



Department of Diagnostic and Interventional Radiology
All India Institute of Medical Sciences, Jodhpur

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THROUGH PROPER CHANNEL

To,

The Dean (Academics)
All India Institute of Medical Sciences, Jodhpur
Jodhpur- 342005



Subject: Submission of thesis in partial fulfilment of the requirement for the degree of MD Radiology

Respected Sir,

I, Dr. Saurabh Badgurjar, Academic Junior Resident in the Department of Diagnostic and Interventional Radiology for the session starting August 2019, hereby submit my thesis in partial fulfilment of the requirement for the degree of MD Radiology.

Kindly find enclosed 05 copies of thesis titled **"A study of demographic factors and treatment outcomes in patients with primary varicose veins of lower limb"** and accept the same. I shall be obliged.

Thanking you,

Yours sincerely,

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Forwarded & recommended.

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A study of demographic factors and treatment outcomes in patients with primary varicose veins of lower limb



THESIS

Submitted to

All India Institute of Medical Sciences, Jodhpur

In partial fulfilment of the requirement for the degree of

Doctor of Medicine (MD)

(Radiology)

**JUNE, 2022
AIIMS, JODHPUR**

DR. SAURABH BADGURJAR



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CERTIFICATE

This is to certify that the thesis titled “**A study of demographic factors and treatment outcomes in patients with primary varicose veins of lower limb**” is the bonafide work of Dr. Saurabh Badgurjar carried out under our guidance and supervision, in the Department of Diagnostic and Interventional Radiology, All India Institute of Medical Sciences, Jodhpur.

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I hereby declare that the thesis titled “**A study of demographic factors and treatment outcomes in patients with primary varicose veins of lower limb**” embodies the original work carried out by the undersigned in All India Institute of Medical Sciences, Jodhpur.



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Saurabh Badgurjar

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LIST OF ABBREVIATIONS

CVD – Chronic Venous Disease

GSV- Great Saphenous Vein

SSV – Small Saphenous Vein

IVC – Inferior Vena Cava

SFJ – Sapheno Femoral Junction

SPJ – Sapheno Popliteal Junction

DVT – Deep Venous Thrombosis

VCSS - Venous Clinical Severity Score

CEAP - Clinical impact, Etiology, Anatomy and Pathophysiology

CI - Confidence interval

VSDS - Venous Segmental Disease Score

AVVQ - Aberdeen Varicose Vein Questionnaire

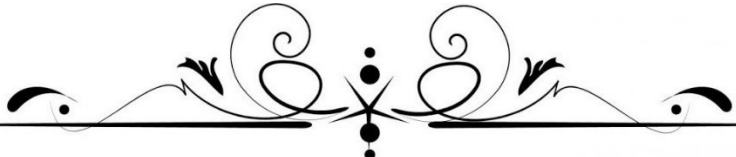
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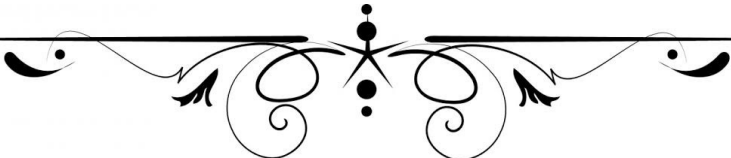
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INTRODUCTION



INTRODUCTION

Terminology: Varicose veins are subcutaneous dilated veins 3 mm or more in diameter with presence of reflux¹. The term varicose is derived from Latin word “varix” which means dilated. The term “varicosity” is generally used for elongated, tortuous, pouched, thickened, inelastic and friable vessels which have lost their valvular efficiency permanently. Though similar changes may also occur in veins, for example in the anal canal as haemorrhoids, varicocele of pampiniform plexus and in cases of portal hypertension at the lower end of oesophagus. Most varicose veins are due to primary venous disease. In patients with primary varicose veins origin of venous reflux in patients can be local or multifocal structural weakness of the vein wall and this can occur together or independently of proximal saphenous vein valvular incompetence². Varicosities can also develop as a result of secondary causes, such as post deep vein thrombosis (DVT), deep venous obstruction, superficial thrombophlebitis, or arteriovenous fistula. It may also be congenital and present as a venous malformation.³

Varicosities are manifestations of chronic venous disease (CVD). Pathogenesis of chronic venous disorders and natural history of the disease remain unclear due to its multifactorial origin. Pathophysiology of the venous system from the hemodynamic point of view and the consequences of valvular dysfunction in superficial, deep, and perforating veins have confirmed in causation of varicose veins and skin trophic changes.⁴

Venous anatomy of the lower limb: The venous drainage of the lower limbs occurs via two channels: the deep and the superficial veins which are separated by the deep muscular fascia. The superficial venous system, which lies superficial to the deep fascia, consists of the great and short saphenous system. The great saphenous vein (GSV) is the continuation of dorsal venous arch anterior to the medial malleolus. It ascends in the medial aspect of calf and drains into the common femoral vein at the saphenofemoral junction (SFJ) piercing the cribriform fascia covering the saphenous opening below the inguinal ligament. Anterior accessory saphenous vein (AASV) is one of the most common tributaries of GSV and courses anterolateral to GSV following its course. Thus, it can be mistaken for duplex GSV (however which is rare). The AASV may drain into the GSV in thigh but it typically drains at or near the SFJ. The lateral end of the dorsal venous arch continues as the short saphenous vein (SSV), passing posterior to the lateral malleolus. It ascends in the posterior aspect of calf and joins the popliteal vein at the saphenopopliteal junction (SPJ). However, the anatomy of this

junction is highly variable. SSV may extend beyond the SPJ (cranial extension of SSV which terminates into deep venous system in posterior thigh by perforating fascia) or it continues as vein of Giacomini (joining the GSV at or near the SFJ).

The superficial and the deep veins are interconnected by valved perforator veins at variable sites. Important perforators among them are the direct perforating veins of medial and lateral calf and communicating veins around knee and mid-thigh.

In the calf, the deep veins are namely, anterior and posterior tibial veins and peroneal vein, are usually paired and accompany the corresponding artery. They join together to form the popliteal vein at the lower border of popliteus muscle, and continues above in the popliteal fossa situating superficial to the corresponding artery. The intramuscular sinuses form soleal and gastronemial veins, which join into tibial or popliteal veins. The popliteal vein then enters the adductor canal thereby becoming the superficial femoral vein, accompanying the corresponding artery till the upper thigh, where it is joined by the profunda femoris vein to form the common femoral vein. The common femoral vein lies medial to the artery. Passing above the inguinal ligament, it becomes the external iliac vein. The external and internal iliac veins join in the pelvis to form the common iliac vein, which joins the vein from the contralateral limb and forms the inferior vena cava.

The veins have valves in their walls, which allows unidirectional flow of blood, i.e caudal to cranial and superficial to deep. The muscular pumps also help in venous return of blood to the heart by contracting the venous sinuses during activity.²

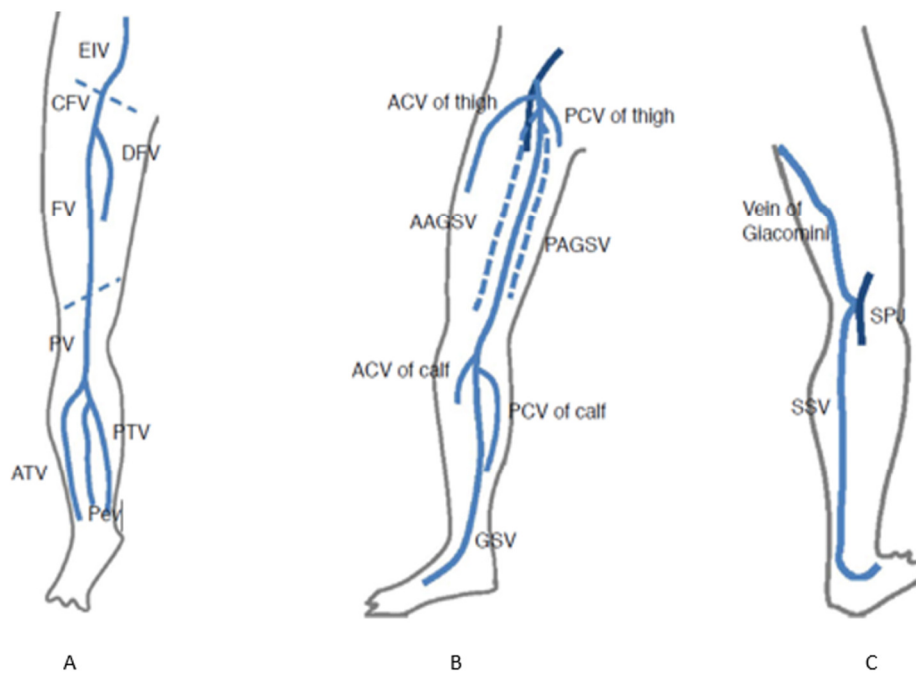


Figure 1 Anatomy of lower limb venous system. A – depicts the deep veins. B and C – shows the superficial veins as seen anteriorly(B) and from posteriorly(C). GSV – great saphenous vein with its tributaries, SFV – short saphenous vein, AASV – Anterior accessory saphenous vein, PAGSV – Posterior accessory saphenous vein, ACV, anterior circumflex vein; PCV, posterior circumflex vein. EIV – external ileac vein, CFV – common femoral vein, FV – superficial femoral vein, PV – popliteal vein, ATV – anterior tibial vein, PTV – posterior tibial vein, Per – peroneal vein, (Figure adapted from Ultrasonography 2017;36:120-130)³

Epidemiology: The prevalence has been variously reported from as little as 2% to over 20% in population studies¹. This enormous variation results from the different populations studied, different definitions applied and the different assessment or examination techniques used. Varicose veins affect up to 32 per cent of women and 40 per cent of men⁶. The majority (60–70 per cent) are due to saphenofemoral and great saphenous vein (GSV) incompetence. The prevalence of varicose veins rises with age in virtually all published studies. Western studies have shown that 20% population suffers from varicose vein and 2% have skin changes preceding the venous ulceration¹.

Risk factors: Many factors which increase the chances of occurrence of varicose veins in lower limbs:

(1) Demographic factors like ¹⁰

- Age
- Sex
- Obesity (BMI > 30)

(2) History of prolonged standing and/or sitting ^{8,9}

(3) Pregnancy

(4) History of varicose veins in first-degree relatives ¹⁰

(5) Secondary to DVT

Clinical Presentation:

- Cosmetically displeasing appearance – venous dilatation
- Pain
- Ankle swelling
- Skin pigmentation
- Eczema

Less common symptoms include ulceration, superficial thrombophlebitis and haemorrhage.

Classification and Scoring of venous disease:

Important changes have been made in the adoption of reporting standards in venous disease over the past few years.

CEAP (Clinical-Etiology-Anatomy-Pathophysiology) classification

It is an internationally accepted standard for describing patients with chronic venous disorders. Before the CEAP classification, the diagnosis of chronic venous disorder lacked precision in diagnosis. This problem had led to reporting errors in studies of the management of venous problems. The ‘Advanced Clinical impact, Etiology, Anatomy and Pathophysiology (CEAP) classification is now well-established tool for grading the severity of venous disease, as well as outcome measurement.’⁹ It was developed in 1993 and as a simpler alternative to the full (advanced) CEAP classification, introduction of a basic CEAP version was also done.

It is most recently revised in 2020 with changes including adding Corona phlebectatica as the C4c clinical subclass, introducing the modifier “r” for recurrent varicose veins and recurrent venous ulcers, and replacing numeric descriptions of the venous segments by their common abbreviations.¹⁰

Venous Clinical Severity Score (VCSS)

The VCSS system includes 10 clinical descriptors (pain, varicose veins, venous edema, skin pigmentation, inflammation, induration, number of active ulcers, duration of active ulceration, size of ulcer, and compressive therapy use), scored from 0 to 3 (total possible score, 30) that may be used to assess changes in response to therapy.^(12, 13)

Venous Segmental Disease Score (VSDS)

VSDS was created with the goal of combining the pathophysiologic designations of reflux and obstruction with the anatomical venous segments as well as the anatomical distribution of sick veins. By summing the coefficients assigned to the sick segments of the vein, each of the two scores that make up the segmental score is determined individually. They are in the range of 0 to 100.

Aberdeen Varicose Vein Questionnaire (AVVQ)

AVVQ is patient reported quality of life measurement system. It is a valid and reliable outcome measurement for patients with varicose veins. It is a type of PROM questionnaire (Patient reported outcome measures).

