"EVALUATION OF ENDOVENOUS LASER ABLATION AS A TREATMENT OF VARICOSE VEINS - A ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY"

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Yours sincerely,

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LIST OF ABBREVIATIONS

SFJ	Saphenofemoral junction
IC	Incompetent
C	Competent
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

Background & objectives

"Varicose veins are defined as dilated and tortuous subcutaneous veins of diameter more than 3 mm when measured in the standing position with demonstrable reflux on valsalva."

In a study done in north India on 1012 subjects, 46.7% & 49.3% of females and 27.8% & 18.9% of males were found to be having varicose veins & venous symptoms respectively.

The symptoms of varicose veins are due to venous hypertension resulting from reflux in one or more of veins of the saphenous system and in their tributaries. The pathophysiology is mainly related to the changes in vein wall leading to venous dilatation and secondary valvular incompetence.

Duplex ultrasound imaging is the mainstay of investigation of varicose veins. Duplex imaging can evaluate valve incompetency, extent of reflux, thrombosis, and number, location & diameter of incompetent perforators.

Several methods have been used to treat varicose veins. Traditional open surgical methods include ligation of GSV near its drainage and stripping. With advances in science and technology, modalities such as "foam sclerotherapy, EVLT and endovenous radiofrequency ablation (RFA), Mechanochemical endovenous ablation (MOCA) and Glue therapy" are being used commonly as they are less invasive.

EVLT was first introduced by Carlos Bone, a Spanish phlebologist, in 1998. It is a minimally invasive procedure for treating varicose veins performed usually on veins that are still fairly straight and less tortuous with the use of catheters & lasers

and ultrasound guidance for insertion of catheter & administration of local anaesthesia.

The objectives of this study are to assess the postoperative pain, complication rates and improvement in symptoms post endovenous laser ablation.

Materials and methods

One year prospective observational study was done in Department of Radio-diagnosis at the KLE'S Dr. Prabhakar Kore hospital & MRC, Belagavi.

50 patients with varicose veins diagnosed clinically and further confirmed by Doppler ultrasound scanwere included in the study.

After considering the inclusion and exclusion criteria, the patients were subjected to:

1. Preoperative Doppler scan of the lower limb to assess the superficial & deep veins and sapheno-femoral junction competence and
2. Venous clinical severity score (VCSS)

Following the operative procedure they were again subjected to VCSS on post-op day1, day 3, week 1, week 2 and at 3months.

Doppler scan using standard protocol was performed immediately after the procedure to check for GSV thrombosis & to rule out deep vein thrombosis and at the end of 3 months to check for recurrences.

Results

The mean age in our study was 45.24 ± 12.81 years with 39 (78%) males and 11 (22%) females.

Among the study population, 1 (1.8%) participant did not have any incompetent perforator in his lower limb, 19 (33.3%) lower limbs had only 1 incompetent perforator, 24 (42.1%) had only 2, 9 had only 3, 2 of the lower limbs had 4 and 2 of the lower limbs had 5 incompetent perforators each.

Among the study population, 28(49.1%) of lower limbs had Perimalleolarpigmentation,19 (33.3%) had Diffuse, lower 1/3 calf pigmentation and 3(5.3%) of lower limbs had Wider, above lower 1/3 calf pigmentation.

Among the study population, 4(7.0%) lower limbs had single active ulcer and 1(1.8%) of the lower limbs had two active ulcers.

The mean of pre-operative VCSS score was 12.42 ± 3.42 in the study population, minimum level was 8 and maximum level was 22, it was 11.79 ± 3.15 in post-operative day 1, it was 10.93 ± 3.13 in the post-operative day 3, it was 9.98 ± 3.1 in post-operative 1st week, it was 8.3 ± 2.49 in post-operative 3rd week and it was 6.91 ± 2.07 in Post-Operative 3rd month.The differences in the total score at day 1, day 3, week 1 and week 3 follow up period with baseline value (pre-operative) were statistically significant (P value <0.001).

No patient in our study had developed Deep vein thrombosis or recanalization of superficial veins on Doppler study at 3 months follow-up.

Interpretation and conclusion

Endovenous approach is advantageous in being able to do the procedure under local tumescent anaesthesia, having smaller number of complications postoperatively like pain, nerve injury, hematoma and also has the added advantage of early discharge. Whereas, Traditional surgery for varicose veins will have major/ minor complications including wound infections (most common), nerve injury, venous thromboembolic complications etc. Traditional surgery is related with higher postoperative pain scores. Recanalisation or persistence of reflux are less common with EVLA compared to conventional surgery.

Thus the study concluded that endovenous laser ablation is one of the best treatment modality for varicose veins with lesser complications and early discharge.

Keywords: Varicose veins, Endovenous laser ablation, Venous clinical severity score.

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INTRODUCTION

"Varicose veins are defined as dilated and tortuous subcutaneous veins of diameter more than 3 mm when measured in the standing position with demonstrable reflux on valsalva."

The prevalence estimates of venous insufficiency vary according to geographical location, with the highest being reported in the western countries.

Among adults, women have greater prevalence of visible varicose veins when compared to men, that is roughly 25-30 % in women & 15 % in men and the prevalence increases with age. Ethnicity has some influence, with the prevalence being higher with increase in BMI and height. Other risk factors are pregnancy, family history, genetics, smoking, deep vein thrombosis, occupations involving prolonged standing with nurses having high risk among health care professionals.

In a study done in north India on 1012 subjects, 46.7% & 49.3% of females and 27.8% & 18.9% of males were found to be having varicose veins & venous symptoms respectively.[1]

The most frequent symptoms in patients with varicose veins include pain and heaviness, which usually increases throughout the day and on prolonged standing. Elevation or compression therapy gives some relief. Other symptoms include ankle swelling, itching & discolouration. Complications include bleeding, eczema, superficial thrombophlebitis, ulceration and lipodermatosclerosis.

The symptoms of varicose veins are due to venous hypertension resulting from reflux in one or more of veins of the saphenous system and in their tributaries. The pathophysiology is mainly related to the changes in vein wall leading to venous dilatation and secondary valvular incompetence.

Duplex ultrasound imaging is the mainstay of investigation of varicose veins. A high-frequency linear array transducer of 7.5-13 MHz is used. Duplex imaging can evaluate valve incompetency, extent of reflux, thrombosis, and number, location & diameter of incompetent perforators. Venous reflux is said to be present when the retrograde flow lasts for more than 1/2 second.

Several methods have been used to treat varicose veins. Traditional open surgical methods include ligation of GSV near its drainage and stripping of abnormal vein. With advances in science and technology, modalities such as "Foam sclerotherapy, Endovenous laser ablation (EVLA), Endovenous radiofrequency ablation (RFA), Mechanochemical endovenous ablation (MOCA) and Glue therapy" are being used commonly as they are less invasive.

20% of patients who undergo traditional surgery for varicose veins will have major/ minor complications including wound infections (most common), nerve injury, venous thromboembolic complications etc. Higher postoperative pain scores and higher rate of recurrence are seen with surgical stripping compared to endovenous approaches. The relapse rate with traditional surgical methods is about 30 - 60 %.[2, 3] This could be owing to the procedure being performed inadequately, incomplete vein stripping and occurrence of neo-revascularization at the site of confluence. The advantage of endovenous approach is being able to do the procedure under local

tumescent anaesthesia, having smaller number of complications postoperatively like pain, nerve injury, hematoma and also has the added advantage of early discharge.

Endovenous laser therapy (EVLT) was first introduced by Carlos Bone, a Spanish phlebologist, in 1998.[3] It is a minimally invasive procedure for treating varicose veins performed usually on veins that are still fairly straight and less tortuous with the use of catheters & lasers under ultrasound guidance for insertion of catheter & administration of local anaesthesia. The laser light emitted at the catheter's tip causes photothermocoagulation of blood and complete destruction of endothelium, denaturating the collagen in the vessel wall resulting in its closure. The benefit of laser is the red spot of light which is evident through the skin at the end of the fiber, allowing for the setting of the tip, in addition to the ultrasound.

Temperature and energy should be watched continually which may harm other cells. Evidence from systematic review suggests that recurrence of reflux at 6 weeks and one year are less commonly seen with Endovenous laser ablation (EVLA) compared with conventional surgery.[4] The success rates are almost similar in RFA and EVLA. But EVLA using radial fiber at 1470 nm is better in terms of pain and satisfaction of the patient compared to RFA.[5] EVLA is generally a safe day care procedure taking about only 1 hour to perform. It also requires just one small incision. Besides being less invasive, it is devoid of scars and normal day to day activities can be continued immediately.

Need of the study

Varicose veins cause serious morbidity and lead to reduction in quality of life. Literature in India using EVLT as a modality of treatment for varicose veins is very limited. Hence, this study was designed to assess the role of EVLA as its treatment option with the objective to estimate the pain, complication rates and improvement in symptoms including ulcer healing post endovenous laser ablation.

AIM AND OBJECTIVES

- To assess the postoperative pain, complication rates and improvement in symptoms post endovenous laser ablation.

REVIEW OF LITERATURE

Varicose veins are elongated, dilated and tortuous superficial veins especially of the lower extremities of the body and are often examined by touching.[6,7] It mainly arises because of incompetent deep, superficial or perforators valves leading to reflux of blood and venous pressure increase in these veins. This condition is considered primarily a cosmetic problem and is given less clinical importance and further lesser importance for treatment. High pressure on legs especially during standing leads to itching, with painful sensation, edema, cramps and discoloration. Varicose veins predominantly affecting the great saphenous vein are a source of distress, pain, disability, and lead to reduced quality of life.[8]

EPIDEMIOLOGY OF VARICOSE VEINS:

The Prevalence of varicose veins varies depending on area of distribution. Highest rates were reported in Western countries. The prevalence for chronically dilated superficial veins varied from less than one percentage to about forty percentage in females and from around less than one percentage to about seventeen percentage in men.[5] This difference is mainly due to differences in the population distribution, their risk factors, the diagnostic criteria used and treatment resources that were available. The prevalence of varicose veins vary widely and ranges from 2% to 56% in males and 1% to 60% in females.[10] The management of chronic venous insufficiency accounts for approximately 2% of the total healthcare in United States.[11] Varicose veins are most common in elderly aged people, chronic smokers, and during pregnancy. Females are more predisposed to this condition than males. A cross-sectional study of 40,000 patients in Poland showed females are more prone to this

condition (61% of women and 38% of men).[12] In a study performed in northern part of India on 1012 subjects, 46.7% of females and 27.8% of males were seen to have varicose veins whereas 49.3% of females and 18.9% of males were seen to be having venous symptoms.[1]

PATHOPHYSIOLOGY

The pathophysiology of chronic venous insufficiency is either due to backward flow or block to venous blood flow. This results in venous hypertension involving the affected part. Superficial incompetence is generally due to weakened or abnormally shaped valves or widened venous diameter which prevents normal valve congruence. Deep vein functional abnormality is likely due to past DVT. Previous DVT causes inflammatory changes, adhesions, scarring of valves and reduced caliber of vessel. High pressures result in dilatation of superficial veins after dysfunction of valves of perforating veins. The resultant dilatation causes improper function of valve cusps in superficial veins. The resting pressure in the veins is influenced by impedance to outflow, capillary inflow, valve function, and muscle pump function. The constant elevation of hydrostatic pressure in venous system results in pain, swelling and microangiopathy involving venous system. Few people were observed to have skin hyperpigmentation due to hemosiderin deposition from the red blood cells. Many patients were also observed to have lipodermatosclerosis. With the progression of pathological process, the impaired microcirculation and skin weakening results in ulcer formation.[13]

CLINICAL PRESENTATION:

"General complaints related to venous insufficiency depends on severity of the insufficiency and accompanying pathologies. Discoloration, pain, cramps, itching, edema and ulcerations at legs are symptoms accompanying to venous insufficiency".[14] The common clinical features are pain and swelling followed by itching, open ulceration, edema, cramps and discoloration.[15] There are various clinical features of this condition. Patients may present with complicating features like venous ulcer, bleeding, lipodermatosclerosis, pulmonary embolism, hematoma or deep vein thrombosis.[16] Risk factors include old age, female sex, pregnancy, obesity, heredity, ingestion of oral contraceptives, smoking, standing or sitting for long periods of time.[14]

CLASSIFICATION OF CHRONIC VENOUS DISORDERS (CVD):

Standardized classification systems are needed to have a universal standard practice for the diagnosis and management of CVD. In order to maintain consistency in medical venous reporting, many classification systems such as CEAP classification system – 2003[17] and its revision in 2004[18], Venous severity scoring - 2000[19] and the nomenclature extensions and refinements of the veins of the lower limbs – 2005[20] have been developed.

CEAP CLASSIFICATION: [17,18,21]

There was deficiency in accurate diagnosis of chronic venous pathology previously. This led to conflicting literature in treatment of the particular venous problems in an era where new modalities are available for simple and complicated venous pathologies. It was thought that these problems could be solved by accurate

diagnosis and classification of the underlying venous problem. To promote proper communication about CVD, the CEAP classification (Clinical-Etiology-Anatomy-Pathophysiology) was adopted globally. This served an important means of better scientific evaluation of treatment modalities. This classification was relied upon accurate diagnosis and was a systematic guide for investigations. It also acted as a base for precise treatment. The international ad hoc committee of the American Venous Forum proposed the CEAP classification for chronic venous disorders (CVD) in 1994. This was recommended by the Society for Vascular Surgery and in 1995 it was included in "Reporting Standards in Venous Disease".[22] CEAP was used in most of the current literature on CVD. For development of a classification system for venous disease, in 1993 at the Fifth Annual meet of the American Venous Forum (AVF) John Porter suggested use of similar approach as the TNM classification (Tumor/Node/Metastasis). The first CEAP consensus document was proposed in February 1994 at the 6th Annual Meet of AVF by international ad hoc committee, chaired by Andrew Nicolaides.

It contained 2 parts: a classification of CVD and a scoring system of the severity of CVD.

The first CEAP classification was based on

1. Clinical features (C),
2. Etiology (E),
3. Anatomic distribution of the pathology (A), and
4. Underlying Pathophysiological features (P).

The severity scoring system was based on 3 elements:

1. Number of anatomic segmentsinvolved,
2. Grading of signs andsymptoms, and
3. Disability caused.

CEAP is a type of descriptive classification. Venous severity scoring was proposed to enable longitudinal outcome measurement and it was realized that CEAP required updating and modification. In April 2002 an ad hoc committee on CEAP appointed by AVF reviewed the classification and maderecommendations for change by the year 2004. The updation includedadditions to or refinements of definitions utilized in CVD; refinement of the C classification; addition of the ndescriptor (no venous abnormality detected); incorporation of the date of classification and level of investigation; and the description of basic CEAP. This was introduced as a simpler alternative to the full (advanced) CEAP classification.[18]

Advanced CEAP: Same as basic CEAP, with addition that any of 18 named venous segments can be used as locators for venous pathology"

1. Superficial veins	Telangiectasias or reticular veins
	Great saphenous vein above knee
	Great saphenous vein below knee
	Small saphenous vein
	Nonsaphenous veins
2. Deep veins	Inferior vena cava
	Common iliac vein

	Internal iliac vein
	External iliac vein
	Pelvic: gonadal, broad ligament veins, other
	Common femoral vein
	Deep femoral vein
	Femoral vein
	Popliteal vein
	Crural: anterior tibial, posterior tibial, peroneal veins
	(all paired)
	Muscular: gastrocnemial, soleal veins, other
3. Perforating veins	Thigh
	Calf

CLINICAL CLASSIFICATION:

A subscript is further added to each clinical category. The subscript for presence of symptoms is S and for the absent of symptoms is A, for example C3A or C4S. Clinical features are due to venous dysfunction and include tightness, pain, heaviness, skin irritation, muscle cramps etc. For betterment of the assignment of designations under E, A, and P a new descriptor, n, is now used where no venous pathology is identified. This n could be added to E (En, meaning no venous cause noted), A (An, meaning no venous location noted), and P (Pn, meaning no venous pathophysiology noted).[23,24] CEAP is not a static classification, with scope of reclassification.

