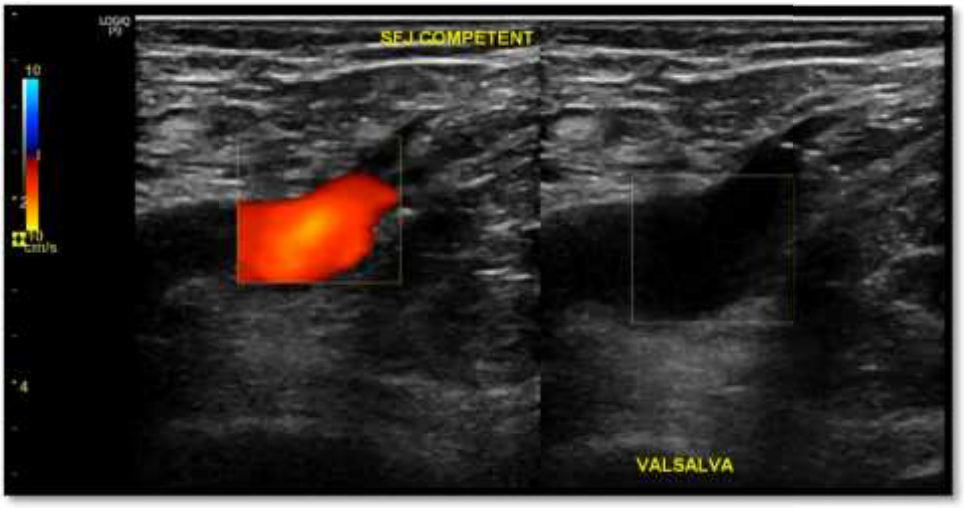


Figure 10: USG Doppler image Showing Sapheno-femoral junction incompetence

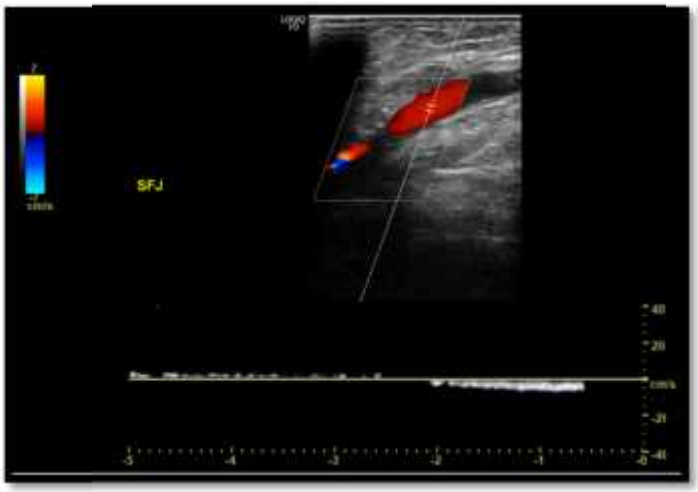


Figure 11: USG image if dilated and tortuous superficial veins

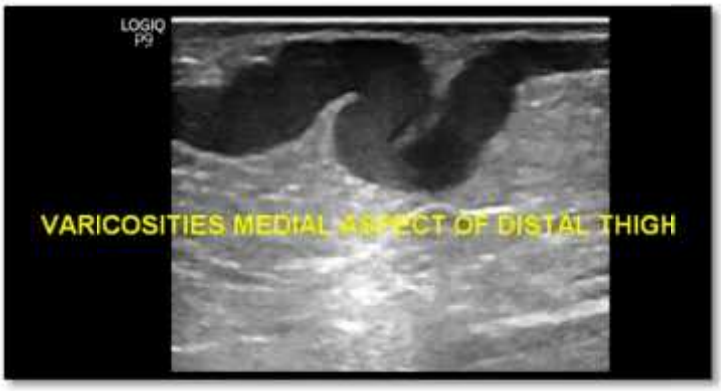