Pathogenesis: The aetiology of varicose vein at a microscopic level is still disputed but the essential defect macroscopically is generally agreed to be the failure of venous valve closure resulting in the superficial veins becoming dilated, elongated and tortuous. Primary valvular incompetence (PVI) is believed to be due to loss of mural elastin and collagen, which leads to dilatation and separation of the valve leaflets.¹⁴

However it has been agreed that it is a complex and multifactorial disease, and it remains an open question as to which inciting factor is responsible for their development, if any one particular factor is in fact solely responsible. Given the numerous environmental, genetic, histologic, and hemodynamic factors identified in the literature, varicose vein aetiology is most likely the result of an imbalance in multiple of these factors.³⁹

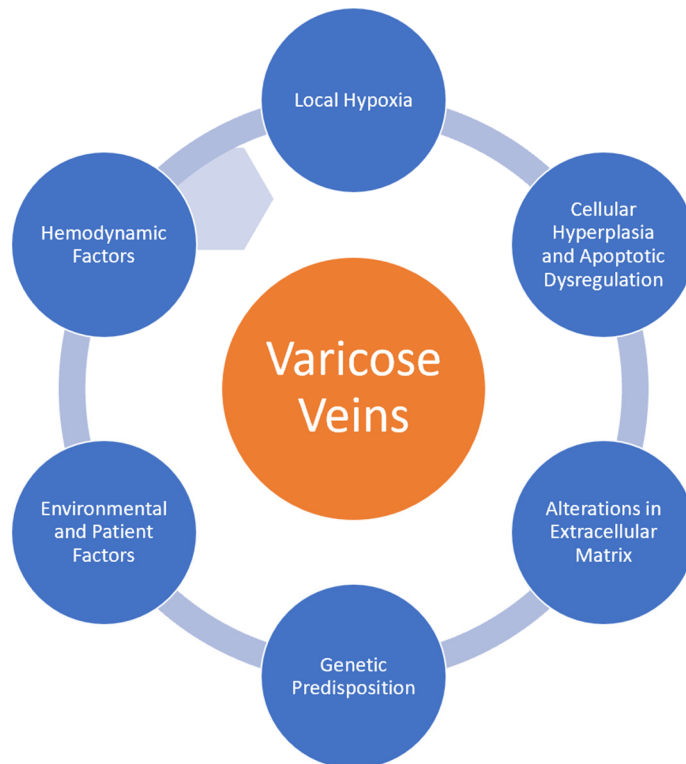


Figure 2: Pathophysiology of varicose veins

Secondary valvular incompetence can be caused by a developmental weakening in the vein wall, which causes secondary expansion of the valve commissures, resulting in valvular incompetence and primary varicose veins. Calf muscle pump dysfunction is linked to any cause of chronic debility or immobility, such as old age, stroke, neuromuscular diseases, arthritis, and trauma. Injury to the ankle that limits or prevents movement has a particularly negative impact on the calf muscle pump.¹⁵

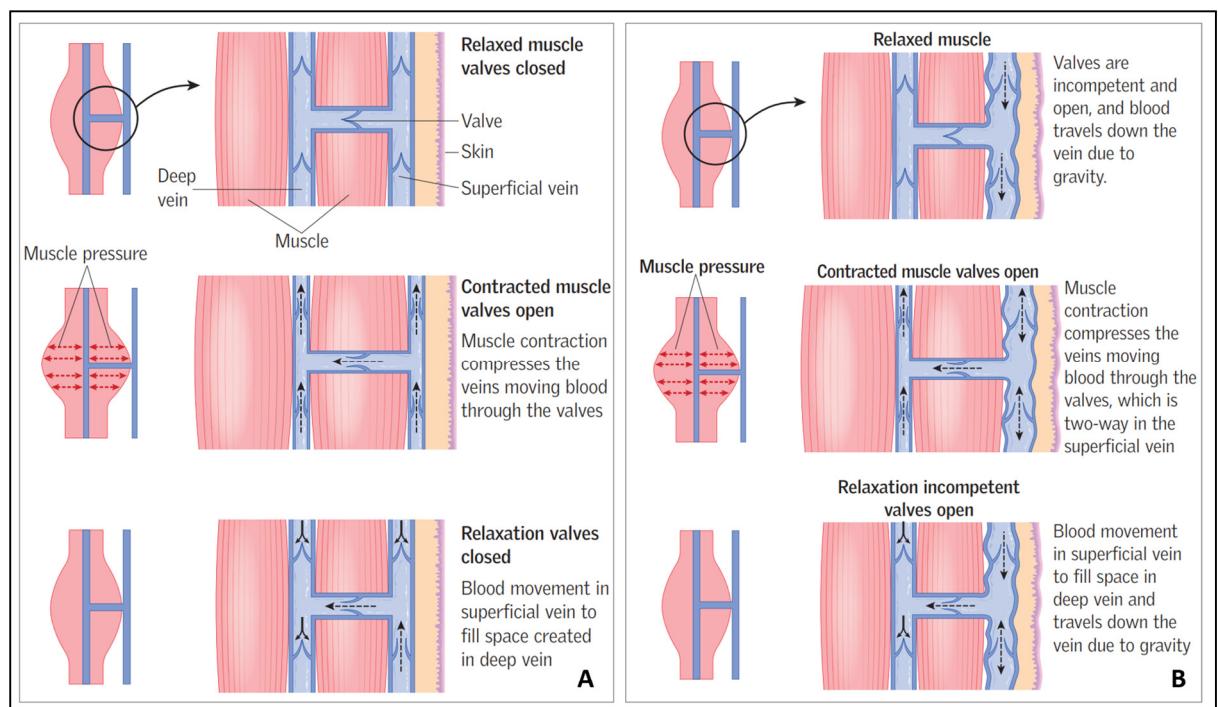


Figure 3: Calf muscle pump in normal veins (A) and varicose veins (B)⁶¹

TREATMENT OPTIONS AVAILABLE

Compression Hosiery

Compression hosiery can be knee length or thigh length. It is classified according to the pressure exerted and according to the British classification class 1 stockings exert pressure of 14 ± 17 mmHg, class 2 exert 18 ± 24 mmHg and class 3 exert 25 -35 mmHg.⁵⁹ The incorrect application of compression hosiery can have serious consequences (pressure necrosis, tourniquet effects). Thus, assessment, prescription and application of compression hosiery should be limited to those with the appropriate skills and training.¹⁷

Ultrasound-guided foam sclerotherapy

Ultrasound- guided foam sclerotherapy involves the injection of sodium tetradecyl sulphate detergent directly into the superficial veins. It destroys the lipid membranes of endothelial cells leads them to shed, followed by thrombosis then fibrosis and obliteration of superficial veins.

Endovenous laser ablation (EVLA)

It was first described in 2001, and it involves the insertion of a Laser fibre into the lumen of an incompetent truncal vein and thermal ablation of the vein. The procedure begins with ultrasound-guided marking of the truncal vein to be treated. The vein is then cannulated percutaneously under ultrasound guidance, a wire is then passed through the needle into the superficial vein. The laser fibre is introduced into the catheter. The tumescent anaesthesia during EVLA provides analgesia and compresses the vein, increasing the contact area between the vein wall and laser fibre.²⁰

Radiofrequency ablation

Radiofrequency ablation is a minimally invasive therapy using a bipolar catheter. It generates thermal energy to ablate the vein. The vein to be treated is cannulated with a sheath using ultrasound guidance and the catheter is introduced through the sheath and then catheter generates heat of $85\pm 120^{\circ}\text{C}$ to ablate the vein.²¹

Endovenous Glue

Non tumescent technique of endoluminal application of cyanoacrylate glue. Treatment catheter is placed within the vein lumen with endovenous administration of the glue via catheter. Patients experience minimal intraprocedural pain.

Open Surgery

The principle of ligation and stripping is to fully dissect the source of junctional incompetence and to remove the refluxing axial vein and dilated tributaries. It involves surgical open ligation of the saphenofemoral or sapheno-popliteal junction combined with stripping of the great saphenous vein or small saphenous vein respectively.

Adjunctive surgical techniques such as phlebectomy and perforator ligation can also be used as sole treatment or following treatment of junctional incompetence and axial vein reflux. Perforator ligation may be done with duplex guided incision or subfascial endoscopic guided perforator ligation.

AIM & OBJECTIVES

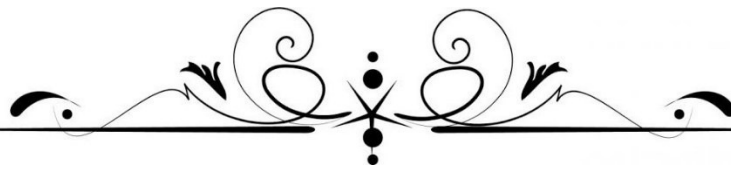
AIM AND OBJECTIVES

Aim:

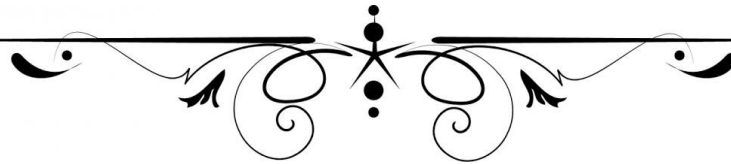
To evaluate the demographic factors, radiological imaging findings and clinical outcome of patients with lower limb varicose veins.

Objectives:

1. To determine the association between risk factors (history of prolonged standing/sitting, family history, gender, age, BMI, pregnancy) and varicose vein disease.
2. To associate imaging findings (USG Doppler) with clinical status of the patient.
3. To evaluate the role of conservative, endovascular and surgical interventions in management of varicose veins.



REVIEW OF LITERATURE



REVIEW OF LITERATURE

Epidemiology: The prevalence has been variously reported from as little as 2% to over 20% in population studies¹. This enormous variation results from the different populations studied, different definitions applied and the different assessment or examination techniques used. Varicose veins affect up to 32 per cent of women and 40 per cent of men⁶.

An increase in varices with age was demonstrated in Edinburgh Vein Study⁵, in common with findings from many other studies.^{22,23} The frequency of varicose veins was higher in person who stands for long time (50.32%) and in 24.51% of patients sitting posture was found as a risk factor.²⁴ Increasing body mass and height are also associated with increased risk of varicose veins.

Risk Factors:

- **Age:** An increase in varices with age was demonstrated in Edinburgh Vein Study⁵, in common with findings from many other studies.^{22,23} The prevalence of varicose veins in the age groups 18-24 years, 25-34 years, 35-44 years, 45-47 years and 55-64 years was 11.5%, 14.6 %, 28.8%, 41.9% and 55.7 % respectively.
- **Sex:** Effect of gender on the varicose veins is controversial. The majority of studies indicate higher prevalence in females than males however community prevalence may defer.¹ It has been suggested that variation in the sex ratio between different studies may be partly because of difference in the age of the populations studied and the methods of measurement used.²⁵
- **BMI:** Obesity causes reduction of physical activity and increases the abdominal pressure and hence central venous pressure; these factors may be contributing to varicose veins.²⁶ BMI is classified as (According to WHO): normal weight (18.5 – 24.9 kg/m²), overweight (25 –29.9 kg/m²) and obese (>30 kg/m²).⁵⁵ A 1.5-fold increase in risk of varicose veins was noted in persons with BMI > 30 kg/m². The age-related increase in BMI was the most important determinant for increase in the cross-sectional area of the GSV.²⁸ It has been proposed that obesity per se results in adverse changes in the structural and functional properties of the lower limb vein wall under the influence of the associated hormonal and hemodynamic alterations.⁴¹
- **History of prolonged standing and/or sitting:** A study indicated that prolonged standing and sitting at work may be a more important risk factor for varicose veins than

biological differences between women and men.²⁹ Further, people working in a standing posture are at a significantly greater risk for CVD than those working in a prolonged sitting posture.³⁰

- **Pregnancy:** The prevalence of varicose veins increases with increasing numbers of pregnancies.²⁷ The odds for women with a history of pregnancy in developing varicose veins significantly increases by 82% compared with women with no history of pregnancy.³¹
- **Family history of varicosities:** Several studies have proposed heredity as a risk factor for varicose veins. They are based on cross-sectional studies.^{32,33,5}
- **Secondary to DVT:** Among adults diagnosed with varicose veins, there was a significantly increased risk of incident DVT. Patients with varicose veins have increased levels of inflammatory and prothrombotic markers. Inflammation is thought to be associated with the pathophysiology of DVT.³⁴ In the present study however patients having varicose veins secondary to DVT were excluded.

Diagnosis:

In clinical practice the patients are categorised as having varicose veins or venous ulcers. These patients may be further classified as uncomplicated or complicated (skin changes, bleeding, etc.); uncomplicated patients may be further classified as asymptomatic or symptomatic.¹

After clinical examination patients undergo duplex ultrasound which has become part and parcel for assessment of varicose veins prior to any intervention. The sonographer should take a thorough medical history before performing a visual examination of the leg with the patient standing under bright light. Knowing where troublesome veins, symptomatic areas, and skin changes are located might assist the sonographer better target the examination. It also assures that no tributaries of varicose veins are missed during scanning of the lower limbs.^{35,36,37}

Role of imaging:

Though the diagnosis of varicose veins is clinical, imaging plays a key role in establishing the location, extent, degree of reflux, superficial vessel sizes, the anatomical location of superficial varices, and other relevant comments such as the presence of anatomical variants, thrombus and other incidental findings to monitor the response to therapy and to plan for any further endovascular intervention. It also helps to assess for secondary causes of varicose veins in a few cases, such as secondary to DVT or a pelvic mass compressing the ileac veins or right common ileac artery compressing left common ileac vein – May-Thurner syndrome.

1. Ultrasound:

Ultrasound is regarded as the primary imaging tool for the evaluation of varicose veins. In majority of the cases, this is the only imaging modality to be used. Grey scale ultrasound is used to assess the superficial varicosities and to measure the diameter for saphenous veins and perforators. Venous edema and skin thickening can also be evaluated. Addition of compression to the B mode ultrasound greatly enhances the diagnostic yield to rule out secondary causes such as DVT.

Apart from that, addition of colour flow mode to greyscale (Duplex scan) and spectral doppler to duplex scan (Triplex scan) are performed routinely as a standard method for the evaluation of varicose veins. Additionally, demonstration of reflux by augmentation of flow with compression of calf muscles and Valsalva manoeuvre can be done with respiratory phasicity as indirect evidence of patency of pelvic and abdominal veins.⁴⁵ American College of Radiology⁴⁵ recommends use of augmentation with squeezing of the calf musculature, valsalva manoeuvre may be used at the groin for demonstrating venous insufficiency in the erect positioning of the patient with examined leg in non-weight bearing position. The location and duration of reflux should be determined during the performance of above manoeuvres.^{36,46} To guarantee a full assessment based on clinical indications, evaluation should be undertaken at as many levels as necessary.^{36,46,47,48,49} Anatomical variants such as significant accessory veins or duplications, hypoplastic or aplastic segments should be noted.

The scan should begin in the groin, with the GSV and CFV lying medial to the common femoral artery (the 'Micky Mouse' sign).