Classifying the disease begins with the patient's first visit and is better evaluated after further investigations. Any CEAP classification be followed by the date.

MANAGEMENT OF VARICOSE VEINS:

Numerous therapies have been developed for the treatment of varicose veins. Treatment of varicose veins includes both conservative and surgical management. In conventional open surgical intervention, the great saphenous vein is ligated at the saphenofemoral junction and stripped. Recently, modalities which are less invasive, such as foam sclerotherapy, endovenous laser therapy (EVLT) and endovenous radiofrequency ablation (RFA), are also being used. Postoperative complications such as hematoma, pain or saphenous nerve injury are fewer with endovenous approaches and allows early discharge following the surgery. The main aim of the surgery is to relieve the patients from symptoms. Surgery is preferred only in CEAP C2 and above stages. Conservative modalities include compression therapy, pharmacotherapy and lifestyle modification.[15,25]

ENDOVENOUS LASER ABLATION (EVLA)

Carlos Bone, who is a Spanish phlebologist, introduced this modality in 1998.[3] EVLA is a minimally invasive procedure which uses laser energy transmitted through a fiber to obliterate the vein.[3] Steam bubbles will be generated due to boiling of blood in the vascular lumen resulting in heat injury to the vein wall. The procedure is done by injecting anesthetic agent locally in the perivascular plane. This is a method for treating superficial dilated veins by using laser light so this is called endovenous laser ablation (EVLA).[3] The advantage of this method is the presence of a red spot of light visible through the skin at the tip of the fiber, which will allow for the positioning of

its tip. Ultrasound also assists in positioning during the procedure. Temperature and energy should be monitored continuously, otherwise it may harm other cells. It is determined empirically on the basis of the power of laser and the speed at which the fiber is pulled. For the 810 nm laser. The values recommended oscillate between 50 to 80 J/cm. The top of the optical fiber should move 1 cm in 5 seconds when the power is set at 14 watts. The temperature reaches up to 800 degrees Celsius at the top of the fiber causing the blood to boil. The high temperature is transferred by blood to the vein wall damaging it evenly within the short segment. Both these processes result in complete destruction of endothelium, denaturating the collagen in the vessel wall, and coagulation of the lumen.[26] This causes blood to stop flowing through the vein. As the body recovers after the procedure, circulation becomes more efficient since blood is not flowing through a faulty vein and the problem vein shrinks and fades. Initially, Laser wavelengths of 810, 940 and 980 nm, were introduced, which are absorbed by deoxyhemoglobin, mostly resulting in heating of the blood due to weaker action on the vessel wall.

"Five mechanisms have now been identified that at least theoretically contribute to the efficacy of EVLA.[26] The first four are the long-term consented thermal laser–tissue interaction mechanisms that cause the temperature of the vein wall to increase, the assumed thermal key mechanism of EVLA efficacy.

1. Direct contact between fiber tip and vein wall.
2. Thermal interactions between the laser light emitted out of the fiber tip and the vein wall.
3. The effects of steam bubbles, which were touted but not proven to be the main EVLA mechanism.[27]

4. The effects of the carbonized blood layer glued on the fiber tip.
5. The sequelae of thermal injury of *blood*, forming coagula within the vein lumen".

Similar success rates are seen with EVLA and RFA. However, EVLA at a wavelength of 1470 nm and using radial fiber is superior to RFA in terms of pain and patient satisfaction.[5] Studies comparing EVLA at low wavelengths (810, 940 and 980 nm) and RFA generally have reported equal success between them, although RFA has fewer side-effects and greater patient satisfaction.[28,29] The 1470-nm diode laser is safe and highly effective for endovenous laser treatment of varicose veins in the great saphenous vein. It significantly minimizes adverse effects compared with the bare laser fiber due to the lower energy level needed with the radial laser fiber.[30] Evidence from systematic review suggests that recanalisation or persistence of reflux at six weeks and at one year are less common when EVLA is performed as compared to conventional surgery.[4]

ADVANTAGES OF EVLA:

EVLA is safe, and although more energy is used, this does not translate to higher complication rates.[31] Its advantages are

1. Generally safe and free of complications
2. It is a day care procedure taking about only 1 hour to perform
3. Requires just 1 small incision
4. Less invasive

5. Absence of scars
6. Resumption of normal day to day activities immediately

DISADVANTAGES OF EVLA:

The following are common complications reported after EVLA in the study by Liu J-J et al.[32]

1. Skin burns (10%)
2. Induration (33%)
3. Swelling (21%)
4. Paresthesia (23%)
5. DVT or PE (<1%)
6. Recanalisation (<1%)

LACUNAE IN LITERATURE:

Varicose veins are a manifestation of chronic venous insufficiency, which can progress to serious morbidity. EVLT is an effective treatment for varicose veins, with probable complications such as burns, recurrence, pain, phlebitis, and others, due to incorrect operation. But reduced exploration of this technique in india has limited the literature. Better understanding of real-world treatment outcomes may improve the management of patients with varicose veins.

MOST RELEVANT STUDIES:

Abd El-Mabood E-S et al[33] conducted a prospective study in 44 patients to determine the advantages and efficacy of endovenous laser ablation versus conventional stripping in the treatment of great saphenous vein reflux. During the study period, participants was grouped into group A and group B based on the intervention performed. The conventional surgical stripping for the great saphenous vein was grouped as A, while endovenous laser ablation as group B. The clinical evaluation, routine hematological tests, and venous duplex of both lower limbs were performed among the participants. The study results revealed that the procedure done in 90.8% of the patients in the group B was under tumescent anesthesia with less mean postoperative time. The mean postoperative time and postoperative pain rate were less in the endovenous laser ablation group with 61± 3 min and 4.05 ± 1.23 min respectively. Bruising and Ecchymosis were the complications present in one week in 23.8%. The superficial phlebitis, thrombosis and skin burn were developed in 14.28%, 9.52% and 4.76% respectively. Group B showed rapid return to normal activity and overall results as compared to group A. They concluded that the simplest, safe and effective method for the treatment of great saphenous vein is the endovenous laser ablation.

Biemans AA et al[34] performed a study in 240 participants "to compare the anatomic success rate, frequency of major complications, quality-of-life improvement of endovenous laser ablation, ultrasound-guided foam sclerotherapy and conventional surgery after 1-year follow-up. The anatomic success was the primary outcome, while complications, improvement of the "C" class of the CEAP classification, improvement of disease-specific (Chronic Venous Insufficiency Quality-of-Life Questionnaire) and general (EuroQol 5) quality-of-life scores were the secondary outcomes. The study results revealed that 80% of the patients were classified as C2 or

C3 venous disease. The highest anatomic rate was after endovenous laser ablation with 88.5% followed by conventional surgery and ultrasound-guided foam sclerotherapy with 88.2% and 72.2% respectively. There was significant improvement in EuroQol 5 and Chronic Venous Insufficiency Quality-of-Life Questionnaire scores after therapy. The improvement in the "C" of the CEAP classification was showed by 84.3% of patients". The study concluded that the endovenous laser ablation is an effective method in the treatment of varicose veins.

Brittenden, J et al[35] conducted a randomized controlled trial study in 798 patients with primary varicose veins "to assess the clinical effectiveness and cost-effectiveness of foam, endovenous laser ablation and surgery for the treatment of varicose veins. The disease-specific [Aberdeen Varicose Vein Questionnaire], generic [European Quality of Life-5 Dimensions], Short Form questionnaire-36 items, quality of life, cost per quality-adjusted life-year gained at 6 months were the primary outcomes. The quality of life at 6 weeks, residual varicose veins, Venous Clinical Severity Score, complication rates, return to normal activity, truncal vein ablation rates and costs were the secondary outcomes. The study results revealed that the health gain achieved in the AVVQ with foam was low as compared to surgery at 6 months which was similar to that achieved with endovenous laser ablation. The health gain in SF-36 mental component score for foam was worse as compared to endovenous laser ablation. The scores were similar in EQ-5D or SF-36 component scores in the surgery versus foam or surgery versus endovenous laser ablation comparisons at 6 months. The foam had the highest probability of being considered cost-effective at a ceiling willingness-to-pay ratio of pound 20,000 per QALY in the trial-based cost-effectiveness analysis". Endovenous laser ablation was less costly and had more QALYs as compared to surgery. Markov modelling revealed the cost

effectiveness of endovenous laser ablation, foam and surgery with 79%,17% and 5% respectively. The health gain was high in endovenous laser ablation as compared to foam at 6th week. The procedural complications were low in the endovenous laser ablation group with 1%. The return to normal work was faster in the endovenous laser ablation or foam group as compared to surgery, Truncal ablation rates were higher for surgery and endovenous laser ablation. The study concluded that EVLA is the treatment of choice for varicose veins.

Carradice D et al[36] performed a study in 280 patients "to compare endovenous laser ablation with conventional surgery for great saphenous varicose veins. The quality of life, Venous Clinical Severity Score, pain scores and time taken to return to normal function were the outcomes included in the present study. The study results revealed that there was a significant improvement in VCSS after treatment which resulted in improved disease-specific QoL and quality-adjusted life year gain in both the groups. The normal function was impaired with pain and disability following surgery". Periprocedural QoL was relatively preserved following endovenous laser ablation, leading to a significant difference between the two treatments groups in terms of pain scores. The time taken to return to work and normal activity was high in the surgery group. The study concluded that endovenous laser ablation is an effective method for the management of varicose veins.

Carroll C et al[37] conducted a systematic review and network meta-analysis to evaluate the effectiveness of minimally invasive techniques compared with other treatments in the management of varicose veins. The study results revealed that the total cost was low for the foam sclerotherapy and was more effective than surgery. The endovenous laser ablation and radiofrequency ablation were also considered as

cost effective. The relative effectiveness was sensitive to the model time horizon. They observed effectiveness and safety in both minimally invasive techniques and surgery.

Carroll C et al[38] performed "a systematic review and economic evaluation to determine the clinical effectiveness, safety and cost-effectiveness of the minimally invasive techniques of foam sclerotherapy, endovenous laser ablation and radiofrequency ablation in comparison with traditional surgical techniques and conservative management, in the management of varicose veins. During the study period network meta-analysis and exploratory cost-effectiveness modeling were carried out. The study results revealed that the clinical outcomes were similar between the minimally invasive techniques and surgery. The rate of recurrence for endovenous laser therapy, radiofrequency ablation and foam sclerotherapy were low for longer follow-up periods". The VCSS Score was lower for endovenous laser therapy and foam sclerotherapy where as higher for radiofrequency ablation. There was a less short term pain for foam sclerotherapy and radiofrequency ablation and it was higher for endovenous laser therapy. The quality-of-life scores were high for all evaluated interventions than for stripping. Foam sclerotherapy had the lowest cost and was more effective than stripping. The present study concluded that the minimally invasive techniques are more effective and safe for the treatment of varicose veins.

Christenson JT et al[39] performed a prospective study "to compare endovenous laser ablation and surgery for treatment of primary great saphenous varicose veins. During the study period Closure rate, complication rate, time to return to normal activity, the Aberdeen Varicose Vein Symptom Severity Score, the Varicose Venous Clinical Severity Score and the Medical Outcome Study Short Form-36 scores were

collected among the participants. The study results revealed that there was no difference in demographics, CEAP class, Widmer class, or severity scores between the groups. There was no major complication identified after the surgery. The return to normal activity and scores for postoperative pain were similar". The postoperative hematomas were more with High ligation & stripping as compared to endovenous laser ablation. The bruising was more with endovenous laser ablation group. Follow up at one year was 100% and 99% for HL & S and endovenous laser ablation respectively. Two great saphenous varicose veins in the endovenous laser ablation was reopened while 3 was partially reopened. The symptoms were not present in 88% of patients in both the groups. They concluded that, there was no difference in the VCSS, AVVSS, and Short Form-36 scores between the groups.

Disselhoff BC et al[40] conducted a study in 43 patients to determine "whether ligation of the saphenofemoral junction improves the results of endovenous laser ablation of the great saphenous vein. The study results revealed that 79% in endovenous laser ablation without saphenofemoral junction group and 65% in the endovenous laser ablation with saphenofemoral junction group were freed from groin varicose vein recurrence. They concluded that, the reasons for the groin varicose vein recurrence in the endovenous laser ablation without saphenofemoral junction group are re-canalisation (9%) and incompetent tributaries (14%), whereas neo-vascularisation (33%) being the major reason in the endovenous laser ablation with saphenofemoral junction group".

Eissawy MG et al[3] conducted a study in 30 patients to determine the value of endovenous laser ablation as a treatment of varicose veins. The majority of the patients were females with a mean age of 38.4 years. The study results revealed that

97% of the patients were identified with immediate postoperative successful occlusion. Failure was identified in one case with large vein. All patients well tolerated the procedure. The mean Great Saphenous Vein diameter measured in upright position was 6.5mm whereas the mean length of treated Great Saphenous Vein was 44.2cm. Two patients were observed with indurations and resolved within 2 weeks. They concluded that the safest feasible and effective method is the endovenous laser ablation for the Great Saphenous Vein reflux.

Flessenkamper I et al[41] performed a study in 449 participants "to compare reflux recurrences at the saphenofemoral junction after endovenous laser ablation (with or without high ligation) with high ligation and stripping of the great saphenous vein in patients with varicosity of the great saphenous vein. The inguinal venous reflux in the proximal section of the great saphenous vein after two years was the primary outcome.

The postoperative ecchymosis, pain or discomfort and saphenous syndrome were the secondary outcomes". The study results revealed that majority of the patients were females with 71.2% with a mean age of 48 years. The postoperative ecchymosis was developed in 69.2% of the HL/ST group followed by endovenous laser ablation group and EVLA/HL group with 50.4% and 50.3% respectively. In the HL/ST group 32.7% was presented with postoperative pain after one day. Discomfort after the surgery was identified in 37.3% in the endovenous laser ablation group followed by EVLA/HL group with 50%. The early postoperative nervus saphenous syndrome was developed in 0.6% of the HL/ST group followed by EVLA/HL group and endovenous laser ablation group with 6.1% and 3.7% respectively. The IVR was persisted in 8.5% of laser group while 2.2% of EVLA/HL group.

Gohel MS et al[42] conducted a study in 450 patients "to determine the effectiveness of Early Endovenous Ablation in Venous Ulceration. They concluded that the early endovenous ablation is preferred for faster healing and more time free ulcer in patients with superficial venous reflux.

Gohel MS et al[43] performed a study in 450 participants to evaluate the clinical effectiveness and cost-effectiveness of compression therapy with early endovenous ablation of superficial venous reflux compared with compression therapy with deferred endovenous ablation in patients with venous ulceration. The time from randomisation to ulcer healing was the primary outcome. The 24-week ulcer healing rates, ulcer-free time, clinical success, costs and quality-adjusted life-years were the secondary outcomes. The study results revealed that the baseline characteristics were similar between the groups. The early superficial endovenous ablation showed less time for ulcer healing as compared to deferred ablation. In the early ablation group the median time for ulcer healing was 56 days while 82 days in the deferred ablation group. The ulcer healing rate in the early ablation group and deferred ablation group were 85.6% and 76.3% at the 24th week. The pain and deep-vein thrombosis were the most common complications of superficial endovenous ablation. Differences in repeated measures of Aberdeen Varicose Vein Questionnaire scores, EuroQol-5 Dimensions index values and Short Form questionnaire-36 items body pain was in the favor of early ablation over the follow up period. The mean difference in total costs was 163 pounds between the early ablation and deferred ablation groups. The early ablation was more cost effective than late ablation with 89%. The incremental cost-effectiveness ratio was 3976 pounds per QALY for one year in early ablation". They concluded that the healing time and cost can be reduced with early endovenous ablation of superficial venous reflux.