Figure 12: USG image of dilated incompetent perforator

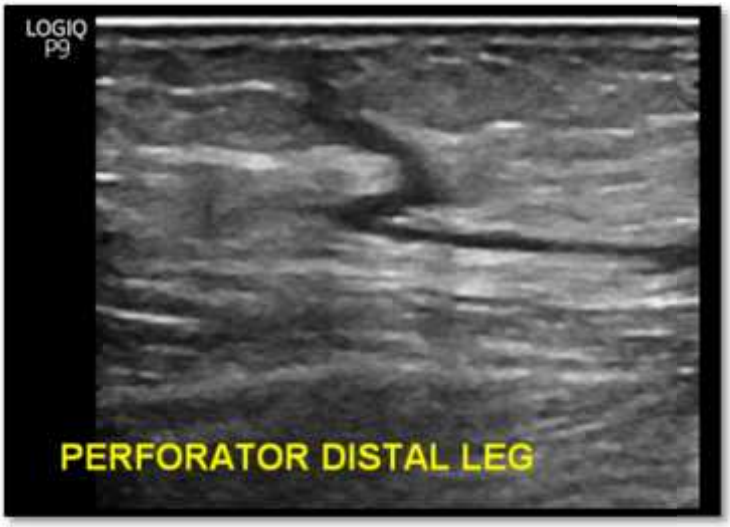


Figure13: EVLT procedure: catheter-tip in position (2cm proximal to SFJ)

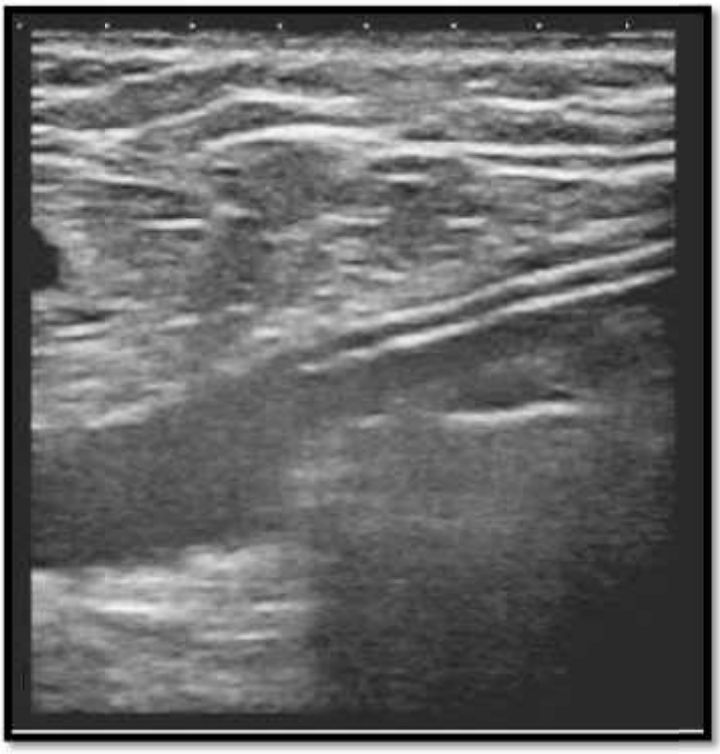


Figure 14: Post EVLT: B-mode image of thrombosis of GSV (axial view)