In the longitudinal view, SFJ competency is examined, and probable reflux destinations such as the GSV, ASV, and other important thigh tributaries superficial to the saphenous fascia are highlighted. Any sign of reflux coming from the pelvis necessitates additional proximal imaging. The GSV should be checked throughout its fascial compartment ('Egyptian eye' sign) and its diameter quantified if necessary. Spectral and/or colour doppler are then used to look for reflux or obstruction in the CFV, superficial femoral vein and SFJ in the groin. The absence of phasic flow in the CFV with breathing indicates upstream obstruction and the necessity for proximal imaging. The presence and function of perforators in the thigh and calf should be noted, and the crural veins should be checked for reflux or obstruction.

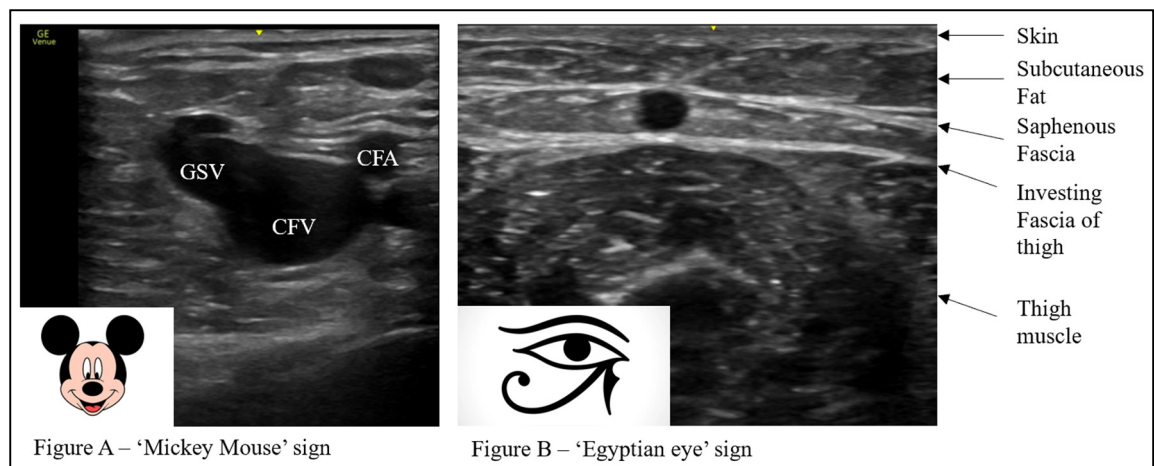


Figure 4: 'Mickey Mouse' sign at SFJ (Figure A) and 'Egyptian eye' sign showing saphenous fascial envelope (Figure B)

For the evaluation of SSV and posterior thigh extension of the SSV (Giacomini vein) patient is positioned facing away, knee slightly bent, heel on the ground, and weight is taken on the opposite leg. If the SPJ is incompetent, the level of the SPJ in respect to the knee crease should be recorded. The SSV vein is traced distally in the transverse view, examining its competency and diameter in the proximal, mid, and distal calf. Finally, the popliteal vein's patency and competency are evaluated. Transabdominal or transvaginal duplex can be used to examine the iliac and pelvic veins.¹

Easy availability, lack of radiation, lower cost, non-invasiveness and no need of intravenous contrast make ultrasound an ideal candidate for all patients.

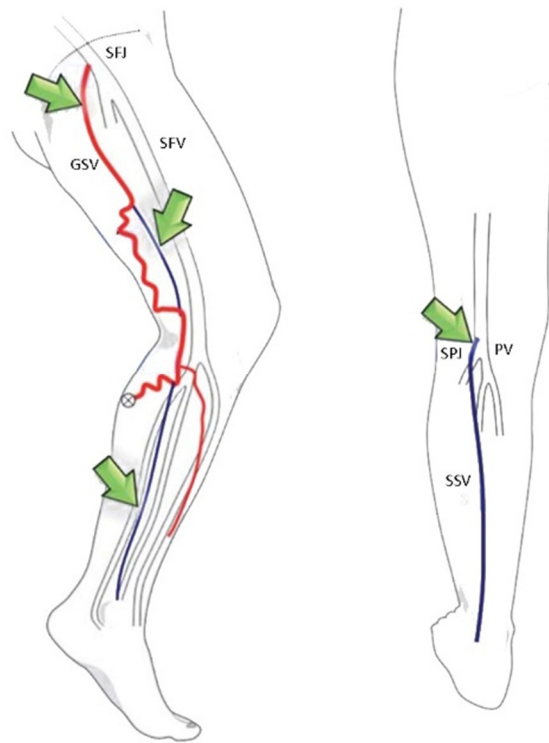


Figure 5: Duplex sampling sites. Assessment for reflux can be easily targeted so that relatively few locations along the superficial venous tree require colour or spectral Doppler sampling. Arrows indicate the few locations which need to be tested.³⁵



Figure A – B mode showing non-apposition of valves at SFJ during Valsalva manoeuvre

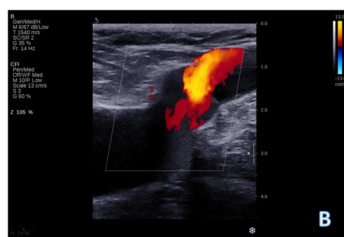


Figure B – Duplex showing reflux at SFJ during Valsalva manoeuvre

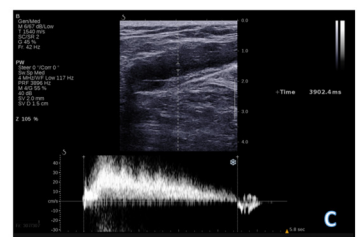


Figure C – Spectral waveform showing reflux at SFJ during Valsalva manoeuvre for >3 seconds

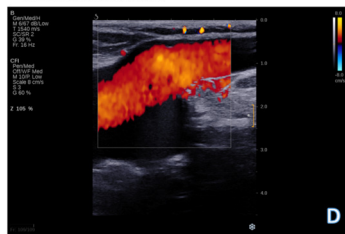


Figure D – Duplex showing reflux at SPJ during Valsalva manoeuvre

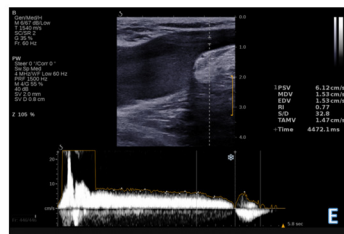


Figure E – Spectral waveform showing reflux at SPJ during Valsalva manoeuvre for >4 seconds

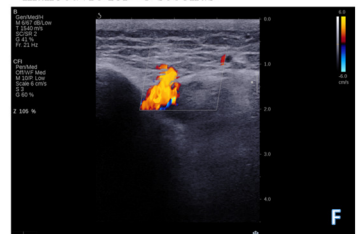


Figure F – Duplex showing incompetent perforator showing reflux

Figure 6: Various USG findings seen in patients of varicose veins

2. Conventional venography

Varicography has now become historical but it was used to identify the sources of incompetence in varicose veins. Dilatation, varicosity, and the absence of recognisable valves were all signs of incompetence in a connecting vein.

Conventional venography can also be done to look for deep venous insufficiency and DVT in doubtful cases. Historically, contrast venography was the first imaging tool used for the diagnosis of DVT. It is still considered the gold standard however it is not routinely used as it is an invasive procedure that requires technical expertise and a large volume of iodinated contrast.



Figure 7: Conventional venography, vascular sheath inserted into the popliteal vein is visible

3. CT venography

In many cases where cause of varicose veins cannot be assessed and secondary causes need to be evaluated then CT venography may be done. It is widely available in most centres and with the advent of multi slice scanners and multi detectors it has become an accurate imaging modality with less invasiveness as compared to conventional venography. Particularly, proximal DVT, extrinsic vein compression in the pelvis by tumours or other structures, collaterals are better evaluated helping in evaluating the complexity of the pathology before intervention.⁵⁰

CT venography scan can be performed by two ways: direct and indirect CTV. In indirect CTV, scan is taken after 120-150 seconds after injection of iodinated contrast into the cubital vein. Direct CTV was first demonstrated by Dr Fredric Thony and team from France. Dorsal vein of the foot is cannulated with a large bore cannula (at least 20 G). It has been observed that direct CTV is more sensitive than indirect CTV and gives more endoluminal details.⁵⁰

4. Magnetic Resonance Imaging (MRI)

MRI is an alternative modality to evaluate primary cause of secondary varicose veins with zero risk of ionising radiation related complications which is desirable in young individuals and when repeat scanning is necessary.⁵¹

Classification and Scoring Systems:

Clinical- Etiological – Anatomical – Pathological (CEAP) classification, Venous Clinical Severity Score (VCSS), Venous Disability Score and the Venous Segmental Disease Score have been used to classify and grade chronic venous insufficiency (CVI).^{11,12,13}

The various scoring and classification systems have been detailed below:

1. CEAP classification

It was developed in 1993 and as a simpler alternative to the full (advanced) CEAP classification, introduction of a basic CEAP version was also done. It is most recently revised in 2020 with changes including adding Corona phlebectatica as the C4c clinical subclass, introducing the modifier “r” for recurrent varicose veins and recurrent venous ulcers, and replacing numeric descriptions of the venous segments by their common abbreviations.¹⁰

CLINICAL CLASSIFICATION

C0: No visible or palpable signs of venous disease.

C1: Telangiectasias or reticular veins.

C2: Varicose veins.

C2r: Recurrent varicose veins

C3: Edema.

C4: Changes in skin and sub cutaneous tissues secondary to chronic venous disease.

C4a: Pigmentation and eczema.

C4b: Lipodermatosclerosis and atrophie blanche.

C4c: Corona phlebectatica

C5: Healed venous ulcer.

C6: Active venous ulcer.

C6r: Recurrent active venous ulcer

Corona phlebectatica: Fan-shaped pattern of numerous small intradermal veins on the medial or lateral aspects of the ankle and foot.¹⁰

Each clinical class sub-characterized by a subscript indicating the presence (symptomatic, s) or absence (asymptomatic, a) of symptoms attributable to venous disease.¹⁰

s: Symptoms including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction.

a: Asymptomatic.

ETIOLOGIC CLASSIFICATION

Ep: Primary

Es: Secondary

Esi: Secondary – intravenous

Ese: Secondary - extravenous

Ec: Congenital

En : No venous cause identified

ANATOMIC CLASSIFICATION

As: Superficial veins.

Ap: Perforator veins.

Ad: Deep veins.

An: No venous location identified

PATHOPHYSIOLOGIC CLASSIFICATION

Pr: Reflux.

Po: Obstruction.

Pr,o: Reflux and obstruction.

Pn: No venous pathophysiology identifiable.

Advanced CEAP: The basic CEAP classification is used for clinical practice, and the full CEAP classification system is used for clinical research. ¹¹ Same as Basic with the addition that any of 18 named venous segments can be utilized as locators for venous pathology. The numbering classification for vein segments in advanced CEAP anatomic seemed to be too difficult to effectively and practically use as they are difficult to recall, have no systematic rationale or other association. Hence, in 2020 revision using standard abbreviations derived from anatomic terms is used which are easier to interpret and remember. ¹⁰

As: Superficial veins

Tel: Telangiectasia

Ret: Reticular veins

GSVa: Great saphenous vein above knee

GSVb: Great saphenous vein below knee

SSV: Small saphenous vein

AASV: Anterior accessory saphenous vein

NSV: Non-saphenous vein

Ad: Deep veins

IVC: Inferior vena cava

CIV: Common iliac vein

IIV: Internal iliac vein

EIV: External iliac vein

PELV: Pelvic veins

CFV: Common femoral vein

DFV: Deep femoral vein

FV: Femoral vein

POPV: Popliteal vein

TIBV: Crural (tibial) vein

PRV: Peroneal vein

ATV: Anterior tibial vein

PTV: Posterior tibial vein

MUSV: Muscular veins

GAV: Gastrocnemius vein

SOV: Soleal vein

Ap: Perforating veins

TPV: Thigh perforator vein

CPV: Calf perforator vein

An: No venous anatomic location identified

2. Venous Clinical Severity Scoring system¹³

The VCSS covers ten venous disease characteristics, each of which is graded on a severity scale of 0 to 3. The VCSS categories are assessed individually to build a dynamic score, which emphasises the most severe venous disease sequelae that are expected to respond well to therapy. Skin alterations and pigmentation, inflammation and induration, and ulcers are among them (including number, size, and duration). The latest edition of the VCSS includes a compression category, with higher scores indicating stronger compliance.

The VCSS has received a lot of attention in research. Its ease of use makes it appealing as a stand-alone scoring instrument for venous disease longitudinal surveillance. The CEAP scale's clarity is displayed in a flexible manner.

Table 1: VCSS scoring system

Attribute	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	>2
Active ulcer size	None	<2 cm	2-6 cm	>6 cm
Ulcer duration	None	<3 months	3-12 months	>1 year
Compression	None	Intermittent	Most days	Fully compliant

3. Venous Segmental Disease Score

CEAP's anatomic and pathophysiologic components are combined in the Venous Segmental Disease Score. The presence of reflux and/or blockage in major venous segments is evaluated. It is based entirely on venous imaging, especially duplex scans but also phlebographic observations. With a maximum score of 10, this scoring system weights 11 venous segments for their relative relevance when dealing with reflux and/or obstruction.

Table 2: Venous Segmental Disease Scoring System

Reflux	Score	Obstruction	Score
SSV	½	Great saphenous (only if thrombosed from groin to below knee)	1
GSV	1		
Perforators, thigh	½		
Perforators, calf	1	Calf veins, multiple	1
Calf veins, multiple	2	Popliteal vein	2
Posterior tibial vein alone	1	Femoral vein	1
Popliteal vein	2	Profunda femoris vein	1
Femoral vein	1	Common femoral vein	2
Profunda femoris vein	1	Inferior vena cava	1
CFV and above	1		
Iliac vein	1		
Maximum reflux score	10	Maximum obstruction score	10

4. Venous Disability Score

This score quantifies the level of work-based disability to assess the impact of venous illness. It is graded on a scale of 0 to 3 for the ability to work an 8-hour day with or without external assistance. The overall score indicates the level of disability caused by venous illness.