Jibiki M et al[44] conducted a retrospective study in 289 participants "to determine the effect of the wide-spread use of endovenous laser ablation on the treatment of varicose veins. During the study period the surgical results and the incidence of surgical site infections were assessed and compared among the patients who underwent stripping and endovenous laser ablation. The patients who underwent stripping were grouped into A while those who underwent endovenous laser ablation as B. The patients who underwent endovenous laser ablation using a 980 nm laser and 240 patients who underwent endovenous laser ablation using a 1470 nm laser were grouped as B1 and B2 respectively.

The study results revealed that 48 +/- 16 minutes was the operative time in group A while 28 +/- 10 minutes in group B. The mean operative time without phlebectomy in group B1 was 31 +/- 9 minutes where as 22 +/-7 minutes in group B2. The level of pain in group A and B1 was peak in day 1 and 3-7 days. Less pain was experienced by group B2. The B2 group patients were identified with surgical site infection at the phlebectomy site". The occlusion rate was 99.6% in endovenous laser ablation after 2 years of surgery. They concluded that the endovenous laser ablation using the 1470-nm laser is the preferred choice of treatment for saphenous vein reflux.

Kheirelseid EAH et al[45] performed "a systematic review and meta-analysis of randomized controlled trials in 2185 legs to evaluate the long-term efficacy of currently available endovenous therapy methods for varicose veins compared with conventional surgery in management of great saphenous vein -related varicose veins. The study results revealed that 61.9% of the patients were followed up for 5 years".

The recurrence rate in both endovenous laser therapy and conventional surgery were similar. They concluded that there was no significant difference in the recurrence rate in radiofrequency ablation with surgery on comparison with endovenous laser therapy.

Lawaetz M et al[46] performed a study in 580 patients "to compare the 5 years outcome after treatment of varicose veins with endovenous radiofrequency ablation, endovenous laser ablation, ultrasound guided foam sclerotherapy or high ligation and stripping by assessing technical efficacy, clinical recurrence and the rate of reoperations. The study results revealed that there was a difference in the rate of Great Saphenous Vein recanalization, recurrence and reoperations across the groups in 5 years". The Great Saphenous Vein s recanalized or failed stripping procedure was present in 5.8% of endovenous radiofrequency ablation, 6.8% of endovenous laser ablation, 31.5% of ultrasound guided foam sclerotherapy and 6.3% of high ligation and stripping .The recurrent varicose vein was present in 18.7% of endovenous radiofrequency ablation, 38.6% of endovenous laser ablation, 31.7% of ultrasound guided foam sclerotherapy and 34.6% of high ligation and stripping. The legs were re-treated within 5 years after the treatment in 17% of endovenous radiofrequency ablation, 18.7% of endovenous laser ablation, 37.7% of ultrasound guided foam sclerotherapy and 23.4% in high ligation and stripping.

Nordon IM et al[47] conducted "a prospective double-blind randomized controlled study in 159 patients to compare radiofrequency ablation and endovenous laser ablation strategies. During the study period patients with primary unilateral great saphenous vein reflux undergoing endovenous treatment were grouped to radiofrequency ablation or endovenous laser ablation. The great saphenous vein

occlusion at 3 months after treatment was the primary outcome. The occlusion at 7 days, postoperative pain, analgesic requirement, and bruising, assessed at day 7 after surgery were the secondary outcome. The study results revealed that there was no difference between the demographics, disease extent, severity, and preoperative QoL between the groups. 100% vein occlusion was confirmed in duplex scanning at 1st week in both the groups. The occlusion was 97% for radiofrequency ablation and 96% for endovenous laser ablation at the 3rd month". The median percentage above-knee bruise area was high after endovenous laser ablation with 3.85% as compared to radiofrequency ablation with 0.6%. The post operative pain was less in radiofrequency ablation. The study concluded the effectiveness of both radiofrequency ablation and endovenous laser ablation in varicose veins.

Rass K et al[31] performed a study in 400 participants. The study results revealed that the clinically recurrent varicose veins after endovenous laser treatment and HLS were 16.2% and 23.1%. In the endovenous laser treatment group the duplex-detected saphenofemoral refluxes were more frequent as compared HLS. There was no difference in the improvement of the medical condition and disease-related quality of life. The adverse effect such as phlebitic reaction, tightness, dyspigmentation were more with the endovenous laser treatment group. The advantages concerning hemodynamics, recovery, and cosmetic outcome were high with endovenous laser treatment group. They concluded that both endovenous laser treatment and HLS are safe and effective for the management of GSV.

Rustempasic N et al[48] conducted a study in 119 participants. The study results revealed that the mean time of return to normal activities in endovenous laser ablation and surgery were 1.21 and 12.24 days. The pain was high for the surgical group as

compared to endovenous laser ablation. Incidence of hematoma greater than 1% of total body surface area was high in the surgical group. There was no difference in the incidence of infection, deep venous thrombosis and post treatment bleeding between the groups. The study concluded that endovenous laser ablation is the treatment of choice for the varicose vein as it is having less post operative pain and faster return to normal activities.

Shepherd AC et al[49] conducted a prospective observational study to determine postoperative pain following endovenous laser ablation, radiofrequency ablation and identify risk factors for increased pain. The post operative pain was less in patients receiving radiofrequency ablation with 3 days as compared to endovenous laser ablation with 10 days. The time taken to return to work was faster in the radiofrequency ablation group. They concluded that radiofrequency ablation can be preferred over endovenous laser ablation in terms of recovery and post operative pain.

Shi H et al[50] performed a retrospective study in 311 participants. The study results revealed that 100% was the technical success rate of endovenous laser ablation of Incompetent perforating veins (IPVs). The complication rates were similar between the two groups. At 1 year follow up, 18.7% were recanalized and still incompetent in the endovenous laser ablation treated IPV group. The endovenous laser ablation treated IPV group had a faster median ulcer healing time. The recurrence rate of varicose vein was similar between the groups. They concluded that the safest method for reducing the number of IPVs is the endovenous laser ablation.

Tassie, E et al[51] in their study observed that the mean cost for the ultrasound-guided foam sclerotherapy and endovenous laser ablation were pound 655 and pound 160 respectively. The cost savings increased to pound 902 and pound 392 when

overhead costs associated with theatre was added. The QALYs produced by ultrasound-guided foam sclerotherapy was low as compared to endovenous laser ablation. Over the 5 years of follow up endovenous laser ablation was associated with increased costs and QALYs. They concluded that the endovenous laser ablation is the cost effective method for the treatment of the varicose vein.

METHODOLOGY

Materials and methods:

Study site: This study was conducted in the Department Of Radio Diagnosis At Jawaharlal Nehru Medical College, Belgaum, Karnataka.

Study population: Patients attending to the Interventional Radiology clinic in Department of Radio diagnosis with symptoms of varicose veins who were evaluated, diagnosis of varicose veins confirmed with USG venous doppler and advised to undergo endovenous laser ablation at KLE'S DR.Prabhakar Kore Hospital & MRC, Belagavi.

Study Design: This study was a prospective observational study.

Sample size:

All the patients who fulfil the inclusion criteria and who give consent to undergo endovenous laser ablation as a treatment for their varicose veins at KLE'S DR. PRABHAKAR KORE HOSPITAL & MRC, BELGAUM. In the last three years number of patients operated was on average, 40-60 each year. Hence, 30 to 40 patients would be studied as a part of the study (with scope to increase depending upon the availability)

Sampling method: All the eligible subjects were recruited into the study consecutively by convenient sampling till the sample size is reached.

Study Duration: The data collection for the study was done between January 2018 to December 2018 for a period of 1 year.

Inclusion criteria:

- Symptoms affecting quality of life such as aching, throbbing, fatigue, heaviness, restlessness, night cramps, pruritus, spontaneous hemorrhage.
- Skin changes associated with chronic venous hypertension such as eczema, and pigmentation, Lipodermatosclerosis, Healed or active ulceration, Edema, Superficial phlebitis (SVT) in varicose veins
- Cosmetic concerns due to unsightly appearance of the dilated veins.
- Significant reflux documented on DUS examination (reflux >0.5 seconds)
- Age between 20 and 80 years.

Exclusion criteria:

- Non consenting subjects.
- Patients who are pregnant or breastfeeding (concerns related to anesthetic use and heated blood effluent that may pass through the placenta to the fetus).
- Obstructed deep venous system.
- Liver dysfunction or allergy to local anesthetic.
- Severe uncorrectable coagulopathy.
- Severe hypercoagulability syndromes.
- Inability to adequately ambulate after the procedure.
- Thrombus or synechiae in the vein or tortuous vein.

Ethical considerations: This Study was approved by institutional human ethics committee. Informed written consent was obtained from all the study participants and only those participants willing to sign the informed consent were included in the study. The risks and benefits involved in the study and voluntary nature of

participation were explained to the participants before obtaining consent. Confidentiality of the study participants was maintained.

Data collection tools: All the relevant parameters were documented in a structured study proforma.

Methodology:

Patients referred to the Department of Radio-Diagnosis at The KLE'S Dr. Prabhakar Kore hospital & MRC, Belgaum with varicose veins diagnosed clinically and further confirmed by Doppler ultrasound scan.

The subjects were enrolled in the study after they give written informed consent for the procedure.

A detailed history was taken in the form of a systematic proforma regarding patient age, sex, past medical/surgical history.

Baseline parameters like pulse, blood pressure, temperature were recorded. Weight and height of the patient also documented.

After considering the inclusion and exclusion criteria, the patients were subjected to:

1. Preoperative Doppler scan of the lower limb to assess the superficial & deep veins and sapheno-femoral junction competence and
2. Venous clinical severity score (VCSS)

Following the operative procedure, they were again subjected to VCSS on post-op day1, day 3, week 1, week 2 and at 3 months.

Doppler scan using standard protocol was performed immediately after the procedure and at the end of 3 months to check for recurrences.

Doppler scan was done using ultrasound machine models GE LOGIQ P9 and LOGIQ P7 and high frequency linear transducer probe of frequency 8 to 12 MHz was used.

Statistical Methods:

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.[52]

RESULTS

Statistical methods:

Total score was considered as the primary outcome variable. Age, gender, total pre-operative revised VCSS with its components like varicose veins, venous edema and others are main explanatoryvariables.

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Non normally distributed quantitative variables were summarized by median and interquartile range (IQR). Data was also represented using appropriate diagrams like bar diagram, pie diagram.

All Quantitative variables were checked for normal distribution within each category of explanatory variable by using visual inspection of histograms and normality Q-Q plots. Shapiro- wilk test was also conducted to assess normal distribution. Shapiro wilk test p value of >0.05 was considered as normal distribution.

The change in the quantitative parameters, before and after the intervention was assessed by paired t-test (In case of two time periods)

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.[52]

1. IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.

Results:

A total of 50 participants (57 limbs) were included in the final analysis.

Table 1: Descriptive analysis of age in study population (N=50)

Parameter	Mean ± SD	Median	Minimum	Maximum	95% C. I	
					Lower	Upper
Age	45.24 ± 12.81	45.00	20.00	73.00	41.60	48.88

The mean age was 45.24 ± 12.81 in the study population, minimum age was 20 years and maximum age was 73 years in the study population (95% CI 41.60 to 48.88). (Table 1)

Table 2: Descriptive analysis of gender in the study population (N=50)

Gender	Frequency	Percentages
Male	39	78.0%
Female	11	22.0%

Among the study population, 39 (78%) were male participants and remaining 11 (22%) participants were female. (Table 2 & Graph 1)

Graph 1: Pie chart of sex in the study population (N=50)

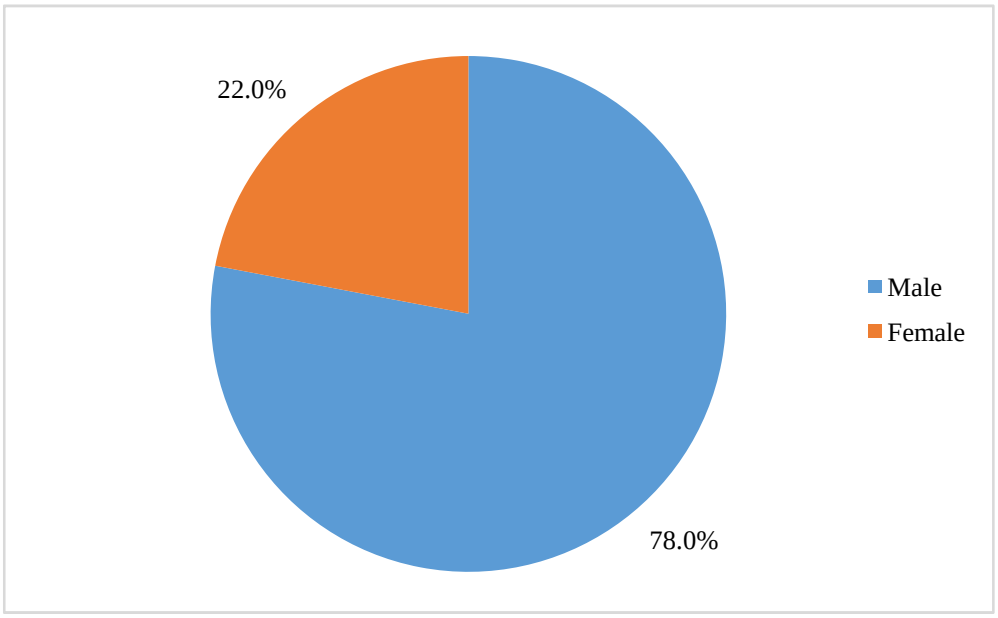


Table 3: Descriptive analysis of laterality in the study population (N=50)

Laterality	Frequency	Percentages
Unilateral	43	86.0%
Bilateral	7	14.0%

Among the study population, 43 (86%) participants had undergone EVLT for single lower limb and 7 (14%) participants for both lower limbs. (Table 3 & Graph 2)

Graph 2: Bar chart of laterality in the study population (N=50)

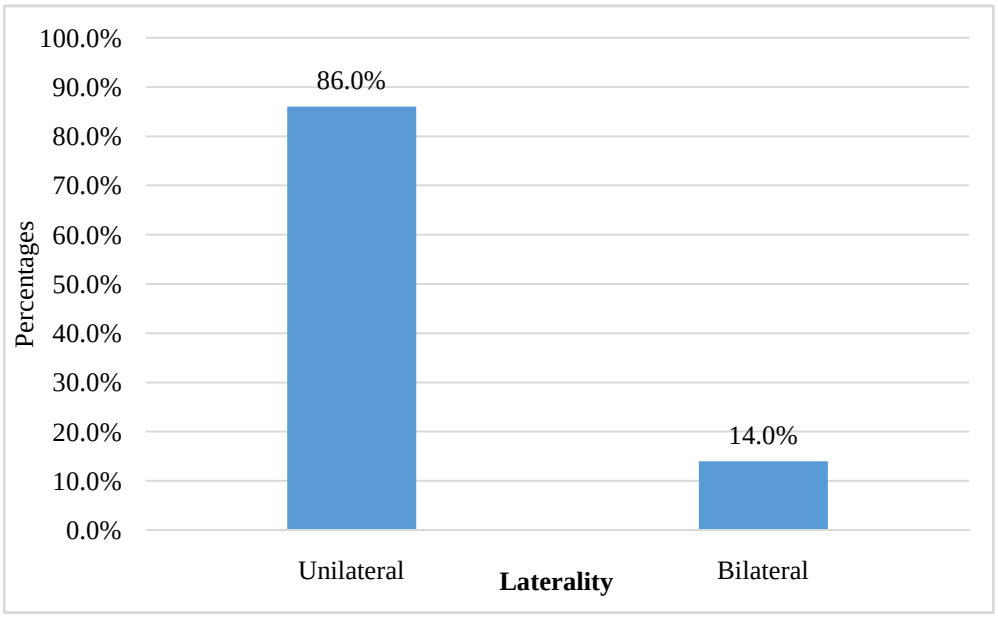


Table 4: Descriptive analysis of number of IC perforators in each limbs (N=57) in the study population