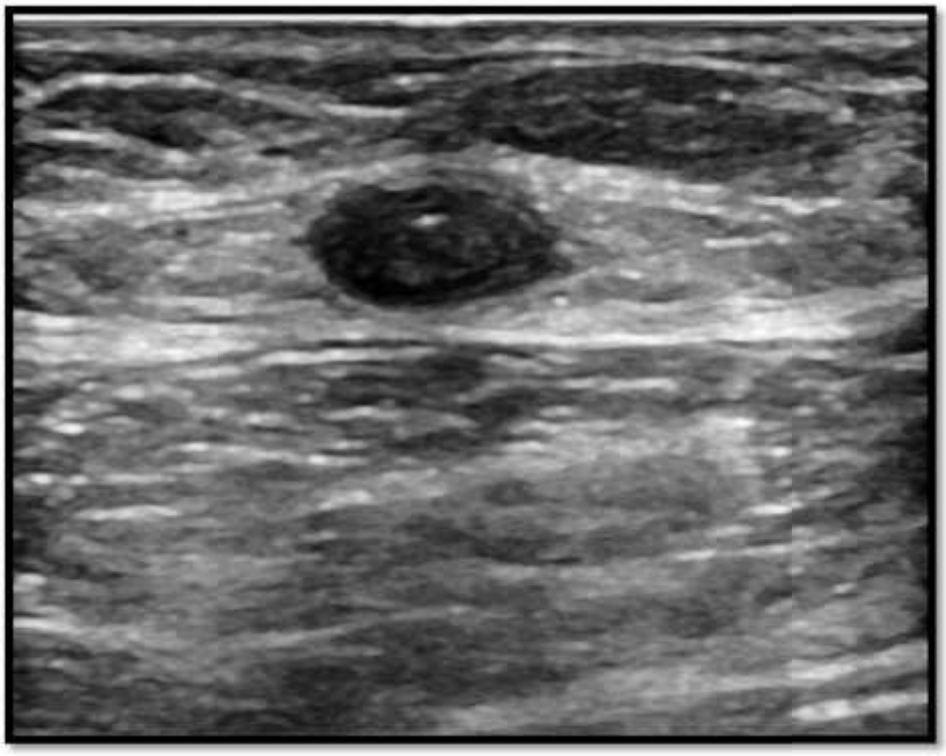


Figure 15: Post EVLT: Duplex imaging of thrombosis of GSV(longitudinal view).GSV- Great saphenous vein, SFV- Superficial femoral vein

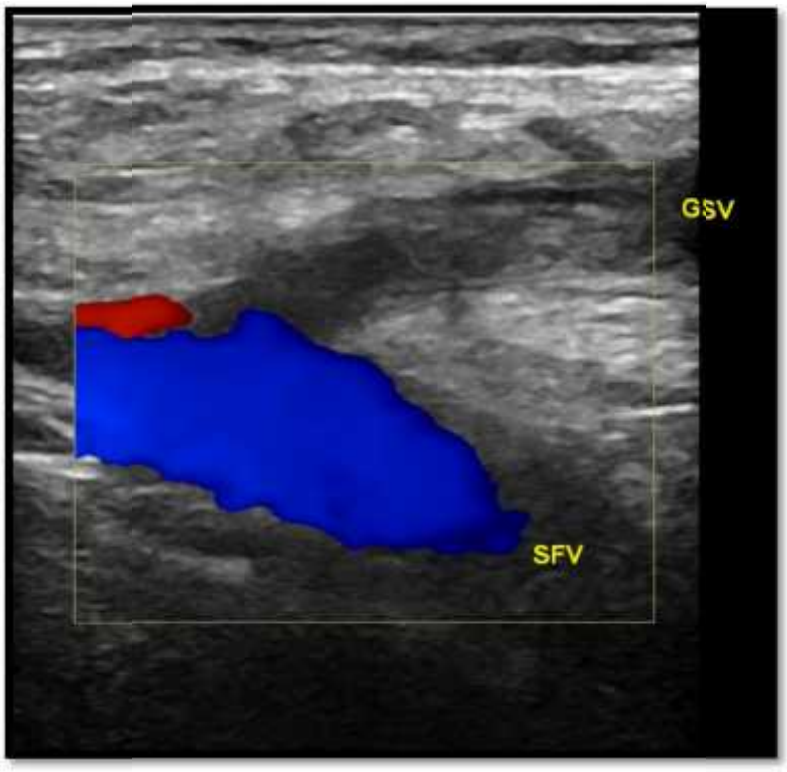


Figure 16: Colour Doppler image of thrombosed GSV (longitudinal vein)