Table 3: Venous Disability Score

Score	Definition
0	Asymptomatic
1	Symptomatic but able to carry out usual activities without compressive therapy
2	Can carry out usual activities* only with compression and/or limb elevation
3	Unable to carry out usual activities* even with compression and/or limb elevation

*Usual activity in VDS denotes patient activities before onset of disability from venous disease

Treatment of varicose veins

1. Elastic Compression Stockings: Their main function is to reduce the oedema, feeling of heaviness and improve the daily functioning. In British classification of compression hosiery according to the pressure they exert: Class 1 stockings exert pressure of 14-17 mmHg; Class 2 exert 18–24 mmHg and Class 3 exert 25–35 mmHg.⁵⁹ Graded compression stockings of 18-24 mmHg (class II) are commonly prescribed. Both above knee and below knee stockings can be used as there is no significant difference between their effectiveness. The patient is told to wear them throughout the day and remove during bed time. If 18-24 mm Hg stockings do not adequately control the symptoms, higher pressure (25-35 mm Hg) stockings can be prescribed. Compliance and long-term tolerance are factors which often restricts the use of ECS, patient feeling sweating, pruritus with use of ECS. Atherosclerotic disease is the only contraindication for the use of ECS as it can exacerbate tissue ischemia.

2. Endothermal Ablation: Endothermal ablation technologies are marginally safer, have extremely high technical efficacy, offer superior quality of life post procedure (with a rapid recovery), and offer comparable improvements in quality of life over time. The procedures are cost-effective since they can be done as an outpatient procedure with a local anaesthetic.

The main premise is that a therapy device is percutaneously placed into an inadequate axial vein. A tumescent local anaesthetic solution surrounds the vein. Tumescent anaesthesia offers three purposes – (a) Vein is compressed against the treatment device, which causes it to empty of blood (b) It also hydro-dissects tissues away from the damage zone, such as nerves. (c) Serves as a heat sink, absorbing excess thermal energy and preventing damage from afar.

The therapy device subsequently emits heat energy, which damages the vein's structure and causes permanent blockage. There are two types of ablation technologies: laser and radiofrequency ablation.

Endovenous Laser Ablation (EVLA)

A small flexible glass fibre is introduced into the vein for endovenous laser ablation (EVLA). Laser energy is transferred down the fibre and absorption of this radiation causes a large amount of thermal energy to be produced. The tip of the fibre can be (a) Bare - focussing the energy in a limited area (c) Divergent forward firing - spreads the energy out over a broader region (d) Divergent side or radial firing - spreads the energy out over a greater area. The

latter two designs provide for a more uniform distribution of energy, decreasing vein wall perforations, which are linked to postprocedural pain and bruising.

Procedure: In our institute diode laser source (LEONARDO® - Biolitec) with a wavelength of 1470 nm and a power of 15 W was used to perform EVLA. The saphenous veins were reached by percutaneous route from the caudal aspect at the lowest point of reflux with a 21 gauge (G) micropuncture needle under local anaesthetic and ultrasound supervision. For GSV patient should be supine with the leg to be treated externally rotated and slightly flexed and for SSV the patient is placed in the prone position. Under ultrasound direction, a tumescent anaesthetic solution of 15 ml of 2% lignocaine, 500 ml Normal Saline and 15 ml of 8.4% sodium bicarbonate was injected around the saphenous vein using 19–21 G lumbar puncture needle. Under ultrasound direction, a bare-tip radial laser fibre connected to a 1470 nm diode laser source was advanced via the catheter and put 1.5 cm from the SFJ before tumescent local anaesthetic was administered. The laser energy was provided in pulsed mode.

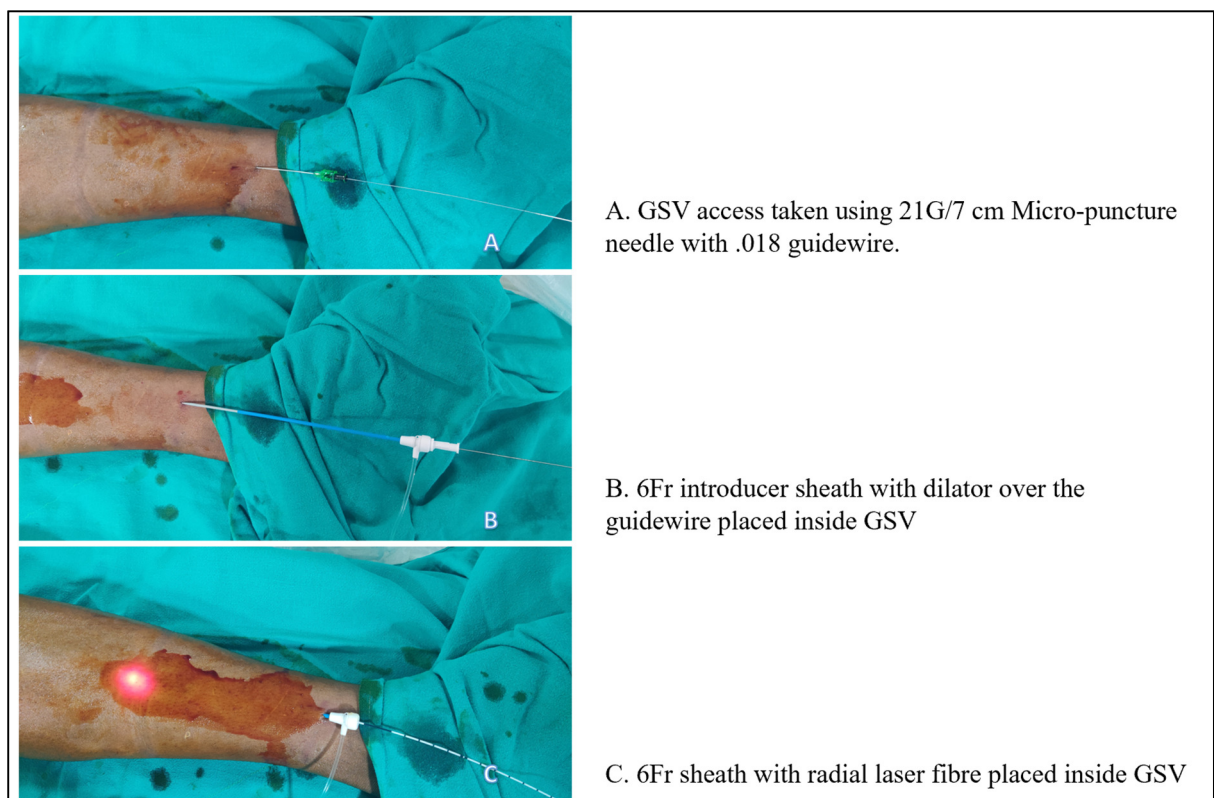


Figure 8: Steps for gaining access of laser fibre in GSV

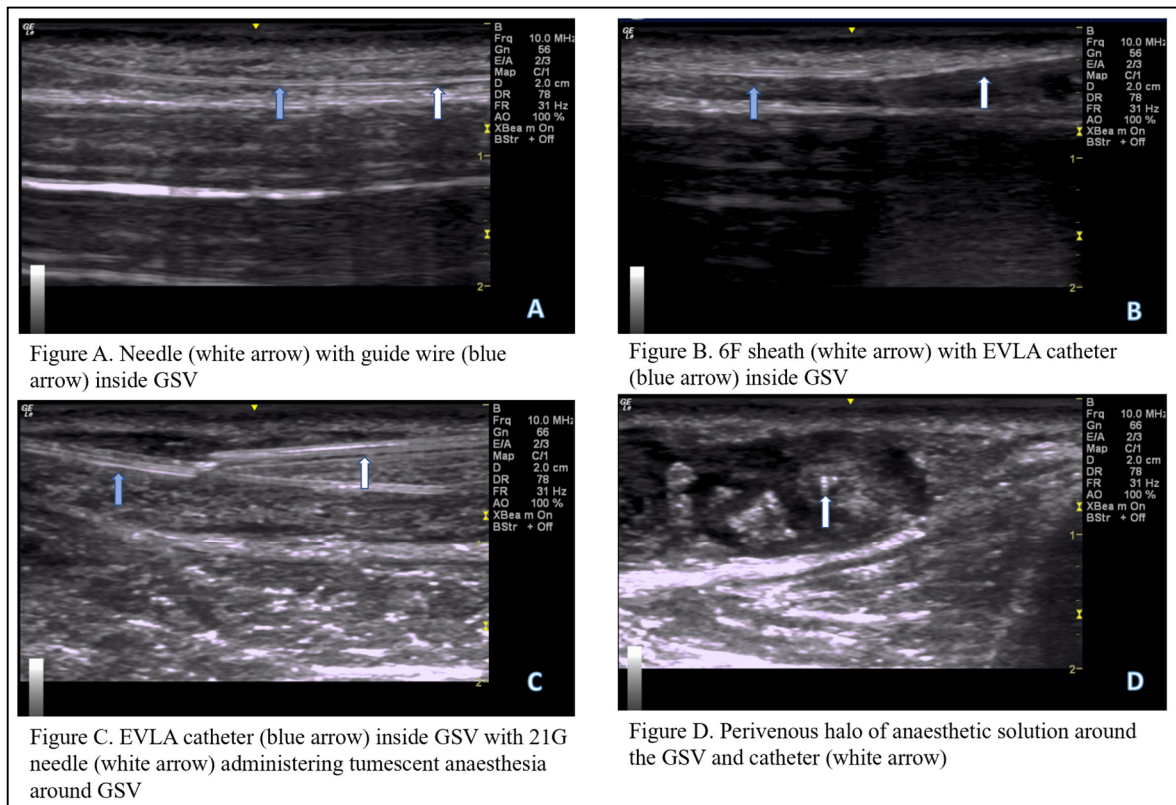


Figure 9: USG images showing various steps of EVLA

Radiofrequency Ablation

The same treatment concepts apply in radiofrequency ablation (RFA), but the heat energy is generated by an electromagnetic current. A variety of devices have been developed, but the Closure Fast™ device (Medtronic) is the most popular and has the most supporting evidence. A wire coil is attached to the end of a therapy catheter in this device. The generator sends an electrical current through the coil until the temperature around it reaches 120 degrees Celsius. This is then maintained for a 20-second treatment cycle. After that, the coil is removed for a predetermined amount of time, and a new treatment cycle begins. 3 cm and 7 cm coils are available, with the latter boosting treatment speed while still being acceptable for most anatomies.¹

3. Non-endothelial non-tumescent ablation: These techniques do not require tumescent anaesthesia to the patients hence more comfortable.

Ultrasound Guided Foam Sclerotherapy: Tessari method is most widely used for preparation of the foam. 1:3 or 1:4 ratio of sclerosant and air is mixed using two syringes connected via 3-way tap. This foam maximises the endothelial contact and increased the effective volume of agent compared to using sclerosing agent alone.⁶⁰

Initially the patient should stand and the sites of venous cannulation are marked using ultrasound.¹⁸ Then patient is in supine position and the major venous trunks and superficial varicosities to be treated are all cannulated using ultrasound guidance. The leg is then elevated to empty the veins of blood and then injection of foam first with superficial varicosities and ends with injection of the great saphenous vein or short saphenous system. Maximum volume of foam which should be injected at a single session should not exceed 10-12 mL.

Compression bandaging or hosiery is then applied and left in situ for 21 days. Sclerotherapy improves symptoms related to varicose veins but recurrence rates and the need for reintervention is relatively high.¹⁹

Endovenous Glue: It involves endoluminal application of cyanoacrylate adhesive. Catheter is placed within the vein lumen and the adhesive is infiltrated via the catheter. The consumable costs are relatively highest compared to other ablative techniques.¹

4. Open Surgery: Traditional ligation and stripping principles include completely dissecting the point of junctional incompetence and removing the refluxing axial vein and dilated tributaries. The procedure is normally done under general anaesthesia, but some prefer loco-regional anaesthesia, and infiltrating tumescent local anaesthetic around the axial vein before stripping may have some benefits, but it is not widely used.

With the development of the minimally invasive techniques described above, the role of open surgery as a primary treatment for a refluxing superficial axis has been challenged. The long-term results are at least comparable to open surgery, and with significantly less morbidity and faster recovery.

Saphenofemoral ligation and great saphenous stripping: An oblique groin incision is done above the groin crease, at the level of and lateral to the pubic tubercle. To avoid unintentional transection of the superficial femoral vein, the GSV should be clearly defined and recognised.