Number of IC perforators	Frequency	Percentages
0	1	1.8%
1	19	33.3%
2	24	42.1%
3	9	15.8%
4	2	3.5%
5	2	3.5%

Among the study population, 1 (1.8%) participant did not have any incompetent perforator in his lower limb, 19 (33.3%) lower limbs had only 1 incompetent perforator, 24 (42.1%) had only 2, 9 had only 3, 2 of the lower limbs had 4 and 2 of the lower limbs had 5 incompetent perforators each. (Table 4 & Graph3)

Graph 3: Bar chart of number of IC perforators in each limbs (N=57) in the study population

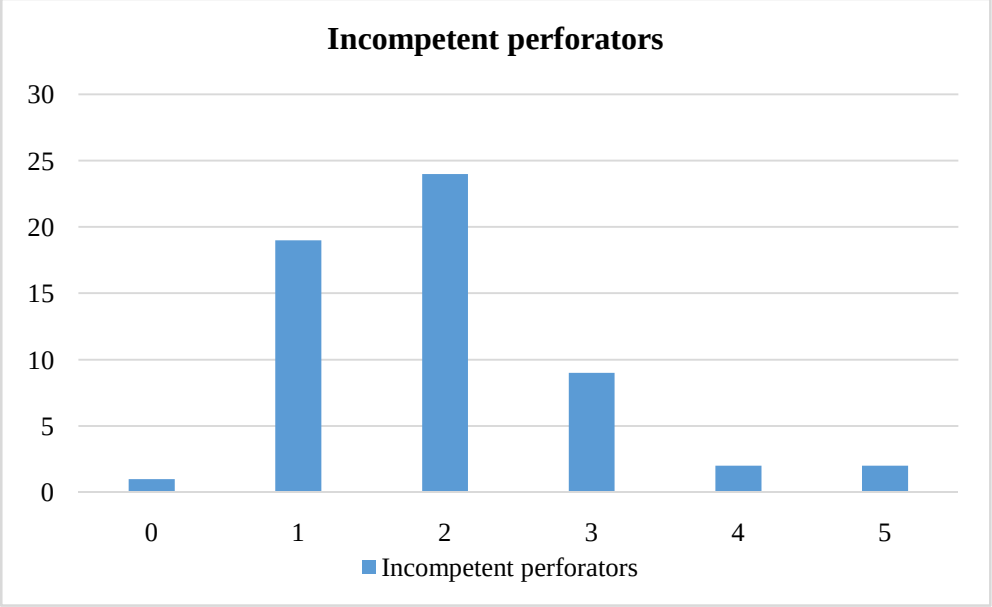


Table 5: Descriptive analysis of pre-operative revised VCSS of pain in each limbs (N=57) in the study population

Pre-operative revised VCSS Pain	Frequency	Percentages
Occasional	3	5.3%
Daily	43	75.4%
Daily limiting	11	19.3%

Among the study population, occasional pain was present in 3 (5.3%) of the lower limbs, 43 (75.4%) had daily pain and 11 (19.3%) had daily limiting pain. (Table 5 & Graph4)

Graph 4: Bar chart of pre-operative revised VCSS of pain in each limbs (N=57) in the study population

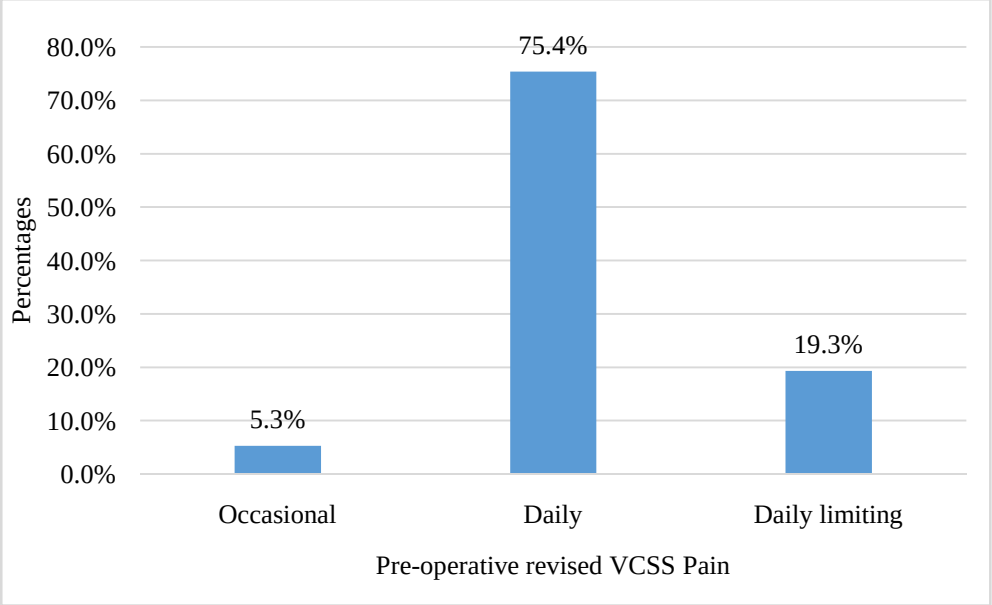


Table 6: Descriptive analysis of pre-operative revised VCSS of varicose veins in each limbs (N=57) in the study population

Pre-operative revisedVCSS Varicose veins	Frequency	Percentages
Calf or thigh	10	17.5%
Calf and thigh	47	82.5%

Among the study population, 10 (17.5%) of the lower limbs had varicose veins in calf or thigh and 47 (82.5%) had varicose veins in both calf and thigh.(Table 6 & Graph5)

Graph 5: Pie chart of pre-operative revised VCSS of varicose veins in each limbs (N=57) in the study population

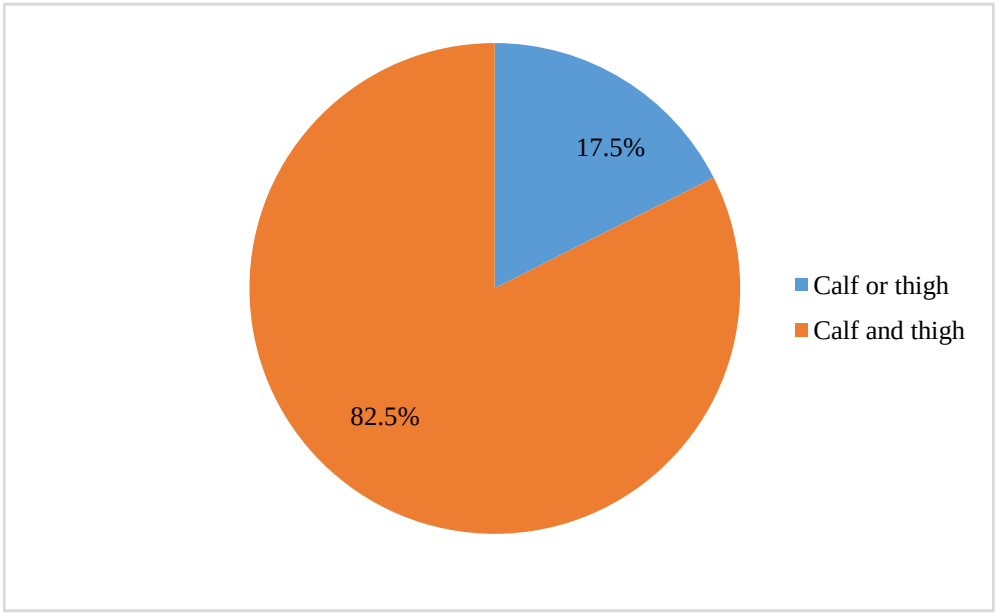


Table 7: Descriptive analysis of pre-operative revised VCSS of venous edema in each limbs (N=57) in the study population

Pre-operative revisedVCSS Venous edema	Frequency	Percentages
Foot and ankle	22	38.6%
Above ankle, below knee	34	59.6%
To knee or above	1	1.8%

Among the study population, 22(38.6%) of lower limbs had Venous edema in foot and ankle,34(59.6%) had in both above ankle and below knee and only 1(1.8%) lower limb had it to knee or above. (table 7 & Graph6)

Graph 6: Bar chart of pre-operative revised VCSS of venous edema in each limbs (N=57) in the study population

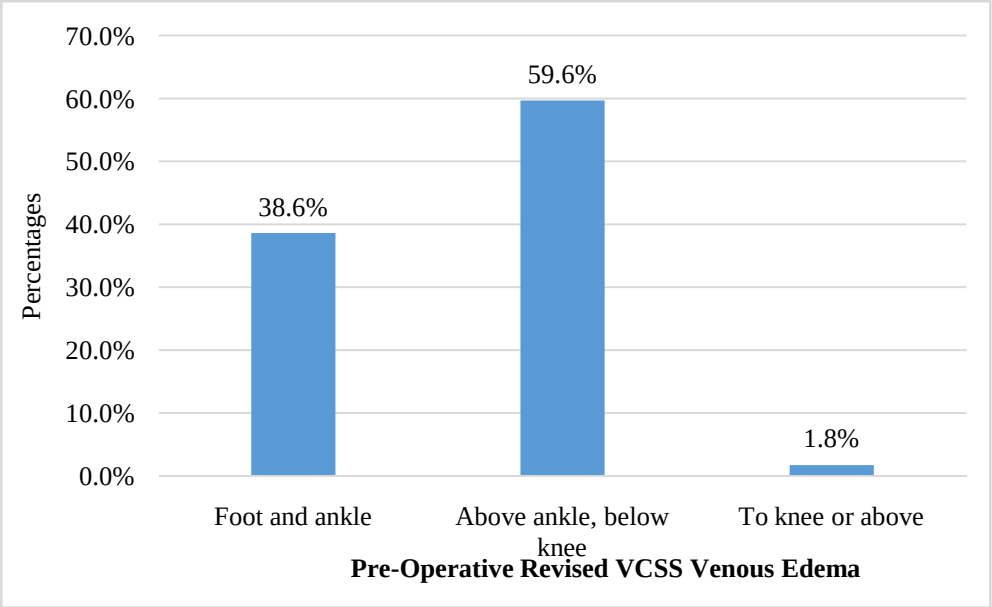


Table 8: Descriptive analysis of skin pigmentation in each limbs (N=57) in the study population

Skin pigmentation	Frequency	Percentages
None	7	12.3%
Perimalleolar	28	49.1%
Diffuse, lower 1/3 calf	19	33.3%
Wider, above lower 1/3 calf	3	5.3%

Among the study population, 28(49.1%) of lower limbs had Perimalleolarpigmentation, 19(33.3%) had Diffuse, lower 1/3 calf pigmentation and 3(5.3%) of lower limbs had Wider, above lower 1/3 calf pigmentation. (Table 8 & Graph7)

Graph 7: Pie chart of skin pigmentation in each limbs (N=57) in the study population

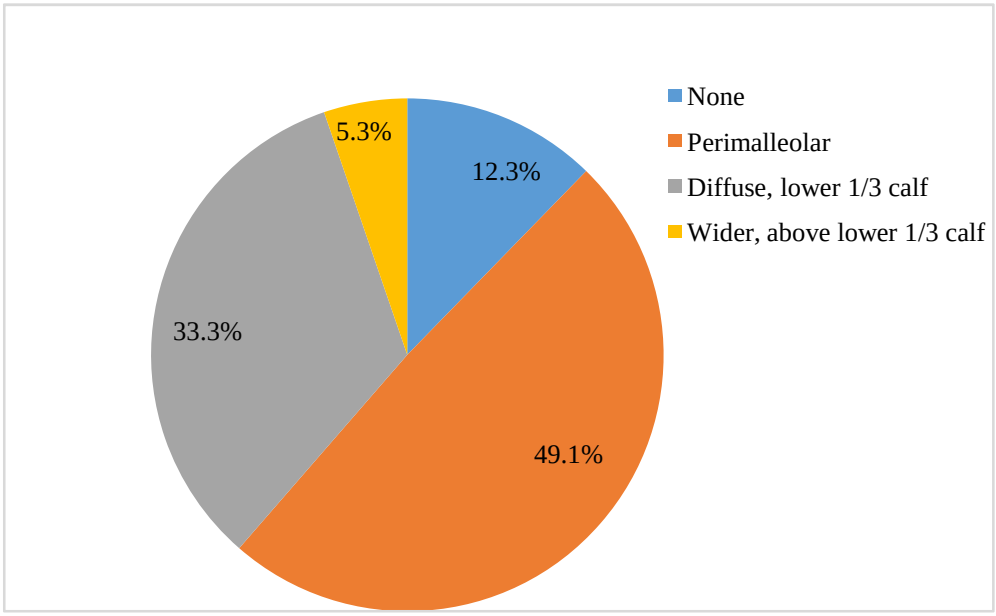


Table 9: Descriptive analysis of inflammation in each limbs (N=57) in the study population

Inflammation	Frequency	Percentages
None	9	15.8%
Perimalleolar	30	52.6%
Diffuse, lower 1/3 calf	16	28.1%
Wider, above lower 1/3 calf	2	3.5%

Among the study population, 30(52.6%) of lower limbs had PerimalleolarInflammation, 16(28.1%) had diffuse, lower1/3rd calf and 2 (3.5%) of lower limbs had wider, above lower 1/3rd calf Inflammation (Table 9 & Graph8)

Graph 8: Bar chart of inflammation in each limbs (N=57) in the study population

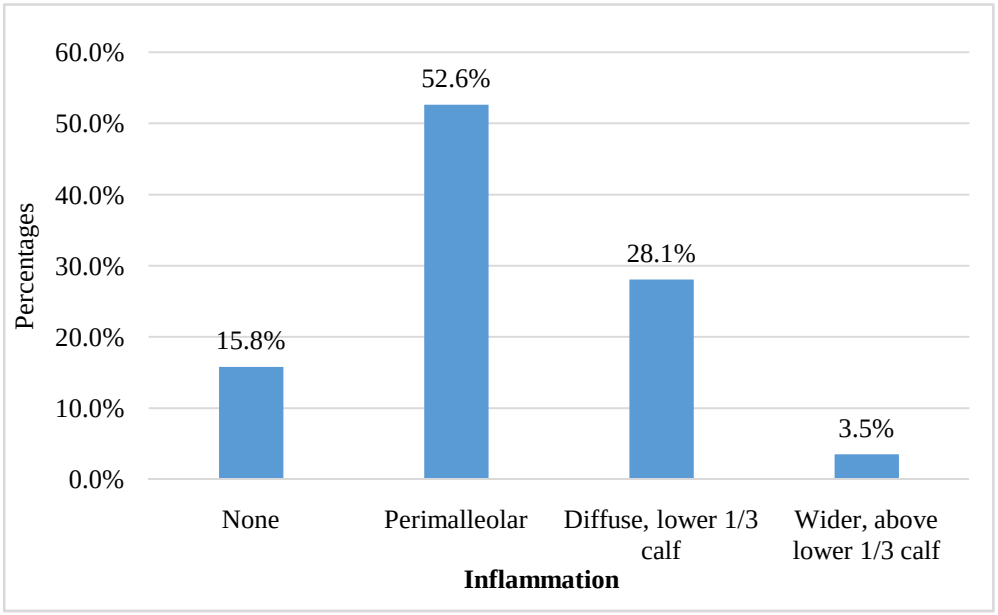


Table 10: Descriptive analysis of induration in each limbs (N=57) in the study population

Induration	Frequency	Percentages
None	26	45.6%
Perimalleolar	22	38.6%
Diffuse, lower 1/3 calf	7	12.3%
Wider, above lower 1/3 calf	2	3.5%

Among the study population, 22(38.6%) of lower limbs had Perimalleolar induration, 7(12.3%) had diffuse, lower 1/3rd calf induration and 2(3.5%) of the lower limbs had wider, above lower 1/3rd calf induration (table 10 & Graph 9)