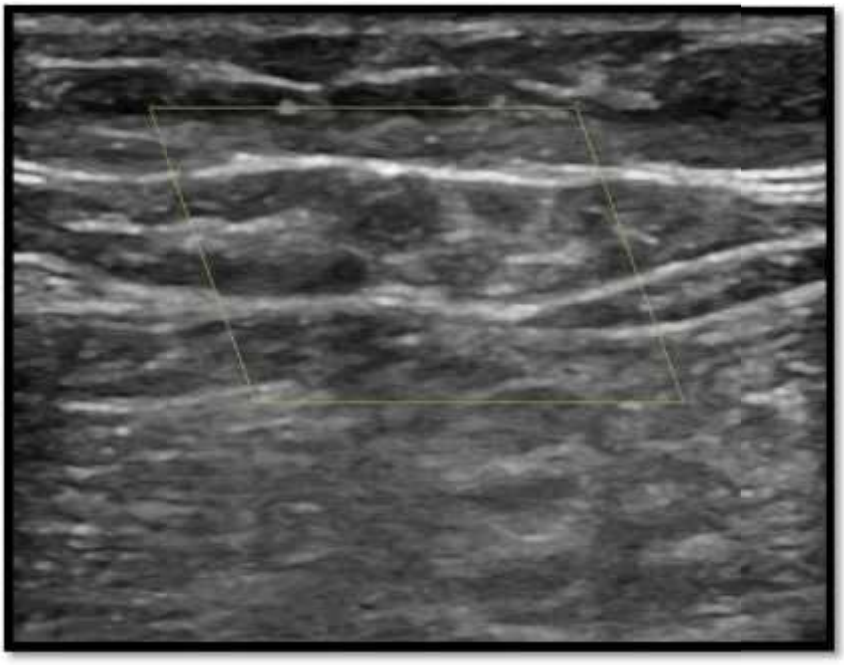


Figure 17: Wound healing post procedure- at 1 month

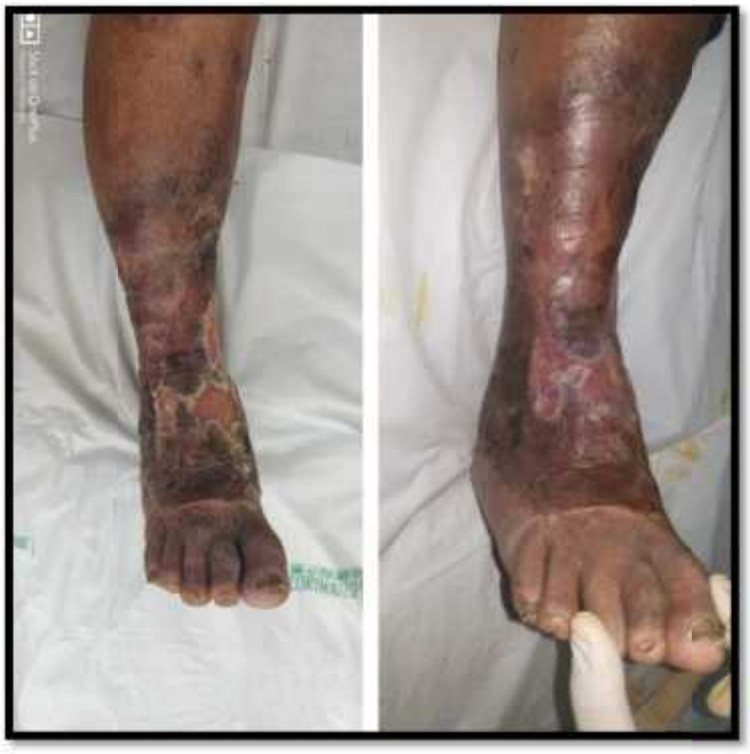


Figure 18: Wound healing post procedure- at 1 month