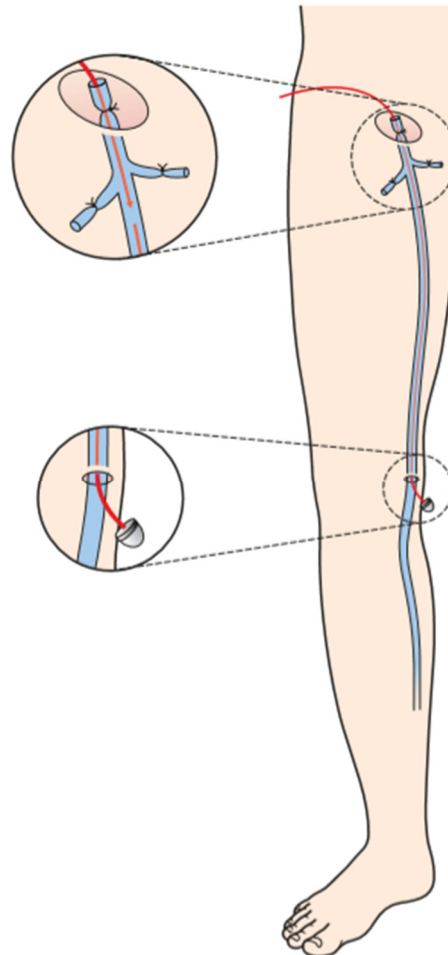
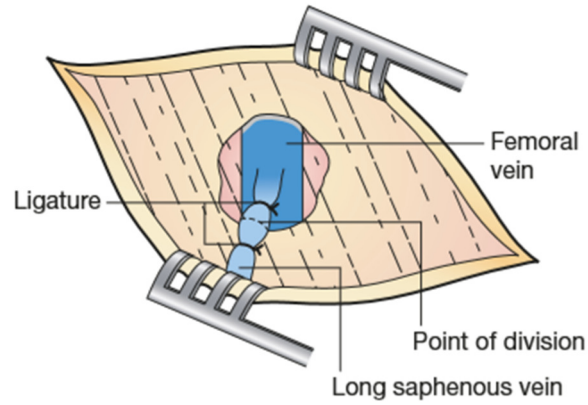


Figure 10: Saphenofemoral junction ligation and great saphenous vein stripping¹

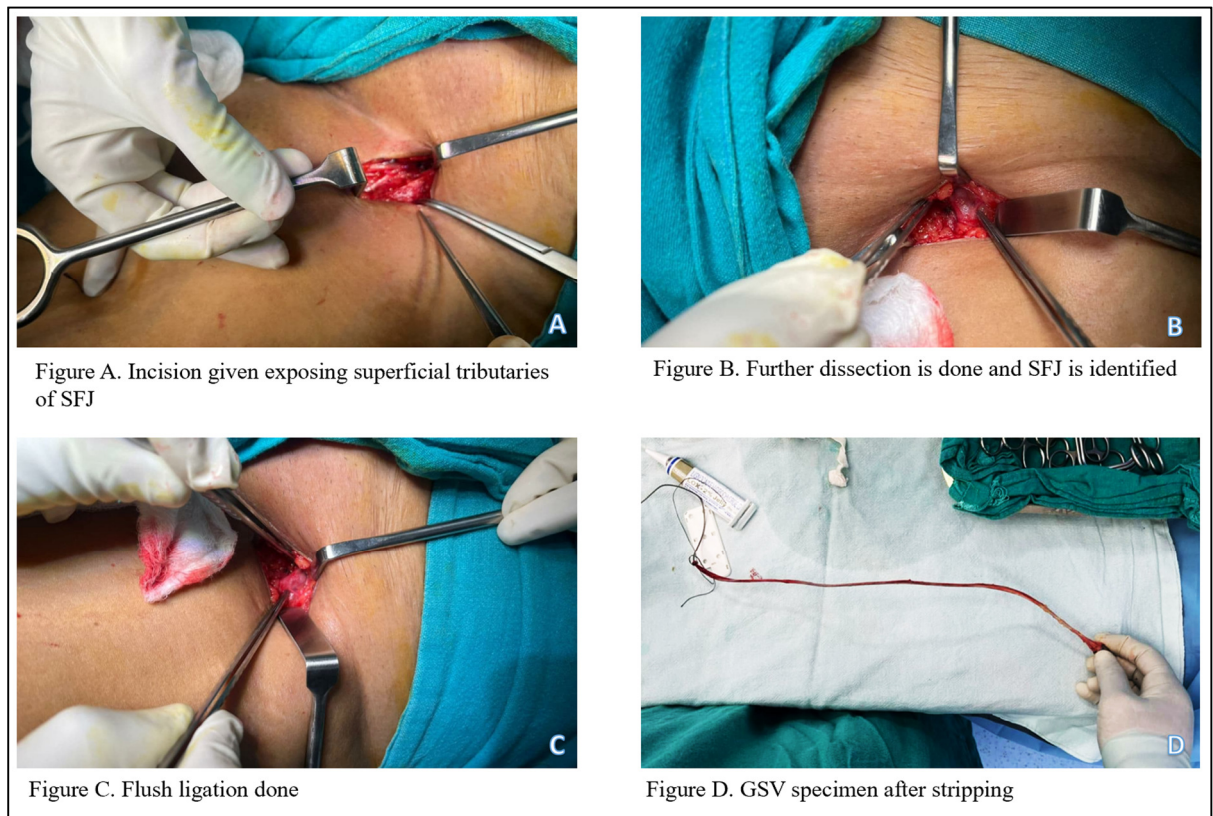


Figure 11: Intra-operative images of GSV stripping

Saphenopopliteal junction ligation and small saphenous stripping: The use of a preoperative duplex to designate the position of the SPJ is strongly advised. A transverse incision is made over the pre-marked SPJ, the fascia is separated, and the SSV is exposed with the patient in the prone position. The SPJ can then be dissected with a flush ligation or the SSV can be gently retracted and ligated as close to the SPJ as possible. The SSV can subsequently be stripped or the vein's proximal segment can be resected.

5. Ulcer management: Presence of ulcer makes the disease severe grade and may take a long time to heal. A multi-disciplinary team consisting of wound care nurse, plastic surgeon, vascular surgeon must be consulted for the proper wound care. Sterile dressing is to be applied. If there are no improvements, a 4 layer compression dressing with silver and hydrogel components may be helpful. Refractory cases may require surgical care in the form of skin grafting.

6. Life style modifications: Physical exercises that strengthen the calf musculature may help improve the muscular pump action. Limb elevation during night is also helpful

facilitating the venous return. As obesity is a risk factor for varicose veins, weight reduction must be instructed to the patient, helping the patient in reducing intraabdominal pressure and relieving of any venous compression thereof.

Published literature

Robertson et al⁶ performed the Edinburg Vein Study which is one of only a few cohort studies that has looked at the prevalence of varicose veins and CVI in the general population. Invitations were sent to 1456 men and women out of which 880 individuals participated. Varicose veins and CVI were shown to be substantially linked with increasing age from 9.8% in those aged 18 to 34 years to 25.7% in those aged 55 to 64 years ($P < .001$) and did not differ significantly by sex; age-adjusted incidence of varicose veins was 15.2% (10.4%-20.0%) in men and 17.4% (13.1%-21.7%) in women ($P = .97$). Those with a family history of varicose veins were more likely to develop them (odds ratio, 1.75; 95% CI, 1.12-2.71), and those with a higher BMI were more likely to have CVI; incidence (95% CI) was 6.1% (3.7%-9.6%) in individuals of normal weight and 23.6% (14.2%-37.0%) in obese individuals.

Vuylsteke et al⁵⁶ evaluated the prevalence of chronic venous disease (CVD) in Belgium and Luxembourg in this epidemiological study. The symptomatology and possible risk factors were assessed. The patients' average age was 53.4 years, and they were mostly female (67.5%). The most prevalent complaints among the 3889 symptomatic individuals were heavy legs, discomfort, and a sensation of leg swelling. A higher C-class was associated with age and female gender ($p.001$). Patients with a higher C-class (C3-C6) have much more pain, swelling, and burning sensations in their legs, as well as nocturnal cramps, itching, and the sensation of "pins and needles." Patients who exercised regularly and did not have a family history had a lower C-class.

Lars Ismail et al³¹ performed systematic review and meta-analysis of the risk for development of varicose veins in women with a history of pregnancy. They used PubMed, Embase, Robert Koch-Institute and Cochrane Central databases, as well as the references of included studies, to conduct a systematic literature search. All epidemiologic observational studies with the outcome "varicose veins" and a history of pregnancy were considered eligible. According to the findings of their meta-analysis, women with a history of pregnancy

have an 82 percent higher chance of developing varicose veins than women without a history of pregnancy (odds ratio, 1.82; 95 percent CI, 1.43-2.33).

In a study “Prevalence and risk factors of varicose veins, skin trophic changes and venous symptoms among northern Indian population” by **Agarwal V et al**⁸ found that 46.7 percent of females and 27.8 percent of males have varicose veins, while 49.3 percent of females and 18.9 percent of males have venous symptoms. First-degree related history of varicose veins (OR 3.85, p=0.046) and age (OR 1.06, p=0.021) were also significant risk factors for varicose veins in both sexes. Age (OR 1.14, p=0.002), thromboembolic illness history (OR 3.95, p=0.063), and pitting edema (OR 7.42, p=0.016) were all found to be significant risk factors for skin trophic alterations in varicose veins patients.

In Union Internationale de Phlébologie (UIP) consensus document for Duplex Ultrasound Investigation of the Veins of the Lower Limbs after Treatment for Varicose Veins by **A.Cavezzie et al**^{36,46} recommends standard methodology and formally defined variables to be used in the investigation, which can be customised to the intervention. After varicose vein therapy, duplex ultrasonography is an important part of the evaluation of the lower limb venous system. The timing of outcome investigations should be divided into four categories: immediate (1-4 weeks), short-term (1 year), mid-term (2-3 years), and long-term (4 years) (5 years or more).

Perrin SR et al⁶⁸ studied about severity scoring system in chronic venous disease of the lower limbs which was an observational study conducted by French angiologists. 398 French angiologists analysed 1900 patients, the majority of whom had class C4, C5, and C6 venous illness according to the CEAP classification, and they assessed Rutherford et al's revised CVD severity scores i.e. VCSS and Venous Segmental Disease Score (VSDS). They found out that VCSS and VSDS are an easy-to-rate and useful tool whose measurement varies with the degree of venous disease, but are primarily designed to assess the efficacy of CVI treatment. Finally, the VSDS is very difficult to score and interpret. It necessitates further studies that cannot be performed at an angiologist's office. This rating appears to be designated for clinical trials. It is, nonetheless, useful to explore its correlation with the VCSS in order to facilitate its interpretation.

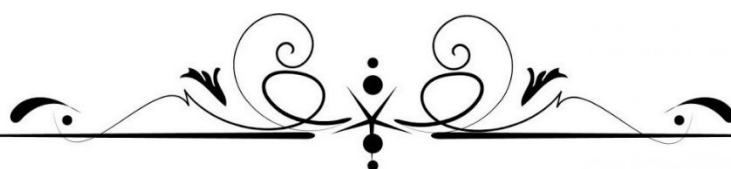
Rasmussen et al⁵³ conducted randomised clinical trial comparing clinical outcome of EVLA with surgical stripping of GSV. The clinical outcome was compared by assessing quality of life, recurrence and VCSS. A total of 121 individuals (137 legs) were randomly assigned to

receive either EVLA or saphenofemoral ligation and GSV stripping. Clinical and duplex ultrasound examinations, as well as VCSS and quality of life questionnaires, were used as part of the follow-up. Between the EVLA and surgical groups, there were no significant differences in clinical or ultrasound recurrences. Research also found that both therapies resulted in equivalent improvements in clinical severity levels and quality of life.

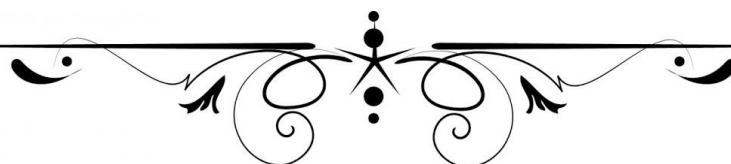
Another randomised clinical trial by **Rasmussen et al**⁵⁸ assesses recurrence, Venous Clinical Severity Score, and quality of life three years after treatment of varicose veins with endovenous laser ablation, radiofrequency ablation, ultrasound-guided foam sclerotherapy, or surgery. A total of 500 patients (580 legs) were randomly assigned to one of three endovenous treatments or high ligation and stripping of the great saphenous vein. All treatment approaches were effective and resulted in equivalent VCSS and quality of life improvements. However, following ultrasound-guided foam sclerotherapy, there were more recanalization and reoperations.

Shepherd et al⁵⁴ performed a randomised clinical trial comparing radiofrequency ablation versus laser treating varicose veins at a single centre. 131 patients with primary great saphenous vein reflux were randomly assigned to either EVLA (980 nm) or RFA (VNUS ClosureFAST). Postprocedural discomfort after three days was the major outcome measure. Clinical improvement was measured by the Venous Clinical Severity Score (VCSS). After 6 weeks, the two therapies had equivalent clinical and quality-of-life benefits.

Lacunae in current literature: There are only limited studies regarding the recent advances in the endovenous techniques for management of varicose veins. The available literature about the varicose veins in the setting of Indian population is lacking currently.



MATERIALS & METHODS



MATERIALS AND METHODS

- The study was carried out at the Department of Diagnostic and Interventional Radiology, AIIMS, Jodhpur.
- Type of study: Prospective single group observational study.

Study population:

Inclusion Criteria

1. Clinically diagnosed patients of primary varicose veins presenting to outdoor or emergency departments of AIIMS Jodhpur.
2. Age equal to or more than 18 years.

Exclusion Criteria

1. Patients of suspected varicose veins with normal Doppler study.
2. Patients of varicose veins of Secondary Etiology such as DVT, Arterio Venous Malformations, etc.

Study duration: One and half years.

Sample size: The sample size is calculated based on previously published study done by Nandhra et al.⁶² Assuming a proportion of 0.77 and 0.84 in clinical success in two groups with risk difference of 0.07, and absolute precision of 80% with clinically significance level of 0.05, a sample size of 30 per group has been calculated. With a dropout rate of about 10 %, 34 samples will be required to be included in each group. Therefore, the sample size is estimated to be 102 for the study.

A total of 100 subjects (119 limbs) presented to AIIMS OPD during the study period that fulfilled the diagnostic criteria for primary varicose veins and were enrolled in the study.

Imaging Modalities used

- Ultrasound: WIPRO GE LOGIQ S8, PHILIPS CLEARVIEW 350 or SIEMENS ACUSON X300 machines were used as per the convenience. Grey scale imaging with compression, colour and spectral doppler evaluation done in the superficial and deep veins of the lower limbs.

Data Collection

Patients attending the Interventional Radiology, General Surgery and PMR OPD with clinical complaints of varicose veins underwent lower limb venous doppler. The qualified subjects were evaluated as per the following.