Graph 9: Pie chart of induration in each limbs (N=57) in the study population

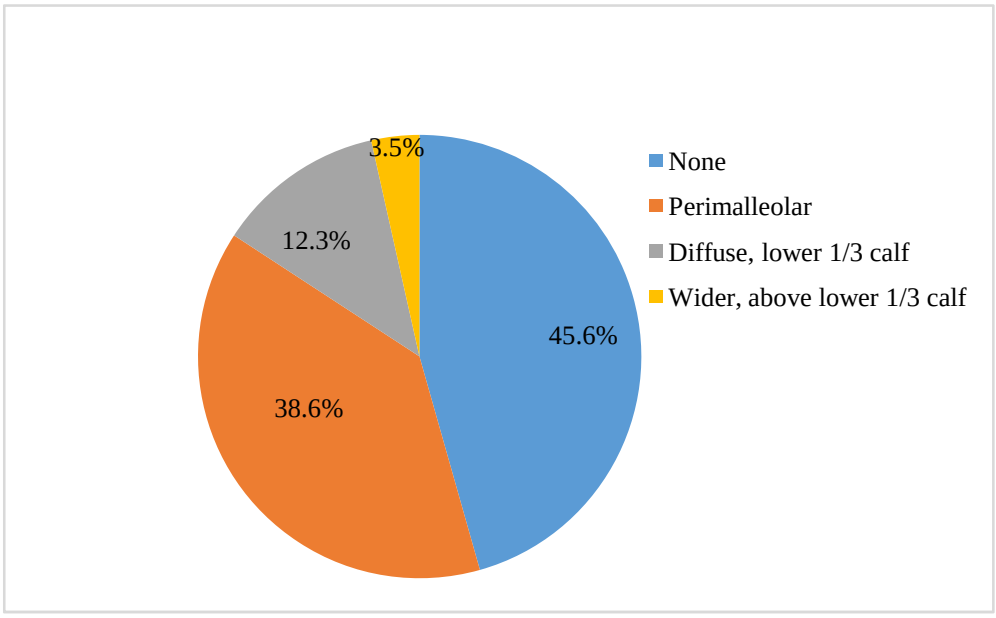


Table 11: Descriptive analysis of no. of active ulcers in each limbs (N=57) in the study population

No. of active ulcers	Frequency	Percentages
None	52	91.2%
1	4	7.0%
2	1	1.8%

Among the study population, 4(7.0%) lower limbs had single active ulcer and 1(1.8%) of the lower limbs had two active ulcers. (Table 11 & Graph10)

Graph 10: Bar chart of no. of active ulcers in each limbs (N=57) in the study population

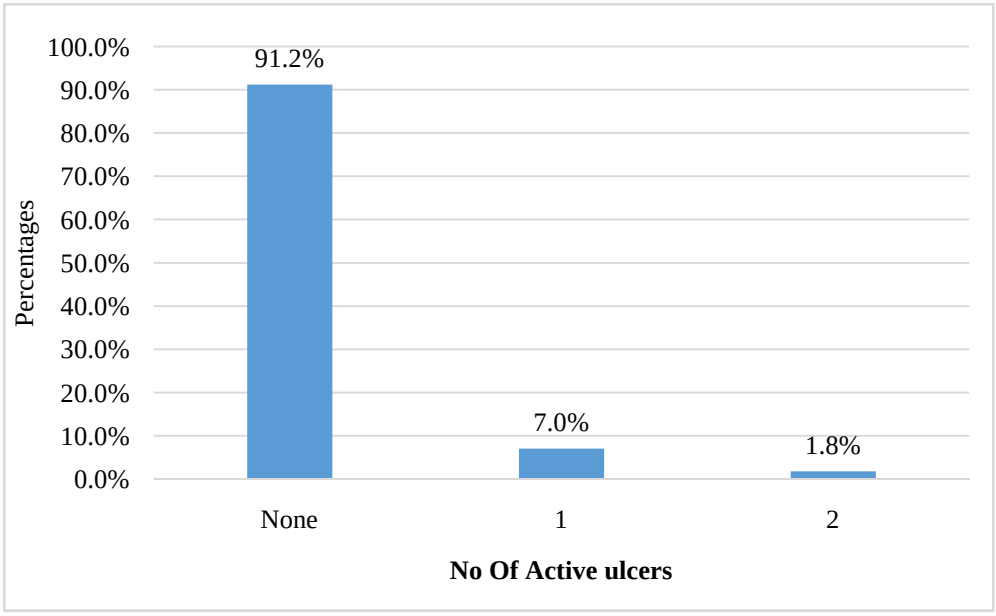


Table 12: Descriptive analysis of active ulcer size in each limbs (N=57) in the study population

Active ulcer size	Frequency	Percentages
None	52	91.2%
<2 cms	2	3.5%
2-6 cm	3	5.3%

Among the study population, 2(3.5%) lower limbs had active ulcers of size <2 cm and 3(5.3%) of lower limbs had active ulcers of size 2 to 6 cm. (Table 12 & Graph 11)

Graph 11: Pie chart of active ulcer size in in each limbs (N=57) in the study population

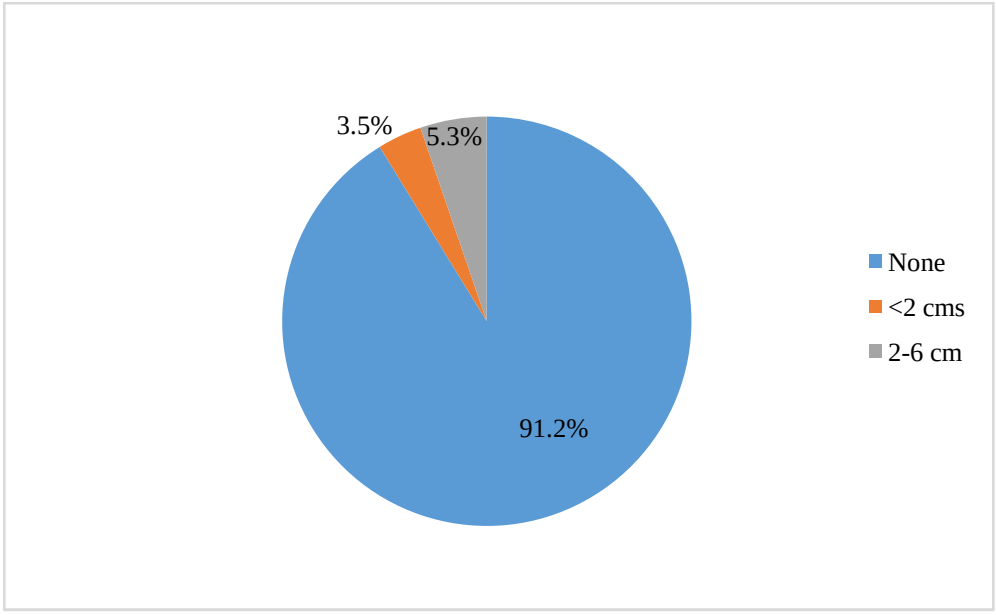


Table 13: Descriptive analysis of ulcer duration in each limbs (N=57) in the study population

Ulcer duration	Frequency	Percentages
None	52	91.2%
<3 months	1	1.8%
3-12 months	4	7.0%

Among the study population, 1(1.8%) lower limb had ulcer for < 3 months and 4 (7%) of lower limbs suffered from ulcers for 3 to 12 months. (Table 13 & Graph 12)

Graph 12: Bar chart of ulcer duration in each limbs (N=57) in the study population

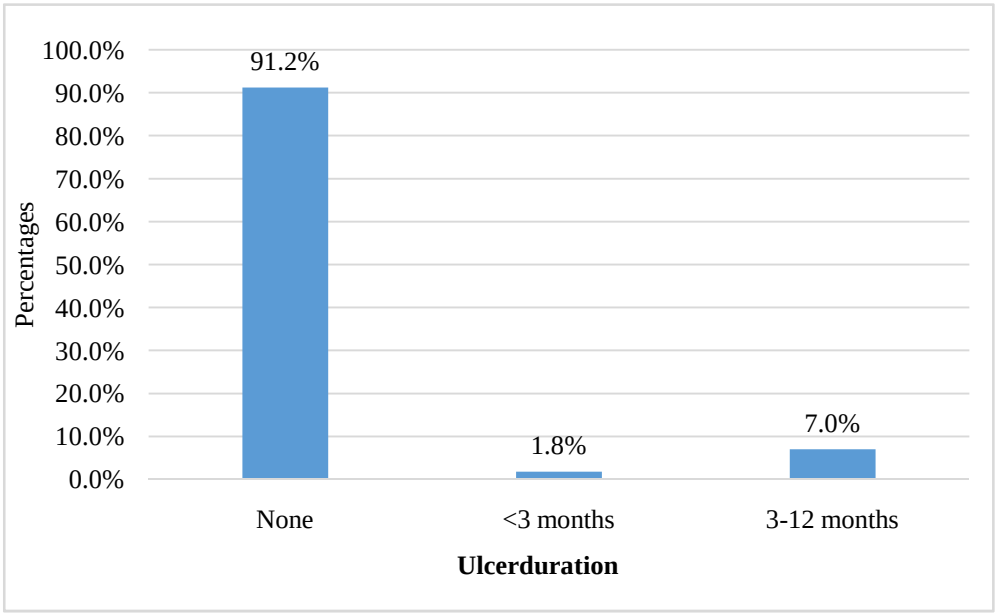


Table 14: Descriptive analysis of compression therapy in each limbs (N=57) in the study population

Compression therapy	Frequency	Percentages
Intermittent	4	7.0%
Most days	39	68.4%
Fully comply	14	24.6%

Among the study population, 4(7.0%) of lower limbswere onCompression therapyintermittently, 39(68.4%) had Compression therapy for most of the days and 14(24.6%) of lower limbs had full compliance to Compression therapy (Table 14 & Graph 13)

Graph 13: Pie chart of compression therapy in each limbs (N=57) in the study population

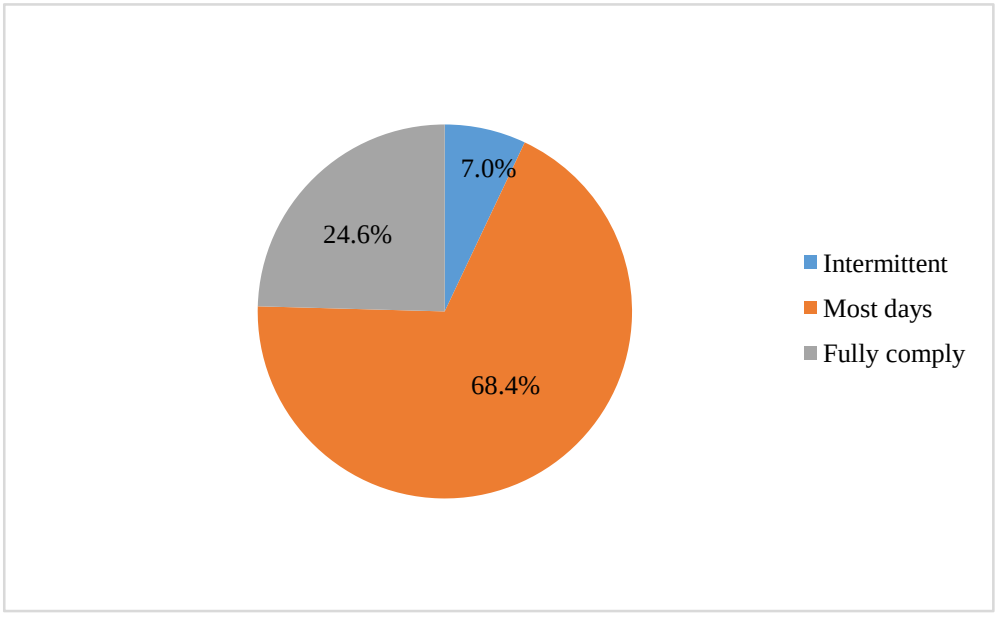


Table 15: Descriptive analysis of total score in each limbs (N=57) in the study population

Total score	Mean ± SD	Median	Minimum	Maximum	95% C. I	
					Lower	Upper
Pre-operative	12.42 ± 3.42	11.00	8.00	22.00	11.51	13.33
Post-Operative Day 1	11.79 ± 3.15	11.00	7.00	20.00	10.95	12.63
Post-Operative Day 3	10.93 ± 3.13	10.00	7.00	19.00	10.10	11.76
Post-Operative Week 1	9.98 ± 3.1	9.00	6.00	18.00	9.16	10.81
Post-Operative Week 3	8.3 ± 2.49	8.00	5.00	15.00	7.64	8.96
Post-Operative 3rd month	6.91 ± 2.07	6.00	4.00	12.00	6.36	7.46

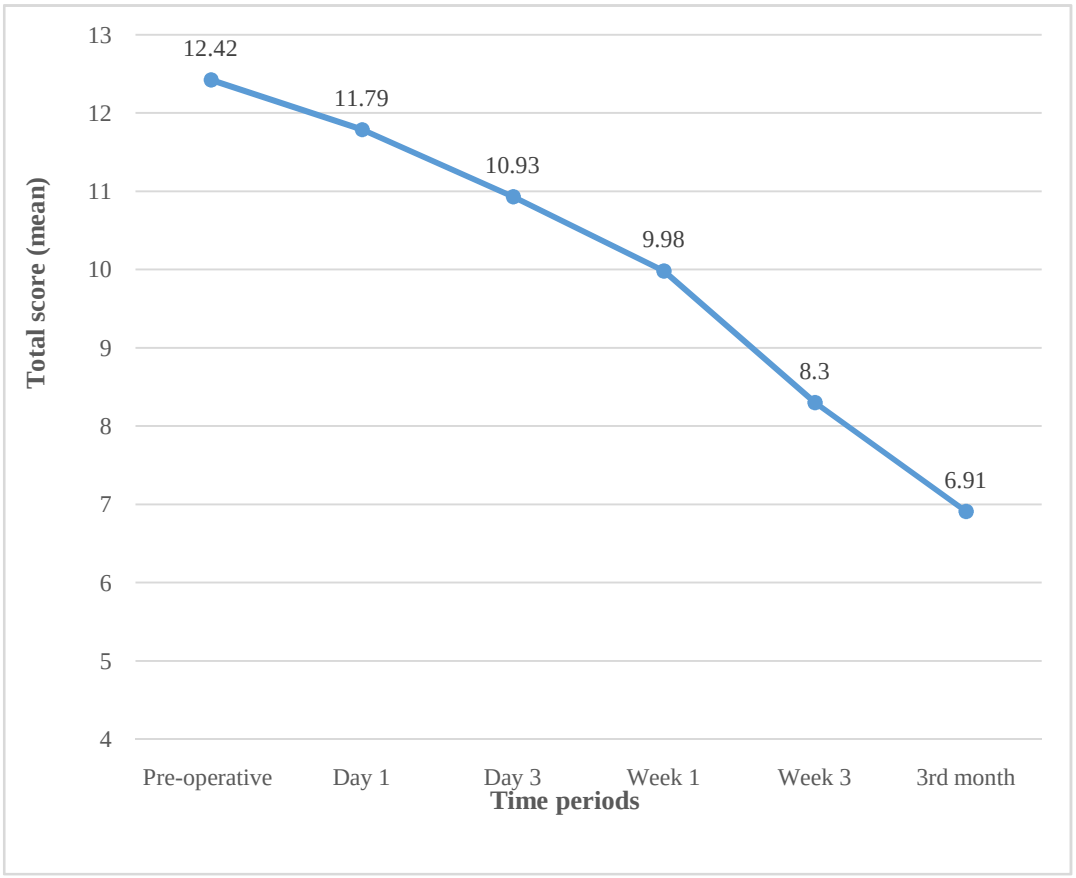
The mean of pre-operative revised VCSS score was 12.42 ± 3.42 in the study population, minimum level was 8 and maximum level was 22 in the study population (95% CI 11.51 to 13.33) , it was 11.79 ± 3.15 in post-operative day 1, minimum level was 7 and maximum level was 20 in the study population (95% CI 10.95 to 12.63) , it was 10.93 ± 3.13 in the post-operative day 3, minimum level was 7 and maximum level was 19 in the study population (95% CI 10.10 to 11.76) , it was 9.98 ± 3.1 in post-operative 1st week, minimum level was 6 and maximum level was 18 in the study population (95% CI 9.16 to 10.81) , it was 8.3 ± 2.49 in post-operative 3rd week, minimum level was 5 and maximum level was 15 in the study population (95% CI 7.64 to 8.96) and it was 6.91 ± 2.07 in Post-Operative 3rd month, minimum level was 4 and maximum level was 12 in the study population (95% CI 6.36 to 7.46) (table 15).