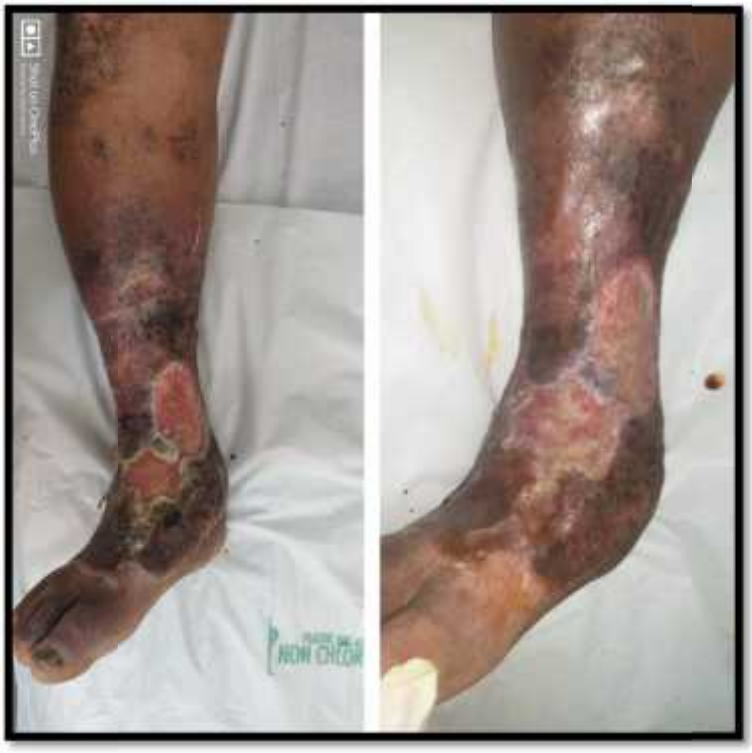


Figure 19: Wound healing post procedure- at 1 month

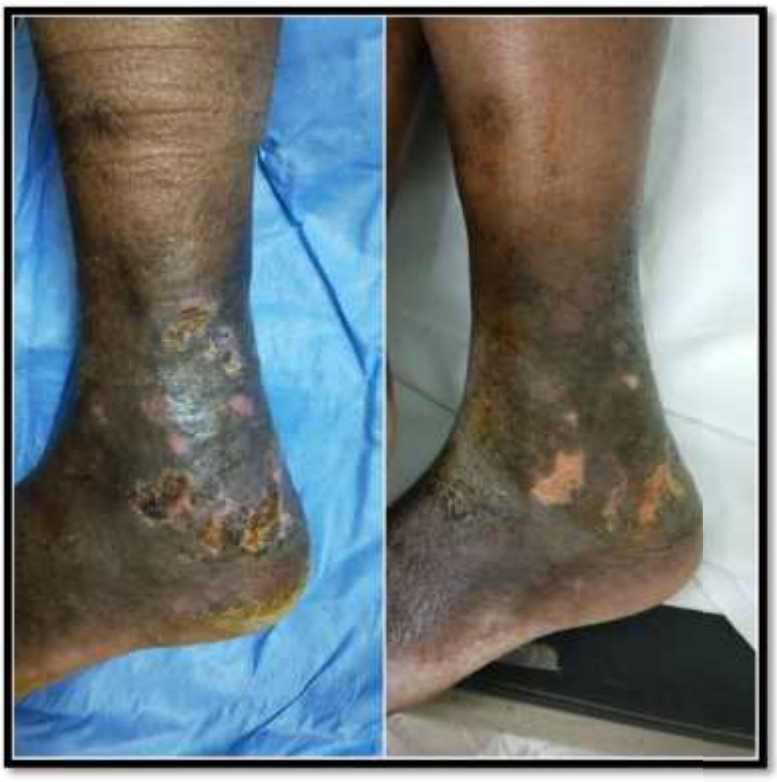


Figure 10: Wound healing post procedure- at 1 month