- Demographic features like age, gender of the patient, occupation
- Presenting symptoms and their severity
- Clinical examination: eliciting the signs like ulcer, induration, pigmentation
- Any predisposing factors for PTS like obesity, history of prolonged standing, pregnancy
- CEAP classification
- VCSS score
- Recording patient's height, weight and calculating BMI
- All the patients were evaluated primary by ultrasound. Further imaging like CT venography and conventional venography were performed in select subjects whenever deemed necessary for the diagnosis of DVT and/or deep venous incompetence. Site of the reflux involving venous segment and laterality were noted with additional features present if any.
- If varicose veins with imaging findings on ultrasound doppler was detected, patient was started on conservative management and was counselled for endovascular/surgical management if deemed necessary.
- The subjects were followed up regularly with monitoring and evaluation of clinical status and ultrasound evaluation of veins.
- After 1 week, 1 month and 3 months of the initial visit, current clinical status of the patient, symptomatology and signs, VCSS score, imaging evaluation by ultrasound were done to note the difference between the initial and current status if endovascular/surgical management was done. For conservatively managed patients follow up was done after 3 months.

Ethical Justification

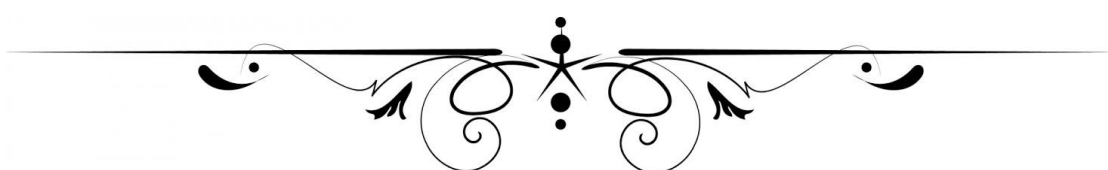
- Informed written consent was taken from all study patients/guardians of all the patients as per the attached proforma. No pressure or coercion was exerted on subjects for participation in the study.
- Confidentiality and privacy were maintained at all stages.
- All the patients were evaluated by ultrasound which is a non-invasive imaging modality with no ionising radiation involved. Further, additional imaging with modalities which have radiation exposure or invasiveness were performed only when deemed necessary for the diagnosis, to plan further treatment or as a part of treatment.
- The treatment protocol followed were part of standard protocol for varicose veins treatment. No additional drug or intervention was performed.

Statistical analysis

SPSS software (Version 28.0) was used for statistical analysis of the data. For numerical variables, arithmetic means and standard deviation were calculated. Analysis of means was done with independent sample t-test between the groups. Median, range were also calculated. Cross tables were applied and Pearson's Chi-square test was used to compare categorical variables. A p-value of less than 5 percent ($p < 0.05$) was regarded as statistically significant and p-value of less than 1 percent ($p < 0.01$) was regarded as statistically highly significant.



RESULTS



RESULTS

During the tenure of thesis, 132 patients presented to the department of Diagnostic and Interventional Radiology, General Surgery and Physical Medicine & Rehabilitation with complaints of varicose veins of lower limbs.

Out of the 132 patients with varicose veins, 28 patients developed varicose veins secondary to DVT and the rest 104 were enrolled in the study.

Out of the 104, 4 patients were lost to follow up.

Out of the remaining 100 patients, 19 had varicose veins in bilateral lower limbs making the effective sample size of the study to be 119. The same is depicted in the flowchart below.

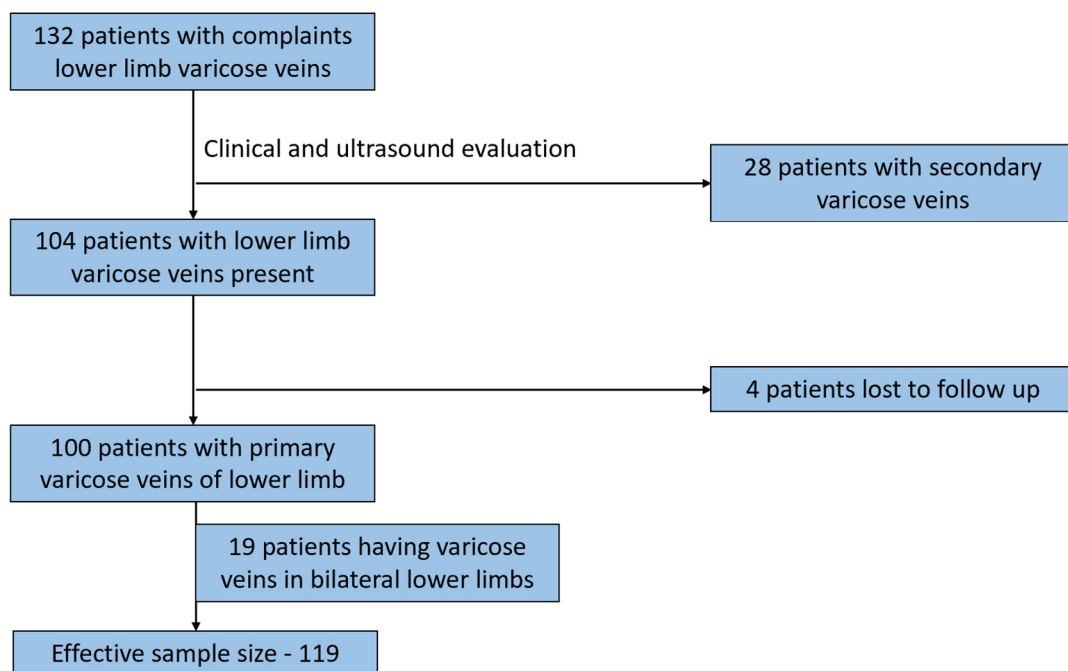


Figure 12: Flowchart for selection of subjects for the study

1. Gender Distribution: Out of the total patients, 72% were males and 28% were females.

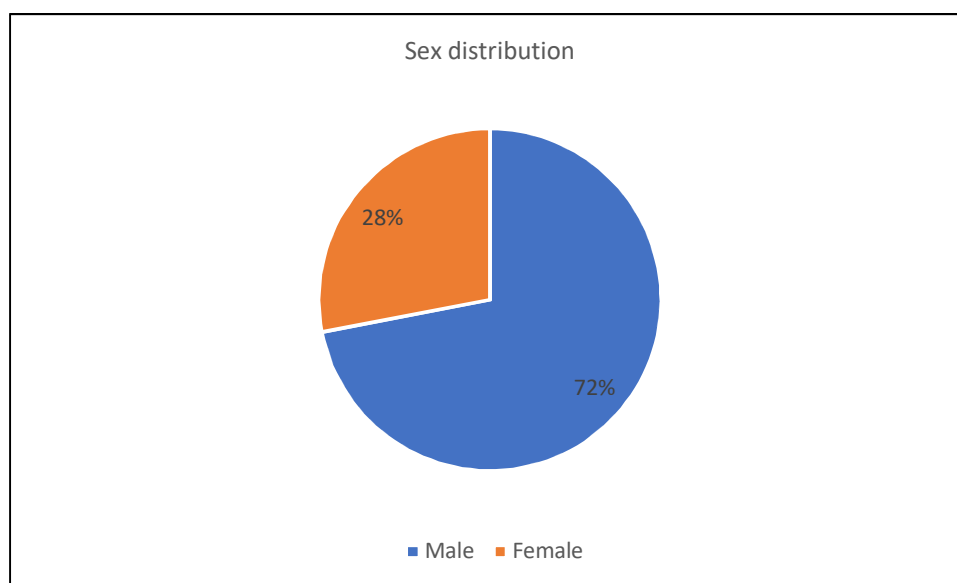


Figure 13: Pie chart depicting the gender distribution in the study population

2. Age Distribution: The maximum number of patients were from age group 21-30 years. Youngest subject being 18 years of age and the oldest subject of 72 years. The mean age was 37.5. P values was <0.001 which is highly significant.

Table 4: Table showing age distribution of patients in our study

Age group	<u>N (%)</u>
18-20 years	15
21-30 years	24
31-40 years	18
41-50 years	18
51-60 years	18
61-70 years	5
>70 years	2
Total	<u>100</u>

Chi square value=27.78 P<0.001 HS

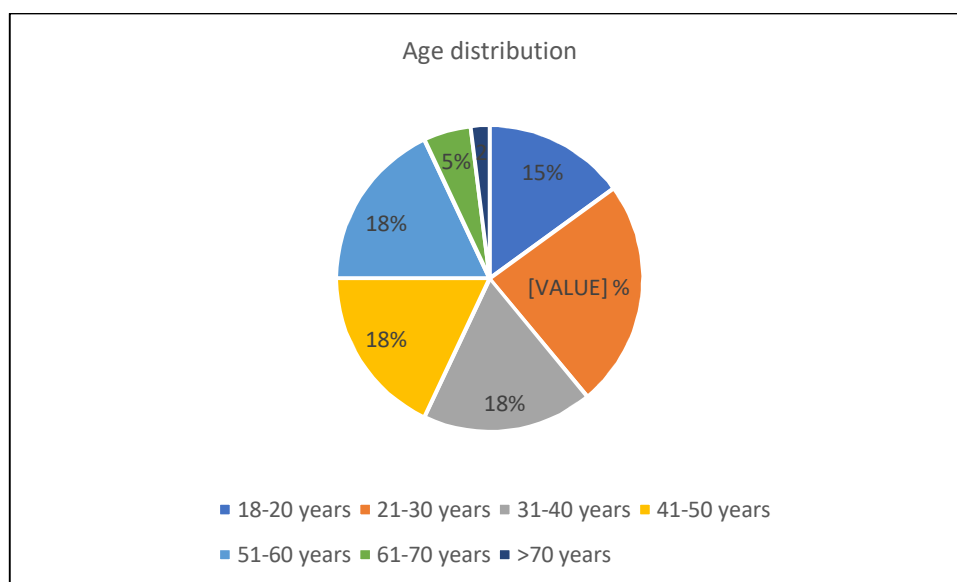


Figure 14: Pie Chart showing age distribution of patients in our study

- 3. Sex wise age distribution:** In younger age group males were primarily affected with varicose veins, however in older age group females formed the majority. In the age group of 18-20 14 out of 15 patients were males and in 21-30 years 22 out of 24 patients were males.

Table 5: Table showing sex wise age distribution of patients in our study

Age group	Male		Female	
	N	%	N	%
18-20 years	14	19.44	1	3.57
21-30 years	22	30.56	2	7.14
31-40 years	14	19.44	4	14.29
41-50 years	8	11.11	10	35.71
51-60 years	10	13.89	8	28.57
61-70 years	4	5.56	1	3.57
>70 years	0	0	2	7.14
Total	72	100	28	100

Chi square value=27.78 P<0.001 HS

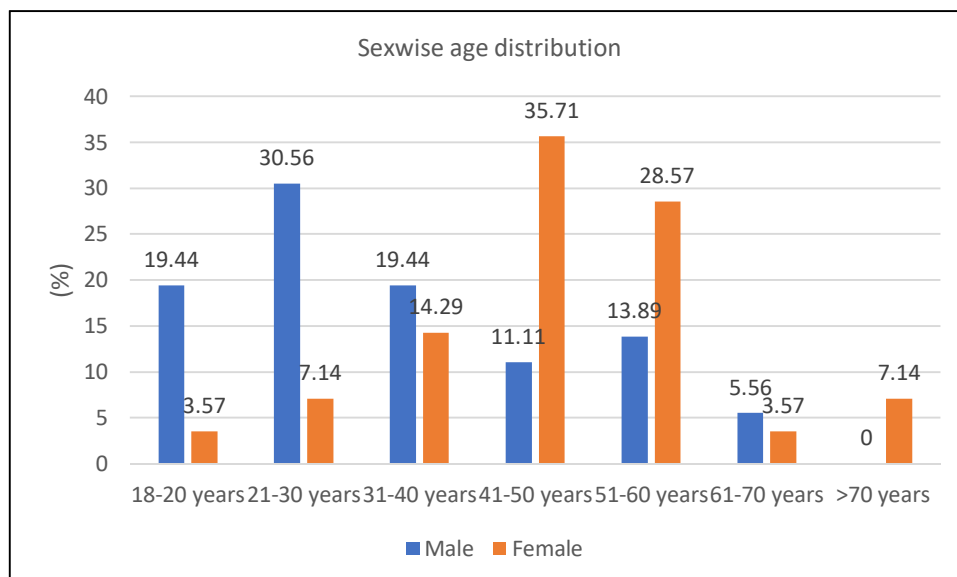


Figure 15: Bar Chart showing sex-wise age distribution of patients in our study

Mean age of the males was 34.03 years with SD 13.85 and for the females was 46.5 years with SD 13.87.