Table 16: Comparison of mean total score in Pre-operative and different follow-up periods (N= 57)

Follow-up periods	Total score (Mean± SD)	Mean Difference	95% CI of mean difference		P-value
			Lower	Upper	
Pre-operative	12.42 ± 3.42				
Post-operative day 1	11.79 ± 3.15	0.63	0.48	0.79	<0.001
Post-operative day 3	10.93 ± 3.13	1.49	1.30	1.69	<0.001
Post-operative week 1	9.98 ± 3.1	2.44	2.22	2.66	<0.001
Post-operative week 3	8.3 ± 2.49	4.12	3.76	4.49	<0.001
Post-operative 3 month	6.91 ± 2.07	5.51	5.02	5.99	<0.001

The mean total score was 12.42 ± 3.42in pre-operative, 11.79 ± 3.15at day 1 follow up, 10.93 ± 3.13 at day 3 follow up, 9.98 ± 3.1 at week 1 follow up, 8.3 ± 2.49 at week 3 follow up and 6.91 ± 2.07 at 3rd month follow up. The differences in the total score at day 1, day 3, week 1 and week 3 follow up period with baseline value (pre-operative) were statistically significant (P value <0.001). (Table 16 & Graph 14).

Graph 14: Line diagram of Comparison of mean total score in Pre-operative and different follow-up periods (N= 57)



DISCUSSION

Varicose veins are elongated, dilated, tortuous and often palpable veins occurring in the superficial venous system of the body especially of the lower extremities. Varicose veins are the result of chronic venous insufficiency. They cause serious morbidity and lead to reduction in the quality of life. **Endovenous laser ablation therapy** (EVLT) is a minimally invasive procedure with smaller number of complications postoperatively besides providing an early discharge. This study was designed to evaluate the role of EVLA as a treatment option for varicose veins to assess the postoperative pain, complication rates and improvement in symptoms post endovenous laser ablation.

BASELINE SOCIODEMOGRAPHIC VARIABLES:

We conducted a prospective observational study in the Department of Radio diagnosis in a tertiary teaching hospital in Karnataka after getting ethical clearance. 50 subjects attending to the outpatient department of Radio diagnosis who were advised to undergo endovenous laser ablation as a treatment for varicose veins constituted the study population. Preoperative Doppler scan, VCSS and SF-36 were done at baseline. Following the operative procedure they were again subjected to VCSS on post-op day1, day 3, week 1, week 2 and at 3 months and also Doppler scan at the end of 3 months to check for recurrences. A total of 57 limbs from 50 participants were included in the final analysis. Eissawy MG et al[3] in their study evaluated the role of EVLA in treatment of varicose veins in 30 subjects. Christenson JT et al[39] in their study compared EVLT (104 limbs) with High ligation and stripping (100 limbs) with regards to VVCSS and other scores. Shi H et al[50] in their study,

investigated the clinical outcome following EVLA in 156 limbs. The mean age of our study subjects was 45 years. Christenson JT et al[39] in their study observed the mean age of study subjects to be 44.6 years similar to our study while Eissawy MG et al[3] in their study observed the mean age of subjects to be around 38.4 years. 78% of the study subjects were males in our study while other authors observed a female preponderance in their study. This could be due to various demographic and social factors. Estimates of the prevalence of varicose veins vary widely from 2-56% in men and from 1-60% in women.[10] Varicose veins occur more commonly in females than males, generally. 86% of our study participants underwent EVLT for single lower limb while 14% underwent the procedure for both lower limbs.

CLINICAL PRESENTATION:

General complaints related to venous insufficiency depends on the severity of the insufficiency and accompanying pathologies. The most common symptoms are Pain and swelling followed by itching, open ulceration, edema, cramps and discoloration.[15] Majority (82.5%) of the limbs had varicose veins in both calf and thigh while the remaining (17.5%) had varicose veins in calf or thigh. 38.6%of limbs in our study had venous edema in foot and ankle while 59.6% had both above ankle and below knee edema. Christenson JT et al[39] in their study observed that 61% of limbs undergoing EVLT before the procedure had edema, while 8% had dermatitis and 1% had venous ulcer. In our study, 7% of limbs had single active ulcer while 1.8% had two active ulcers. 49.1% of limbs in our study had Perimalleolar pigmentation, 52.6% had Perimalleolar Inflammation and 38.6% had Perimalleolar induration. Symptomatology of varicose veins varies greatly.

VENOUS CLINICAL SEVERITY SCORING (VCSS):

The Venous Severity Scoring (VSS) system was derived from the CEAP classification to provide evaluative capabilities. The three elements of the VSS are the venous disability score, the venous segmental disease score and the venous clinical severity score (VCSS). The VCSS facilitates the follow-up of features of venous disease thatchange with treatment. At baseline according to pre-operative revised VCSS pain scale, 75.4% of the limbs had daily pain and 19.3% had daily limiting pain. The mean pre-operative VCSS score was 12.42 with 95% CI of 11.51 to 13.33 in our study. Christenson JT et al[39] in their study observed a mean pre-operative VVCSS (Varicose Vein Clinical Severity Score) of 5.2 with range from 2 to 16. In our study, the mean total score decreased from 12.42 in pre-operative period to11.79 at day 1 of follow up, 10.93 at day 3 of follow up, 9.98 at week 1 of follow up, 8.3 at week 3 of follow up and to 6.91 ± 2.07 at 3rd month of follow up. The differences in the total score at day 1, day 3, week 1 and week 3 follow up period with baseline value (pre-operative) were statistically significant (P value <0.001).Christenson JT et al[39] in their study also observed that between 12 days to 1 year follow up, there was a significant improvement indicated by the decrease in VVCSS from pre-operative levels of 5.2 to 0.26. But there were no significant differences between results at 1 and 2 years of follow up. Similar to our study, Carradice D et al[36] in their study also observed that there was significant improvements in VCSS after treatment in EVLA group (P < 0.001), which resulted in improved disease-specific QoL. Disselhoff BC et al[27] in their study also observed that EVLA of the great saphenous vein was effective. Eissawy MG et al[3] in their study also had observed that EVLA for GSV reflux is a safe, feasible and efficient outpatient technique.

Varicose veins are a manifestation of chronic venous insufficiency, which can progress to serious morbidity. **Endovenous laser ablation therapy** (EVLT) is a minimally invasive procedure that makes use of catheters, lasers, and ultrasound to treat varicose veins. This procedure is performed most often on veins that are still relatively straight and untwisted. EVLA is generally safe and free of complications and is a day care procedure taking about only 1 hour to perform. It also requires just 1 small incision. Besides being less invasive, it is devoid of scars and normal day to day activities can be resumed immediately. EVLT is an effective treatment for varicose veins, with possible complications such as burns, recurrence, phlebitis, pain, and others, due to incorrect operation. But the knowledge about this technique in India is limited. EVLA is safe, and although more energy is used, this has not translated into higher complication rates.[31]

CONCLUSION

- A prospective observational study was conducted on 57 limbs from 50 participants who were advised to undergo endovenous laser ablation as a treatment for varicose veins
- The mean age of study subjects was 45 years. 78% of the study subjects were males
- 86% of our study participants underwent EVLT for single lower limb while 14% underwent the procedure for both lower limbs.
- Majority (82.5%) of the limbs had varicose veins in both calf and thigh while the remaining (17.5%) had varicose veins in calf or thigh.
- 38.6% of limbs had venous edema in foot and ankle while 59.6% had both above ankle and below knee edema.
- 7% of limbs had single active ulcer while 1.8% had two active ulcers.
- 49.1% of limbs had Perimalleolar pigmentation, 52.6% had Perimalleolar Inflammation and 38.6% had Perimalleolar induration.
- At baseline according to pre-operative revised VCSS pain scale, 75.4% of the limbs had daily pain and 19.3% had daily limiting pain.
- The mean pre-operative VCSS score was 12.42 with 95% CI of 11.51 to 13.33
- The mean total score decreased from 12.42 in pre-operative period to11.79 at day 1 of follow up, 10.93 at day 3 of follow up, 9.98 at week 1 of follow up, 8.3 at week 3 of follow up and to 6.91 ± 2.07 at 3rd month of follow up.
- The differences in the total score at day 1, day 3, week 1 and week 3 follow up period with baseline value (pre-operative) were statistically significant (P value <0.001).

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.

SUMMARY

- The study was a prospective observational study.
- Patients attending to the department of radiology with varicose veins and advised endovenous laser ablation as its treatment were included in the study.
- 50 patients (57 limbs) 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
- Preoperative Revised Venous clinical severity score (VCSS) was taken.
- 43 patients underwent endovenous laser ablation of varicose veins for single lower limb and 7 patients for both the lower limbs.
- Doppler scan was performed immediately after the procedure and at the end of 3 months to check for recurrences.
- Following the operative procedure they were again subjected to revised VCSS on post-op day1, day 3, week 1, week 2 and at 3months.
- There was gradual reduction in the mean total revised VCSS score from pre-operative period to day 1, day 3, week 1, week 3 and 3 months.
- No patient in our study had developed Deep vein thrombosis or recanalization of superficial veins on doppler study at 3 months follow-up
- The study concludes that endovenous laser ablation is an effective mode of treatment of varicose veins with lesser complications, early post operative discharge and significant improvement in patient's symptoms.

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ANNEXURE I – INFORMED CONSENT

TITLE OF THE STUDY: "EVALUATION OF ENDOVENOUS LASER ABLATION AS A TREATMENT OF VARICOSE VEINS – A ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY"

PRINCIPAL INVESTIGATOR: _____

INTRODUCTION AND PURPOSE:

Less invasive modalities, such as endovenous laser ablation (EVLA) as a treatment for varicose veins are associated with fewer postoperative complications, such as hematoma, pain or saphenous nerve injury. Thus this study will help in documenting the advantages and disadvantages of minimally invasive procedures such as EVLA.

PROCEDURE:

I request you to kindly participate in the study titled **"EVALUATION OF ENDOVENOUS LASER AS A TREATMENT OF VARICOSE VEINS – A ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY"** at Dr. Prabhakar Kore charitable hospital and Medical Research Centre, Belgaum" is being conducted by _____, post graduate in Radiodiagnosis at J. N. Medical College Belgaum, Karnataka, under the guidance of _____, HOD & Professor, Dept. of Radiodiagnosis, J. N. Medical College, Belgaum and Dr. NavinMulimani, Associate Professor, Dept. of Radiodiagnosis, J. N. Medical College, Belgaum, under KLE University, Belgaum.

We request you to participate in this study as you are eligible to be included. During the study you will be asked questions regarding your present and past medical history and you will be required to answer to the best of your knowledge. You will also be clinically examined as per the protocol drawn.

If you agree to participate in the study please furnish the details pertaining to the study.

BENEFITS:

- Minimally invasive
- Lesser post operative complications
- Early post surgery discharge

COMPLICATIONS:

- Pain, hematoma
- Skin changes such as pigmentation, induration , burns, superficial thrombophlebitis
- Nerve injury
- Deep vein thrombosis

ALTERNATIVES:

If patient is not willing to take part in the study, his / her treatment or any other further investigations the patient wants to undergo, in future, in KLE will not be affected by his / her decision.

VOLUNTARY PARTICIPATION/WITHDRAWAL:

Taking part in this study is voluntary. I may choose not to take part in this study, or if I decide to take part I can later change my mind and withdraw from the study. My decision will not change the present or future health care or other services that I receive. The study doctor or the sponsor may stop my participation in this study. I will tell of any important new findings that may change my willingness to continue to take part. If I choose not to take part in the study I will receive the standard treatment for patients with my condition.

COSTS:

NIL (The study is to be conducted on the participants who are advised EVLA as a treatment for varicose veins by the referring consultant and the participants will bear the charges for it.)

PAYMENT FOR PARTICIPATION: No incentive will be paid to you for participating in this study.

COMPENSATION:

In the event that I become injured as a result of taking part in this study, treatment whatever available at KLE charitable hospital, belagavi, will be offered to me. No reimbursement, compensation or free medical care is given.

CONFIDENTIALITY:

All information collected about me during the course of the study will be kept confidential to the extent permitted by the law. The code numbers will identify me in this research record. Information from this study may be published but my identity will be confidential in any publication.

QUESTION:

If any enquiries in the future or in case of research related injury illness, you may contact following person.

Dr. Roopa Bellad
Professor of pediatrics Chairperson, J.N. Medical College Institutional Ethical Committee for Human Subjects Research
Ph. No: 0831-2473777,Ext. 1529
Mob- 9448863866

CONSENT TO PARTICIPATE IN RESEARCH STUDY:

I consent to the performance of Endovenous laser procedure upon myself in addition to or different from those now contemplated, whether or not arising from presently unforeseen conditions, which the doctor and his associates may consider necessary or advisable in the course of the procedure.

I consent to the administration of such anesthetics as may be considered necessary or advisable by the physician responsible for this service.

I consent to the photographing or recording of the procedure to be performed including appropriate portions of my body, for medical, scientific or educational purposes provided my identity is not revealed in the pictures or by the descriptive texts accompanying them.

For the purpose of advancing medical education I consent to the admittance of observers to the operating room.

The nature and purpose of the procedure, possible alternative methods of treatment, the risks involved and the possibility of complications such as ecchymosis, superficial phlebitis, paresthesia or dysesthesia due to neurologic injuries, skin burns, shock and DVT etc. have been fully explained to me in my own understandable language.

No guarantee or assurance has given by anyone as to the results that may be obtained.

Participant's Name/legally authorized representative :……

Signature/ Left Thumb impression : ……....

Date :……..

Place : ……..……

ANNEXURE II-PROFORMA

PROFORMA FOR DATA COLLECTION

NAME : **AGE :**

WEIGHT/HEIGHT :

OP/IP NO : **MOBILE :**

ADDRESS :

CONSULTANT :

DOA : **DOD :**

CHIEF COMPLAINTS:

HISTORY OF PRESENTING ILLNESS :

PAST HISTORY :

FAMILY HISTORY :

PERSONAL HISTORY :

PHOTOGRAPH OF LIMB CONDITION PRIOR TO THE PROCEDURE

DATE:

DATE:

DOPPLER EXAMINATION OF THE ___ LOWER LIMB

REVISED VCSS :

Descriptor	Absent(0)	Mild (1)	Moderate (2)	Severe (3)
Pain	**None**	**Occasional**	**Daily**	**Daily limiting**
Varicose veins	**None**	**Few**	**Calf or thigh**	**Calf and thigh**
Venous edema	**None**	**Foot and ankle**	**Above ankle, below knee**	**To knee or above**
Skin pigmentation	**None**	**Perimalleolar**	**Diffuse, lower 1/3 calf**	**Wider, above lower 1/3 calf**
Inflammation	**None**	**Perimalleolar**	**Diffuse, lower 1/3 calf**	**Wider, above lower 1/3 calf**
Induration	**None**	**Perimalleolar**	**Diffuse, lower 1/3 calf**	**Wider, above lower 1/3 calf**
No. of active ulcers	**None**	**1**	**2**	**3 or more**
Active ulcer size	**None**	**<2 cms**	**2-6 cm**	**>6 cm**
Ulcer duration	**None**	**<3 months**	**3-12 months**	**>1 year**
Compression therapy	**None**	**Intermittent**	**Most days**	**Fully comply**

TOTAL SCORE :

ANNEXURE-III- ETHICAL CLEARANCE LETTER

K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
(Accredited 'A' Grade by NAAC)

Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 23

Date: 22/11/2017

REG NO. BS0117005

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"A EVALUATION OF ENDOVENOUS LASER ABLATION AS A TREATMENT OF VARICOSE VEINS – A ONE YEAR HOSPITAL BASED OBSERVATIONAL 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.