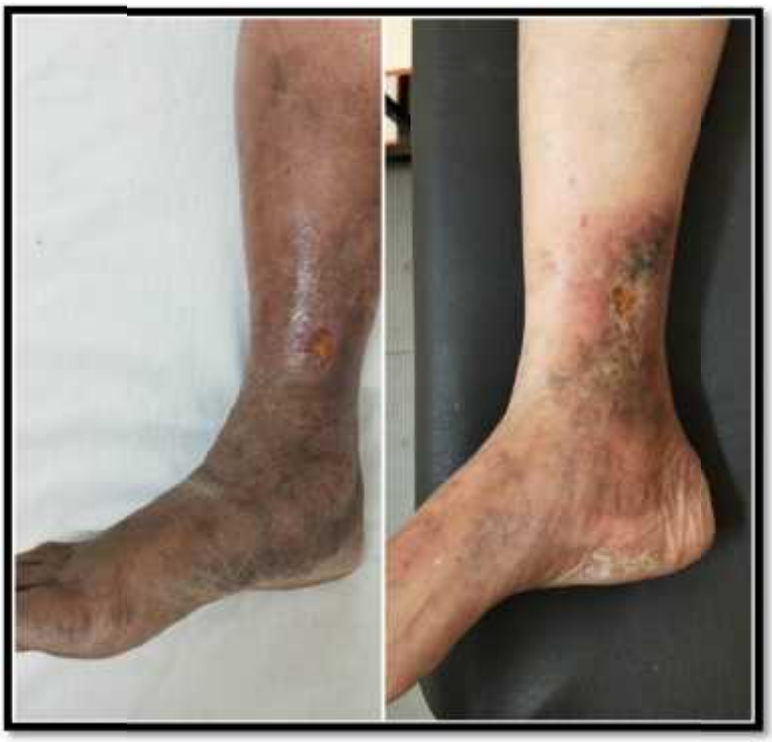


Figure 11: Wound healing post procedure- at 3 months

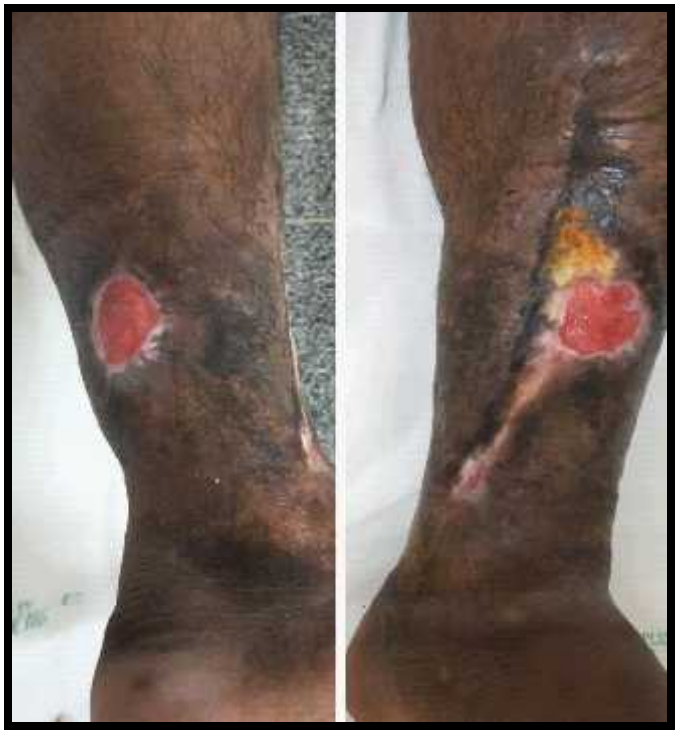
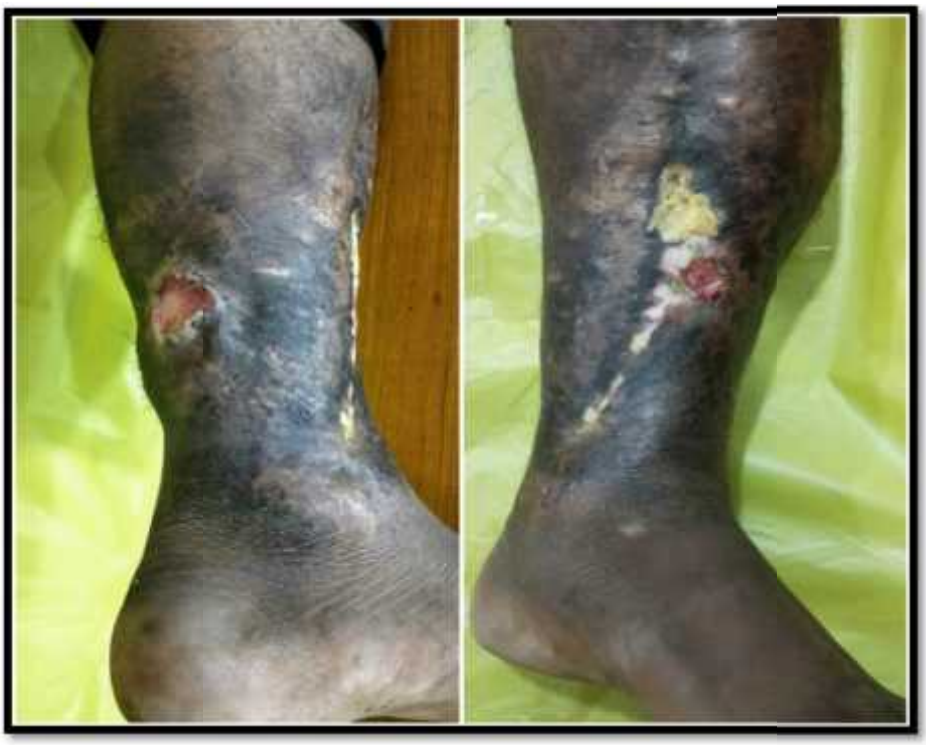