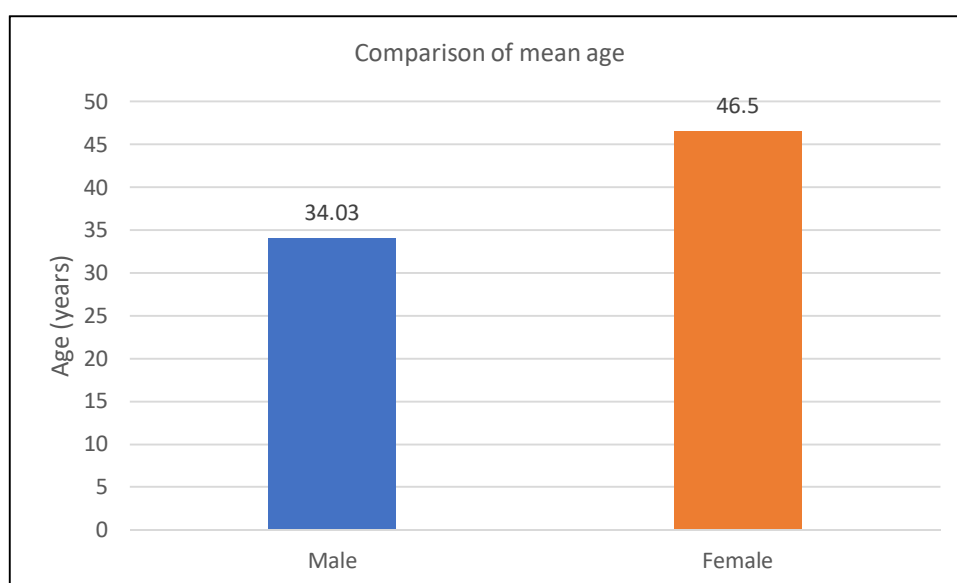


Figure 16: Bar Chart showing comparison of mean age between males and females in our study

Table 6: Table showing mean age of Male and Female patients in our study

Sex	Age in years		P value
	Mean	SD	
Male	34.03	13.85	P<0.001 HS
Female	46.50	13.87	
Total	37.52	<u>15.29</u>	

4. Relation with BMI: Out of the 100 patients, 12 (12%) were obese(BMI > 30). 27 patients were found to be overweight.

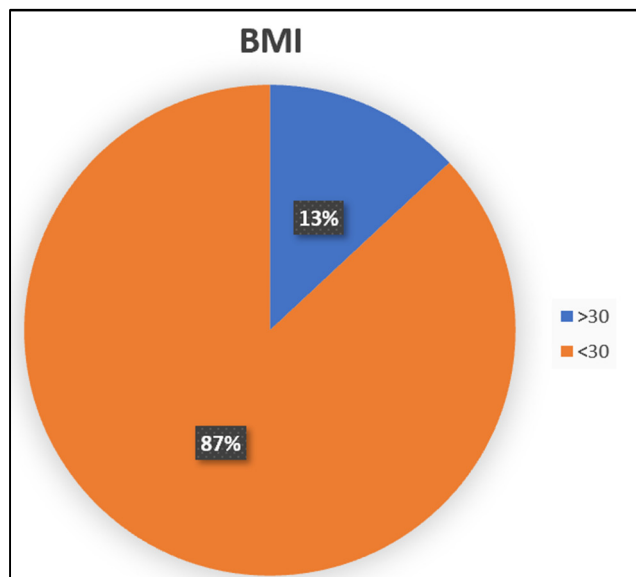


Figure 17: Pie chart showing distribution of BMI into normal (<30) and obese (>30)

5. Risk factors: Presence of history of prolonged standing was the most common predisposing factor, which was present in 81% subjects. Family history of varicose veins was the next most common risk factor (13%). Among females, history of pregnancy was also a significant factor in development of varicose veins (46.4%).

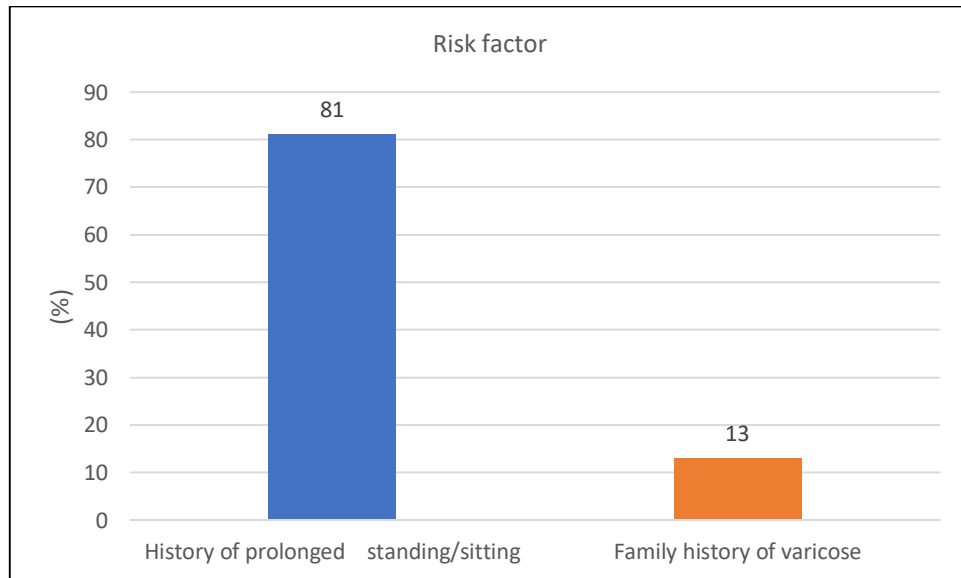


Figure 18: Bar Chart showing presence of risk factors in patients of our study

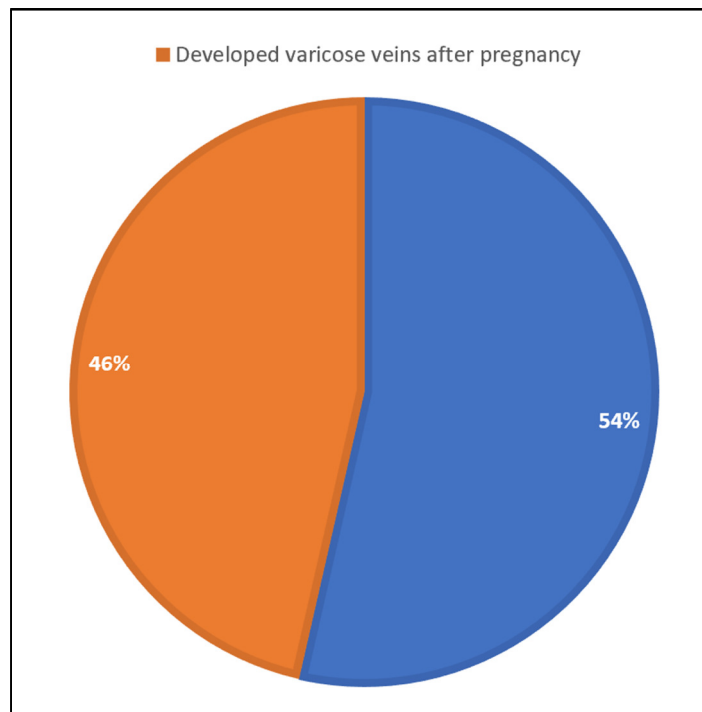


Figure 19: Pie Chart showing percentage of females developing varicose veins after pregnancy

6. Occupation: Among 100 patients, majority of them belonged to occupations requiring prolonged standing and/or sitting such as housewives, teachers, shop keepers etc.

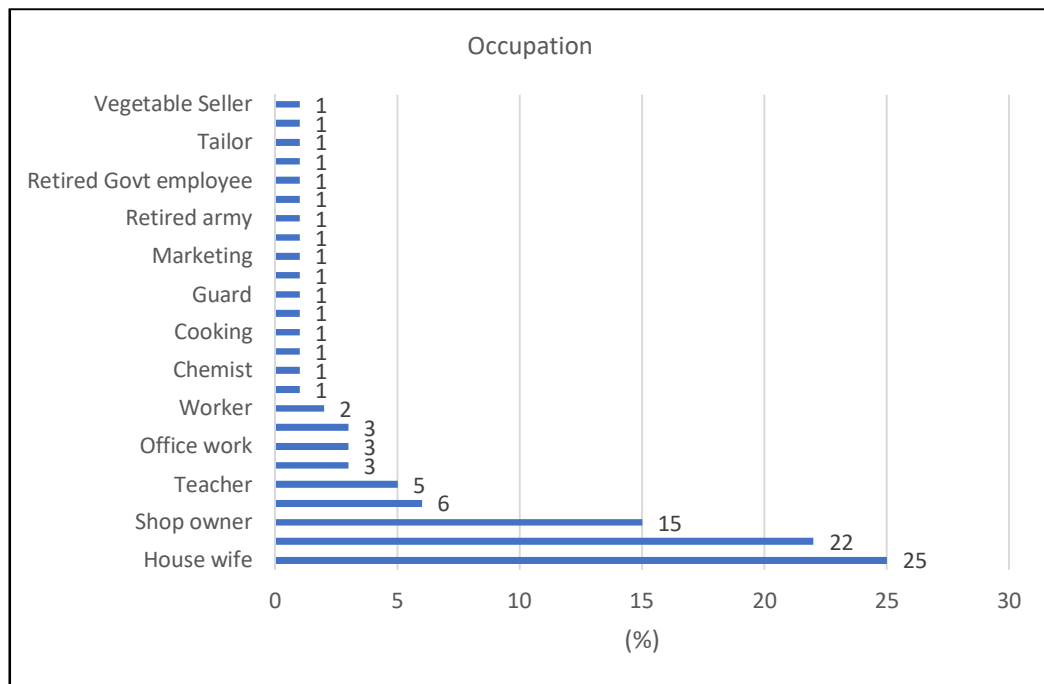


Figure 20: Bar chart eliciting the occupation of subjects

7. Symptomatology:

Pain was the most common symptom reported by the subjects in our study affecting 103 limbs (86.5%). Among these, severe pain limiting daily activities was reported in 53 limbs (44.54%). In the clinical signs, skin inflammation, pigmentation and induration which was present in almost half of the affected limbs. Majority of the limbs having skin inflammation, pigmentation and induration diffuse lower one third of the calf was affected (21.85% - 24.37%).

Active ulceration was the least common sign (8.4 %), however presence of ulcer deemed increased VCSS score. Mean VCSS score of limbs affected with active venous ulcer was 22.2. Healed ulcers were seen in 10.08% of the patients.

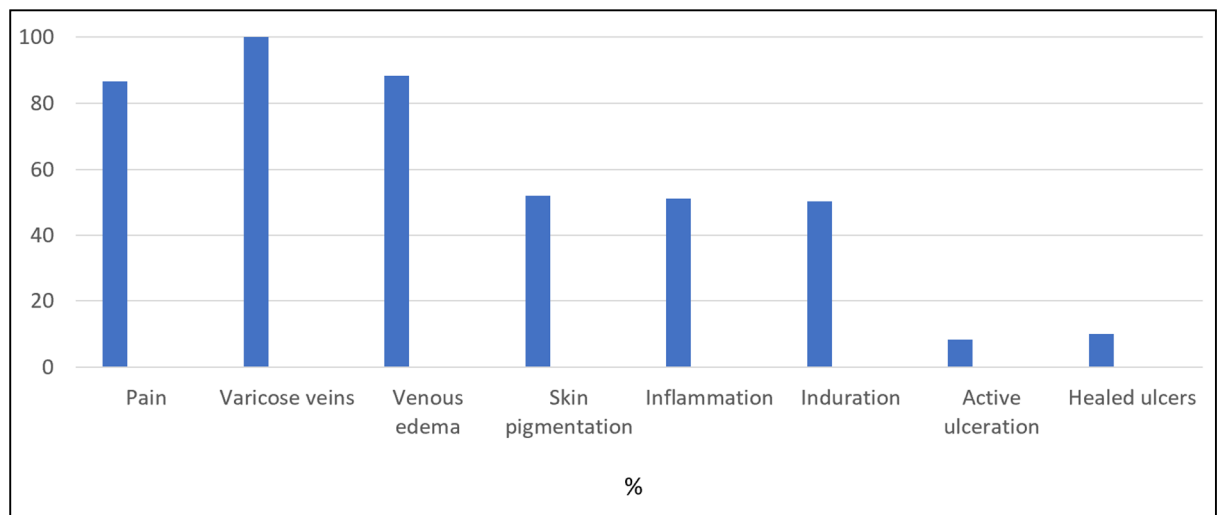


Figure 21: Bar chart depicting the frequency of signs and symptoms in total affected limbs

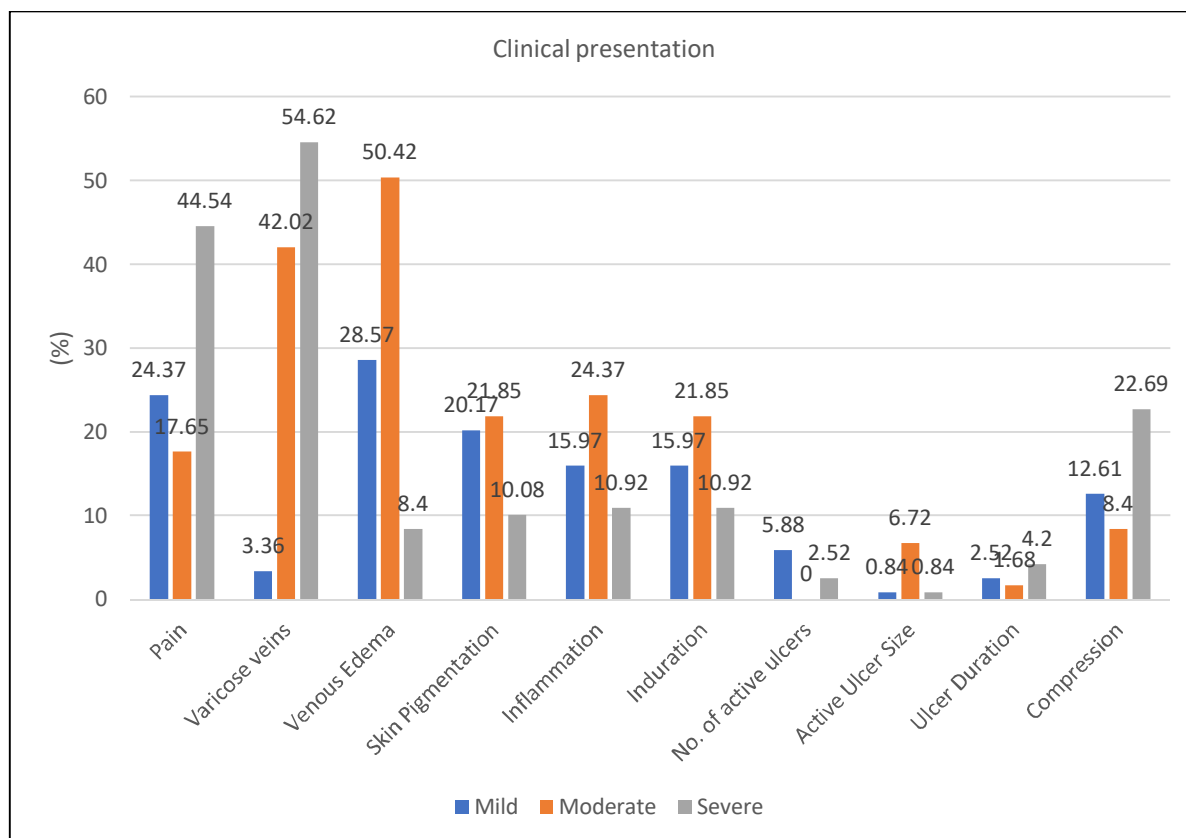


Figure 22: Stacked bar diagram depicting the frequency of individual components of VCSS in total number of limbs having varicose veins with further subcategorization into the severity

VCSS score

Mean VCSS score of total limbs was 10.52 before treatment with maximum being 25 and minimum being 2. Mean VCSS score was slightly higher among the female population.