ANNEXURE IV: FIGURES

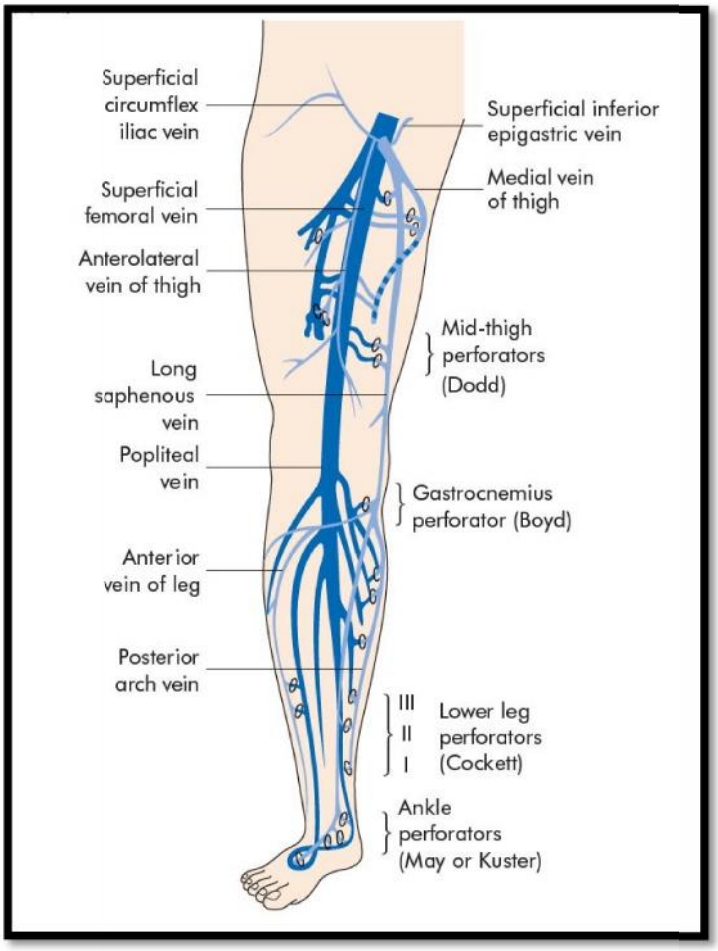

Fig 1. Venous anatomy of lower limb.

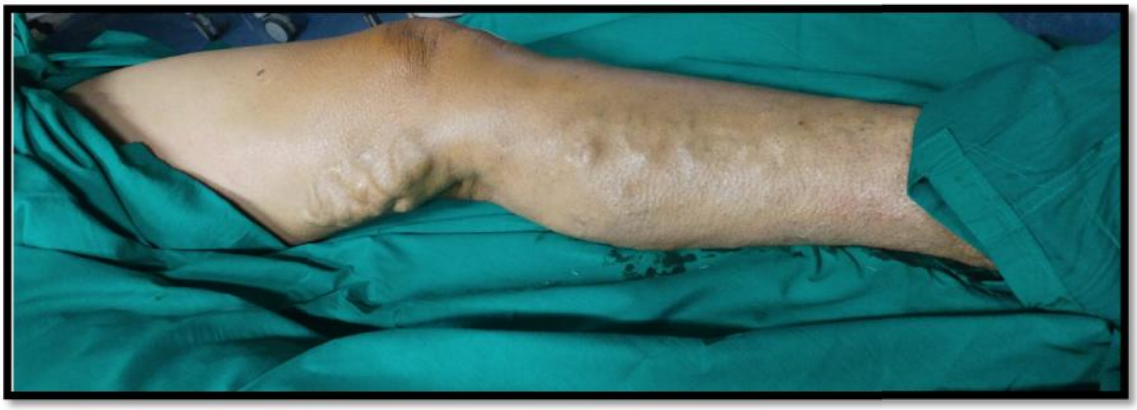

Fig 2: Varicose veins involving the great saphenous vein of left lower limb.

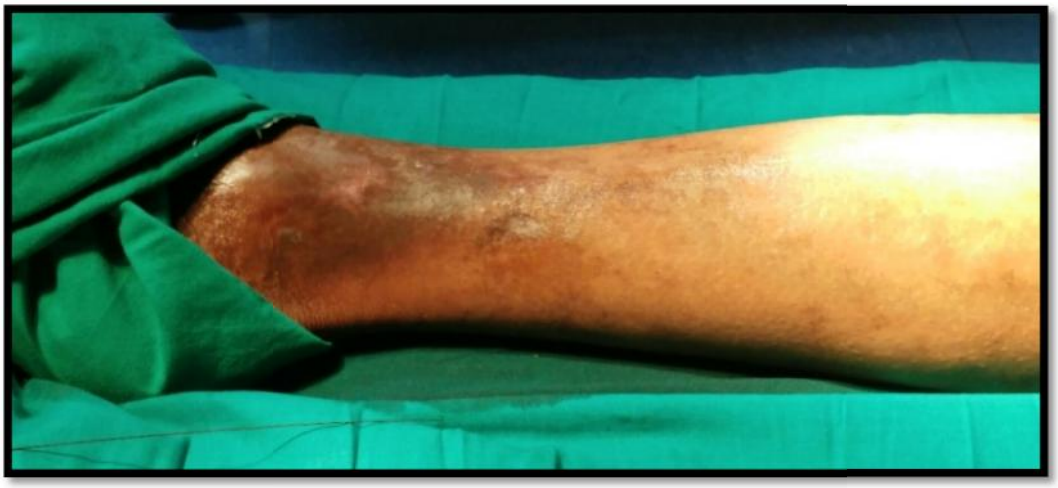

Fig 3: skin pigmentation around the ankle.

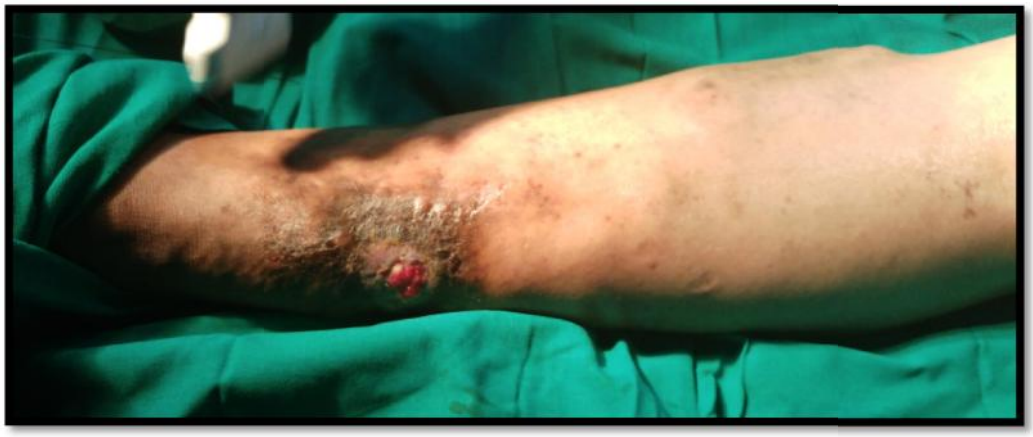

Fig 4: Venous ulcer in the gaiter area of left lower limb.

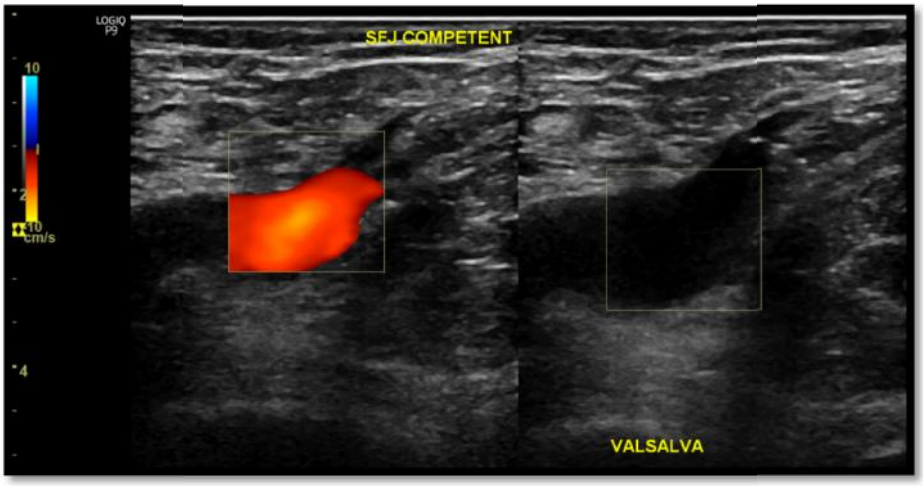

Fig 5: USG Doppler image showing sapheno-femoral junction competence.

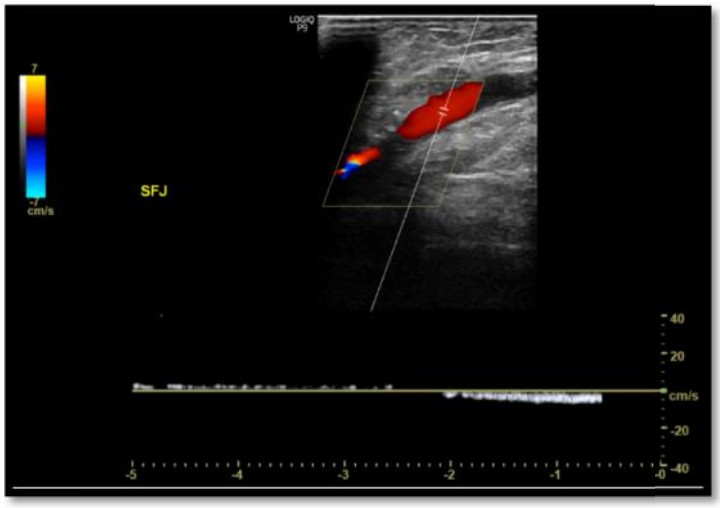

Fig 6: USG Doppler image showing sapheno-femoral junction incompetence.

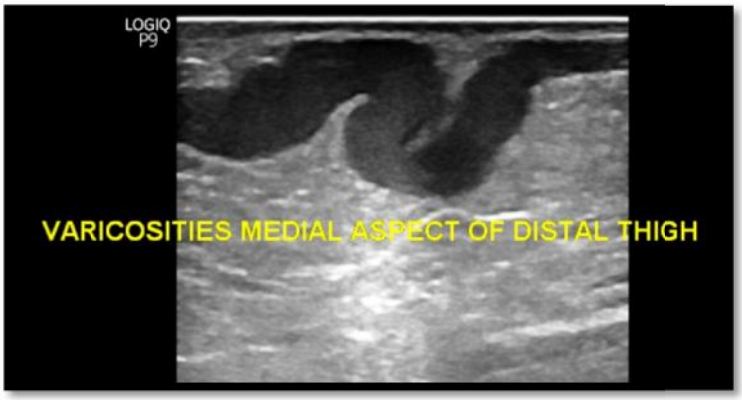

Fig 7: USG image of dilated and tortuous superficial veins.

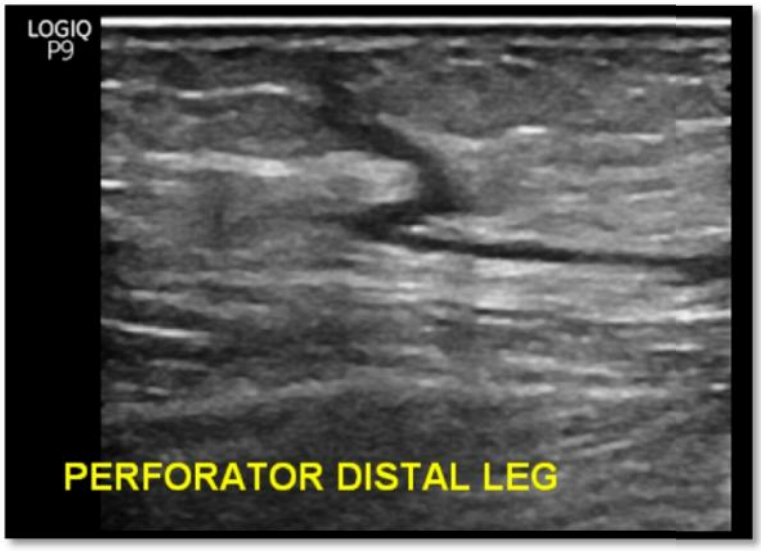

Fig 8: USG image of dilated incompetent perforator.

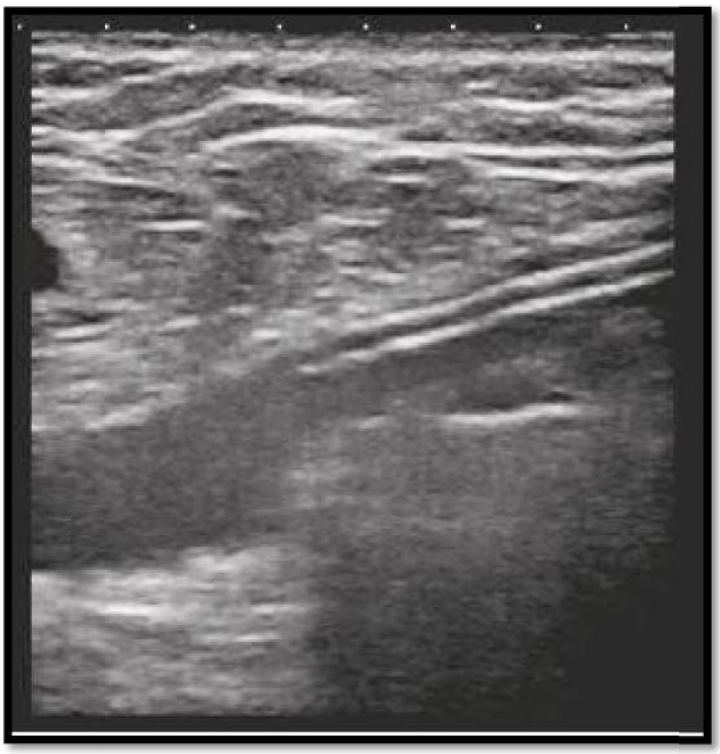

Fig 9: EVLT procedure: catheter-tip in position (2 cm proximal to SFJ)