Figure 12: Wound healing post procedure- at 6 months

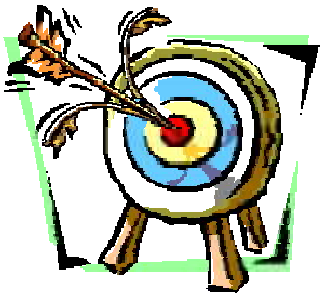


ANNEXURES V - MASTER CHART

SI.NO	IP NUMBER	AGE	GENDER	DIABETES MELLITUS	ULCER SIZE	ULCER DURATION	SKIN PIGMENTATION		LIMB EDEMA	PERFORATORS	SSV INVOLVEMENT	POST OP CHECK DOPPLER	AFTER 1 MONTH	AFTER 3 MONTHS	AFTER 6 MONTHS
1	927505	57	m	present	2	6 months	present	diffuse, lower 1/3rd	none			complete thrombosis of L GSV	1	healed	healed
2	961038	27	m		4	1 year	present	peri malleolar	none			complete thrombosis of L GSV	2	healed	healed
3	923653	51	m		2	4 months	none		present			complete thrombosis of L GSV	healed	healed	healed
4	948331	35	m		5	7 months	present	diffuse, lower 1/3rd	present	present	SSV	complete thrombosis of R GSV	2	healed	healed
5	952691	55	m	present	2	5 months	present	above, lower 1/3rd	present	present	SSV	complete thrombosis of R GSV	healed	healed	healed
6	922938	23	m		4	1 year	present	diffuse, lower 1/3rd	none	present		complete thrombosis of L GSV	2	healed	healed
7	987936	56	m		2	8 months	present	peri malleolar	none			complete thrombosis of R GSV	healed	healed	healed
8	976422	63	m	present	4	9 months	present	peri malleolar	none			complete thrombosis of R GSV	2	healed	healed
9	961488	33	m		2	6 months	none		present	present	SSV	complete thrombosis of L GSV	1	healed	healed
10	988419	23	m		5	8 months	present	above, lower 1/3rd	present		SSV	complete thrombosis of L GSV	3	healed	healed
11	981898	24	m		6	2 months	none		present			complete thrombosis of R GSV	4	2	2
12	990296	39	m	present	8	8 months	present	diffuse, lower 1/3rd	none	present		complete thrombosis of R GSV	4	healed	healed
13	925666	24	m		2	3 months	none		present	present	ssv	complete thrombosis of L GSV	healed	healed	healed
14	989147	26	m		2	1 year	present	above, lower 1/3rd	none			complete thrombosis of L GSV	1	healed	healed
15	985560	27	m		6	13 months	none		present		ssv	complete thrombosis of L GSV	3	healed	healed

SI.NO	IP NUMBER	AGE	GENDER	DIABETES MELLITUS	ULCER SIZE	ULCER DURATION	SKIN PIGMENTATION		LIMB EDEMA	PERFORATORS	SSV INVOLVEMENT	POST OP CHECK DOPPLER	AFTER 1 MONTH	AFTER 3 MONTHS	AFTER 6 MONTHS
16	939308	43	m	present	4	4 months	present	peri malleolar	present	present		complete thrombosis of L GSV	2	healed	healed
17	953419	32	m		2	8 months	present	diffuse, lower 1/3rd	none	present		complete thrombosis of B/L GSV	healed	healed	healed
18	981386	48	m	present	2	14 months	present	diffuse, lower 1/3rd	none		ssv	complete thrombosis of L GSV	healed	healed	healed
19	981050	67	m	present	8	8 months	present	peri malleolar	present		SSV	complete thrombosis of B/L GSV	4	3	2
11	946294	30	m		2	7 months	present	peri malleolar	none			complete thrombosis of R GSV	healed	healed	healed
21	928204	65	f	present	4	8 months	present	diffuse, lower 1/3rd	none			complete thrombosis of R GSV	2	healed	healed
22	956152	45	f		2	3 months	none		present			complete thrombosis of L GSV	healed	healed	healed
23	934470	46	f		2	4 months	none		present	present		complete thrombosis of R GSV	1	healed	healed
24	959786	50	f	present	4	1 month	none		present			complete thrombosis of L GSV	2	healed	healed
25	938713	54	f	present	2	8 months	present	peri malleolar	none			complete thrombosis of R GSV	healed	healed	healed
26	951317	61	f		6	2 months	none		present	present		complete thrombosis of L GSV	4	2	healed
27	978063	41	f		2	13 months	present	above, lower 1/3rd	none		SSV	complete thrombosis of R GSV	healed	healed	healed
28	978018	53	f		2	2 years	present	above, lower 1/3rd	none			complete thrombosis of L GSV	healed	healed	healed
29	976391	64	f	present	4	2 months	none		present			complete thrombosis of L GSV	2	healed	healed
30	920925	29	f	present	2	4 months	present	peri malleolar	present	present		complete thrombosis of L GSV	healed	healed	healed

Introduction



Objectives

Review of Literature

Methodology

Results

Discussion

Conclusion

Summary

Limitations & Recommendations

Bibliography

Annexure-I

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Annexure-II

Annexure-III

Annexure-IV

Annexure-V