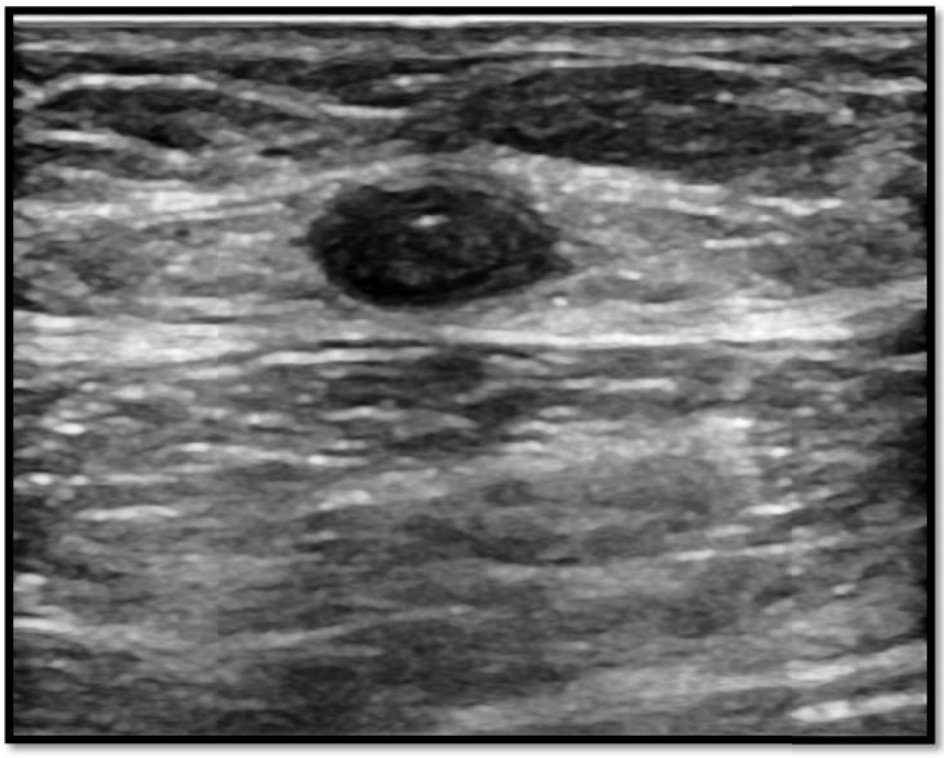

Fig 10: Post EVLT: B-mode image of thrombosis of GSV (axial view)

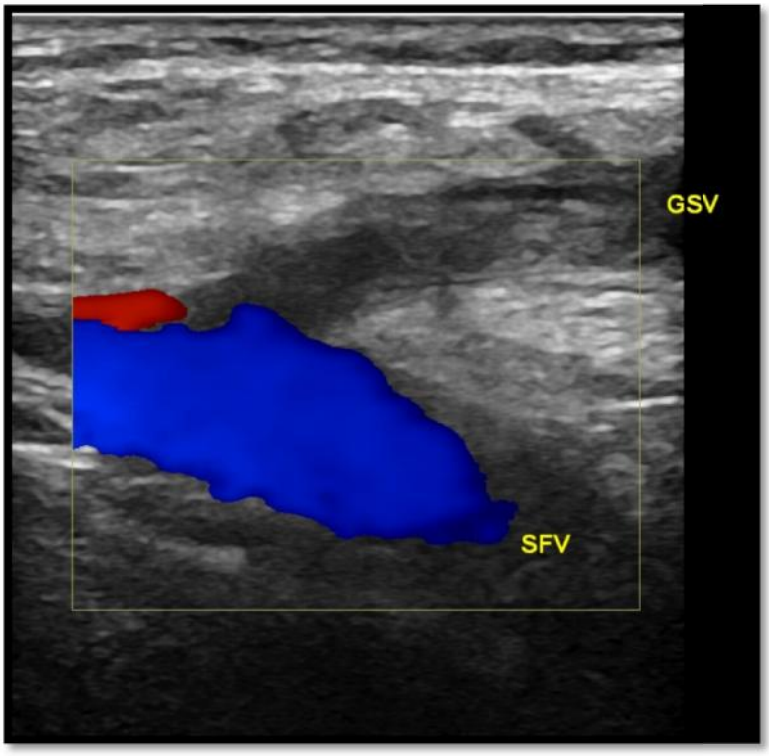

Fig 11: Post EVLT: Duplex imaging of thrombosis of GSV (longitudinal view). GSV: Great saphenous vein, SFV: Superficial femoral vein

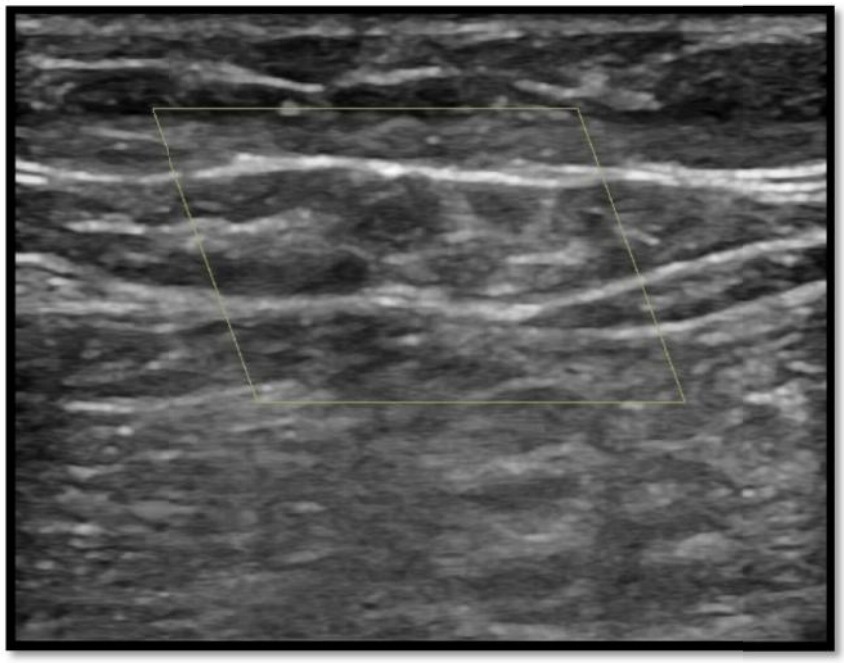

Fig 12: Post EVLT: Colour doppler image of thrombosed GSV (longitudinal view)

ANNEXURES V - MASTER CHART

SERIAL NO	OP/IP NUMBER	AGE	SEX	LATERALITY	SFJ		IC PERFORATORS		PRE OPERATIVE REVISED VCSS										POST OPERATIVE REVISED VCSS (TOTAL SCORE)				
					RIGHT	LEFT	RIGHT	LEFT	PAIN	VARICOSE VEINS	VENOUS EDEMA	SKIN PIGMENTATION	INFLAMMATION	INDURATION	NO. OF ACTIVE ULCERS	ACTIVE ULCER SIZE	ULCER DURATION	COMPRESSION THERAPY	TOTAL SCORE	POST OP DAY 1	DAY 3	WEEK 1	WEEK 3	3 MONTHS
1	828171	45	M	RIGHT	IC		2		3	3	1	2	2	2	0	0	0	1	14	12	11	10	8	9
2	830229	39	M	RIGHT	IC		3		3	3	1	2	2	2	0	0	0	2	15	14	13	12	9	8
3	830422	55	F	BILATERAL	IC		1		3	3	2	1	0	0	0	0	0	2	11	11	10	9	6	5
						C		1	2	3	2	1	0	0	0	0	0	2	10	9	8	7	6	5
4	830641	41	M	BILATERAL	C		1		2	3	1	1	0	0	0	0	0	1	8	8	7	6	5	4
						IC		1	2	3	1	2	2	1	1	2	2	1	17	16	15	14	11	9
5	830750	42	M	BILATERAL	C		2		2	3	1	1	0	1	0	0	0	2	10	10	9	8	7	6
						C		1	2	3	1	1	0	1	0	0	0	2	10	10	9	8	7	6
6	830306	41	F	LEFT		IC		2	2	3	1	1	1	0	0	0	0	2	10	10	9	9	8	7
7	835366	52	M	LEFT		IC		2	2	3	2	2	2	1	2	1	2	3	20	20	18	17	15	11
8	836816	58	M	RIGHT	IC		2		2	3	1	1	1	1	0	0	0	3	12	12	11	10	9	8

9	838090	65	M	LEFT		IC		2	3	3	1	2	2	1	0	0	0	2	14	13	12	11	10	9
10	838744	53	F	RIGHT	IC		2		2	3	2	1	1	0	0	0	0	2	11	10	9	8	7	6
11	840076	47	F	LEFT		IC		1	2	3	1	2	0	0	0	0	0	2	10	9	8	6	6	4
12	841218	73	F	RIGHT	IC		2		2	3	1	0	1	0	0	0	0	2	9	9	8	7	6	5
13	842139	34	M	BILATERAL	IC		2		2	3	2	1	2	1	0	0	0	2	13	12	11	10	8	6
						IC		2	2	3	2	1	2	0	0	0	0	2	12	11	10	9	7	6
14	844412	65	M	LEFT		IC		2	2	3	2	1	1	0	0	0	0	2	11	10	9	8	9	9
15	844413	45	M	LEFT		IC		2	3	3	1	2	2	2	0	0	0	3	16	15	14	13	11	9
16	845365	28	M	RIGHT	IC		4		2	2	1	2	0	0	0	0	0	2	9	9	9	8	6	5
17	846230	38	M	RIGHT	IC		2		2	3	2	2	2	1	0	0	0	2	14	13	12	11	9	8
18	845461	59	M	RIGHT	IC		2		2	3	1	1	0	0	0	0	0	2	9	9	9	8	7	5
19	847601	63	M	LEFT		IC		1	2	3	1	2	1	1	0	0	0	2	12	12	11	10	8	6
20	850021	38	M	LEFT		IC		2	3	3	2	2	2	2	0	0	0	3	17	16	16	15	13	11
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23	854616	48	M	RIGHT	IC		5		2	3	2	2	2	1	0	0	0	3	15	14	13	12	10	8
24	858421	51	M	LEFT		IC		1	2	3	2	0	1	0	0	0	0	2	10	10	9	8	7	6
25	858928	37	F	LEFT		IC		1	2	3	2	2	1	1	0	0	0	2	13	12	11	10	8	7
26	859835	45	M	RIGHT	IC		1		2	3	1	1	1	1	0	0	0	2	11	11	10	9	8	6
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28	869269	67	M	LEFT		IC		3	3	3	3	1	1	1	0	0	0	3	15	15	14	13	10	9
29	873566	36	M	LEFT		IC		1	3	3	2	2	2	2	1	2	2	3	22	20	19	18	14	11
30	873851	56	F	RIGHT	IC		1		3	3	2	3	3	3	0	0	0	3	20	18	18	17	15	12
31	874057	50	M	LEFT		IC		1	2	3	1	1	1	1	0	0	0	2	11	11	10	9	8	7
32	878733	48	M	LEFT		IC		3	2	3	2	2	2	2	0	0	0	2	15	14	13	12	9	7
33	879889	32	M	RIGHT	IC		4		2	3	2	2	2	2	0	0	0	3	16	15	14	13	10	9
34	880103	20	M	BILATERAL	IC		1		2	3	2	1	1	0	0	0	0	2	11	11	10	9	8	7
						IC		1	2	3	2	1	0	0	0	0	0	2	10	9	8	7	6	5

35	880949	50	M	RIGHT	C		2		2	3	2	1	2	1	0	0	0	2	13	13	13	12	10	8
36	882212	34	F	RIGHT	IC		1		2	3	2	3	3	3	0	0	0	2	18	17	16	15	12	9
37	885484	27	M	RIGHT	C		3		1	2	1	1	1	1	0	0	0	2	9	9	8	7	6	5
38	889789	38	F	LEFT		IC		2	2	2	2	0	1	0	0	0	0	2	9	8	7	6	5	4
39	891526	28	M	RIGHT	IC		2		1	2	2	1	1	0	0	0	0	2	9	9	8	7	6	5
40	891545	52	M	RIGHT	IC		3		2	3	2	1	1	0	0	0	0	2	11	10	10	9	7	6
41	872977	64	M	RIGHT	IC		2		3	3	2	2	2	1	1	1	1	3	19	18	16	15	12	10
42	893785	41	M	RIGHT	C		3		2	2	2	1	1	0	0	0	0	2	10	10	9	9	8	7
43	901543	66	F	RIGHT	IC		2		2	3	2	1	1	0	0	0	0	2	11	11	10	9	6	5
44	902033	44	M	RIGHT	IC		2		3	3	2	1	1	1	1	2	2	3	19	18	18	17	13	11
45	903156	59	M	RIGHT	C		1		1	2	1	1	1	0	0	0	0	2	8	7	7	7	6	5
46	906768	23	M	LEFT		IC		2	2	3	2	1	1	0	0	0	0	2	11	10	9	9	6	5
47	907327	26	M	LEFT		IC		3	2	3	2	1	1	1	0	0	0	2	12	11	10	9	8	6
48	908548	34	M	BILATERAL	IC		1		2	2	2	3	1	1	0	0	0	3	14	13	13	12	9	6
						IC		0	2	2	2	2	1	0	0	0	0	3	12	11	9	8	7	6
49	911846	35	M	LEFT		C		5	2	2	1	0	1	0	0	0	0	2	8	8	8	7	6	5
50	920925	29	M	LEFT		C		3	2	2	1	0	1	0	0	0	0	3	9	9	8	7	6	5

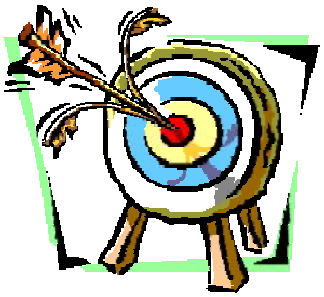
ANNEXURE VI: KEY TO MASTERCHART

SFJ	**Saphenofemoral junction**
IC	**Incompetent**
C	**Competent**
Sl No.	**Serial number**

REVISED VCSS (Venous Clinical Severity Scoring):

Descriptor	Absent(0)	Mild (1)	Moderate (2)	Severe (3)
Pain	**None**	**Occasional**	**Daily**	**Daily limiting**
Varicose veins	**None**	**Few**	**Calf or thigh**	**Calf and thigh**
Venous edema	**None**	**Foot and ankle**	**Above ankle, below knee**	**To knee or above**
Skin pigmentation	**None**	**Perimalleolar**	**Diffuse, lower 1/3 calf**	**Wider, above lower 1/3 calf**
Inflammation	**None**	**Perimalleolar**	**Diffuse, lower 1/3 calf**	**Wider, above lower 1/3 calf**
Induration	**None**	**Perimalleolar**	**Diffuse, lower 1/3 calf**	**Wider, above lower 1/3 calf**
No. of active ulcers	**None**	**1**	**2**	**3 or more**
Active ulcer size	**None**	**<2 cms**	**2-6 cm**	**>6 cm**
Ulcer duration	**None**	**<3 months**	**3-12 months**	**>1 year**
Compression therapy	**None**	**Intermittent**	**Most days**	**Fully comply**

Introduction



Objectives

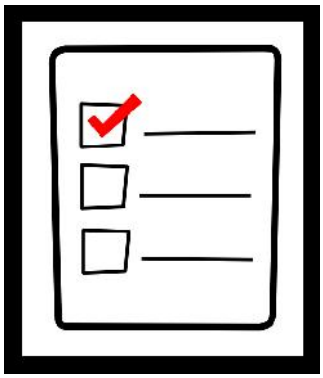
Review of Literature

Methodology

Results

Discussion

Conclusion

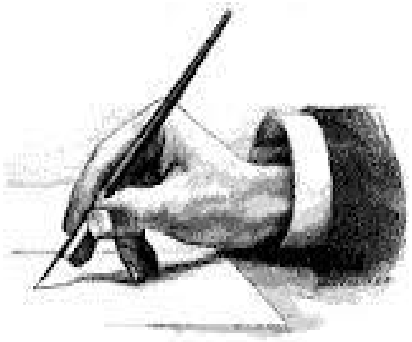


Limitations

Recommendations

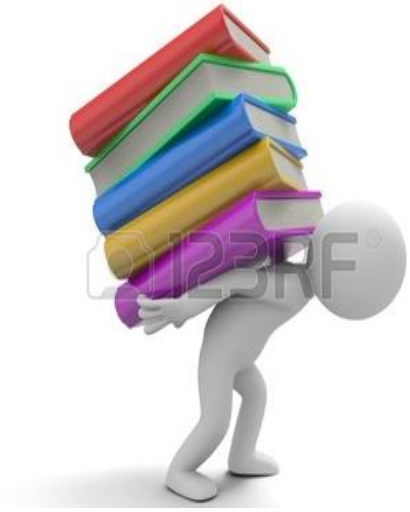
Summary

Bibliography



Annexure-I

Annexure-II



Annexure-III

Annexure-IV

Annexure-V