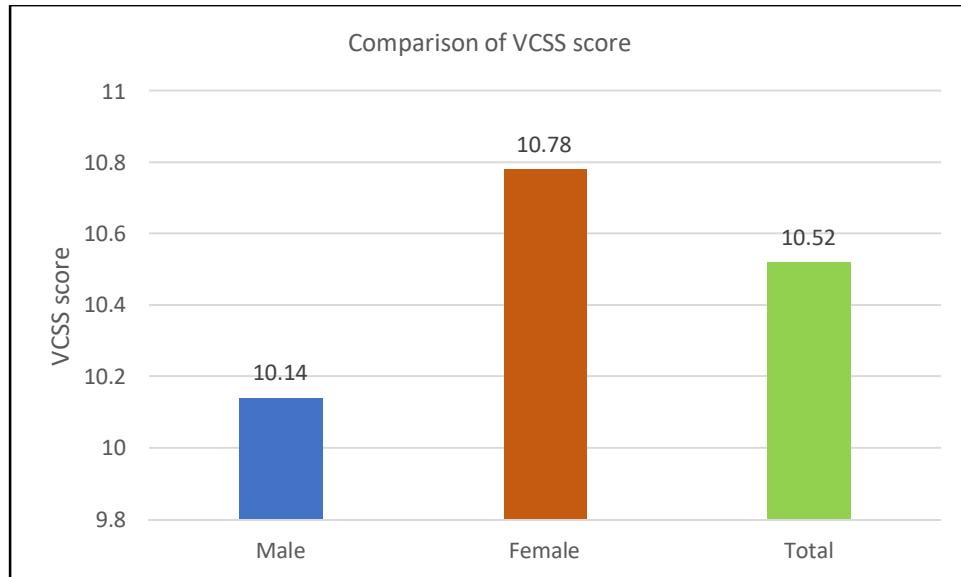


Figure 23: Histogram depicting the mean of VCSS score in males, females and total population

8. CEAP classification: As per the CEAP classification in the class C, 36 limbs (36.13%) had complaints of varicose veins only and were classified as C2. Among 19 limbs with severe disease (C4-C6), 35 limbs (29.41%) had skin changes, 10 limbs (10.08%) had healed ulcers and 9 (9.24%) limbs presented with active ulcers.

Table 7: Table showing CEAP classification C category distribution of subjects in our study

CEAP classification	N (%)
C1	-
C2	43(36.13%)
C3	18(15.13%)
C4	35(29.41%)
C5	12(10.08%)
C6	11(9.24%)
Total	119(100%)

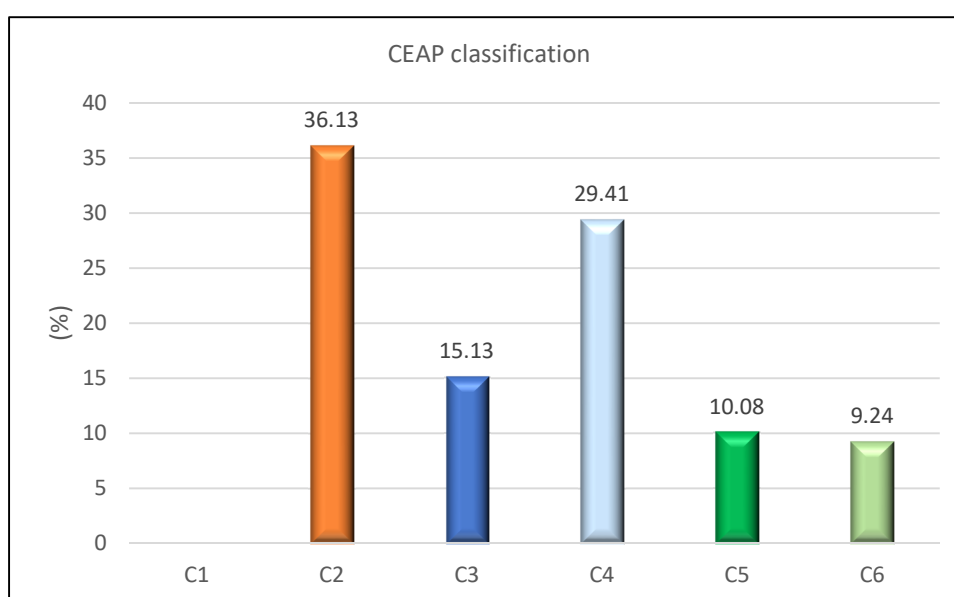


Figure 24: Bar chart showing the classification of limbs over class C of CEAP classification

9. Laterality of limbs and venous territory affected: Out of the 100 subjects, 19 had bilateral disease, 49 had varicose veins on left side, while 32 had the disease on the right lower limb. The gamut of findings on ultrasound included dilated GSV, SSV, superficial varicosities, reflux in the saphenofemoral junction, saphenopopliteal junction, perforators or even superficial veins.

SFJ and SPJ incompetence was seen in 89 limbs (74.78%) and 21 limbs (17.67%) respectively. Among these limbs, both SFJ and SPJ incompetence was seen in 12 limbs (10.1%). Incompetent perforators were seen in 71 limbs (59.66%), however no isolated case of incompetent perforator was seen.

In one limb incompetent GSV was an isolated finding and in one limb SFJ incompetence was associated with dilated GSV and AASV.

Table 8: SFJ, SPJ involvement and incompetent perforators in our study

Junction involved	No of limbs	Percentage of limbs
SFJ	89	74.78%
SPJ	21	17.67%
Incompetent Perforators	71	59.66%

Cut off for dilated GSV was taken as 3 mm and it was found in 94.11% of total limbs with mean diameter of 5.51 mm with S.D. of 1.66. Similarly cut off for dilated SSV was taken as 3 mm, mean diameter of dilated SSV was 3.75 mm with S.D. of 1.39. Maximum value for GSV and SSV diameter was 12.5 and 9.5 mm respectively.

Table 9: Involved veins in our study

Segment involved	Mean Diameter (mm)	S.D.
Dilated GSV (>3 mm)	5.51	1.66
Dilated SSV (>3 mm)	3.75	1.39

10. Modality of treatment:

The patients underwent conservative, endovascular and surgical treatment for the management of varicose veins. Out of 119 limbs 64 (53.78%) were treated conservatively, 45 (37.81%) were treated by endovascular ablation and 10 (8.4%) were treated surgically.

Table 10: Distribution of the modality of management in our study

Management	No of limbs	Percentage of limbs
Conservative	64	53.78%
Endovascular	45	37.81%
Surgical	10	8.40%
Total	119	100%

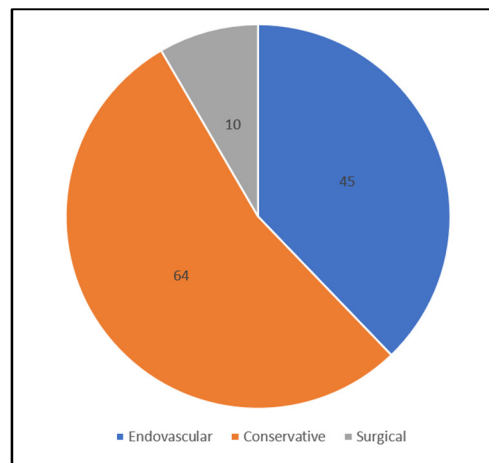


Figure 25: Pie Chart showing the distribution of limbs undergoing conservative, surgical and endovascular management

11. Post treatment follow up and VCSS comparison:

There was decreasing trend in the severity of varicose veins post intervention with significant decrease following surgical and endovascular intervention. For conservative management only single time follow up after 3 months was done.

The baseline VCSS score and the VCSS score recorded in subsequent follow up has been tabulated as below:

Table 11: Mean VCSS score at the initial and follow up visits under each modality

VCSS score (Mean $\pm$ SD)	Treatment		
	Conservative	Endovascular	Surgical
Baseline	8.84 $\pm$ 5.56	12.60 $\pm$ 5.81	10.1 $\pm$ 3.98
At 1 week	-	10.84 $\pm$ 5.56	8.5 $\pm$ 4.01
At 1 month	-	9.02 $\pm$ 5.30	7.1 $\pm$ 4.15
At 3 months	7.34 $\pm$ 4.73	7.29 $\pm$ 4.63	6.2 $\pm$ 3.91

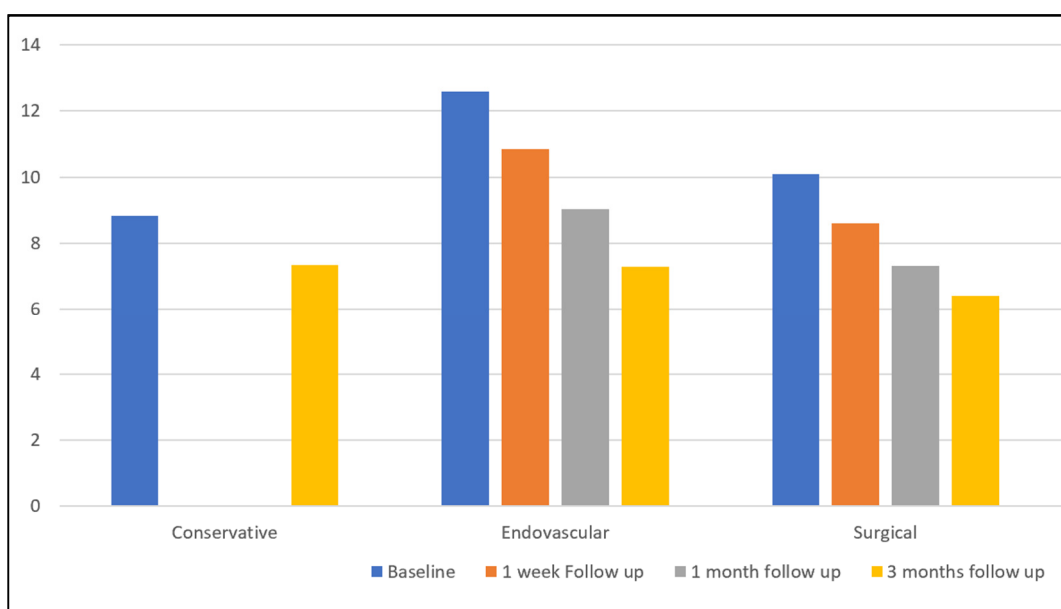


Figure 26: Bar Chart showing comparison of mean VCSS score before and after intervention by conservative, endovascular and surgical modalities

The baseline VCSS score and the VCSS score recorded in subsequent follow ups showed maximum change in the endovascular management with mean change of 5.31 with SD 2.84 at the end of 3 months. Surgical management showed change of 3.7 with SD of 2.5. Patients undergoing conservative management alone showed least change in VCSS score with mean of 1.5 and SD 2.1. 8 out of 64 limbs (12.5%) managed conservatively showed worsening of VCSS score and 15 limbs (23.4%) showed no change in the VCSS score.

Table 12: Mean change in VCSS score at the initial and follow up visits under each modality

Change in VCSS score (Mean $\pm$ SD)	Treatment		
	Conservative	Endovascular	Surgical
At 1 week	-	1.75 $\pm$ 1.09	1.6 $\pm$ 0.84
At 1 month	-	3.58 $\pm$ 1.83	3 $\pm$ 1.76
At 3 months	1.5 $\pm$ 2.1	5.31 $\pm$ 2.84	3.9 $\pm$ 2.23

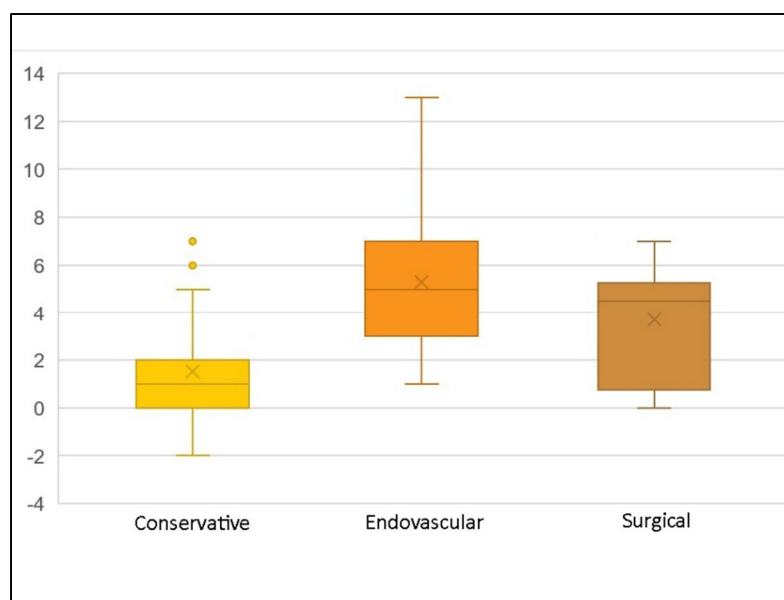


Figure 27: Box and whisker chart showing comparison of change in VCSS score before and after intervention by conservative, endovascular and surgical modalities at 3 months follow up.

In follow up recorded at 3 month showed VCSS score of 2 limbs returning to 0 – one limb each in surgical and endovascular modality.

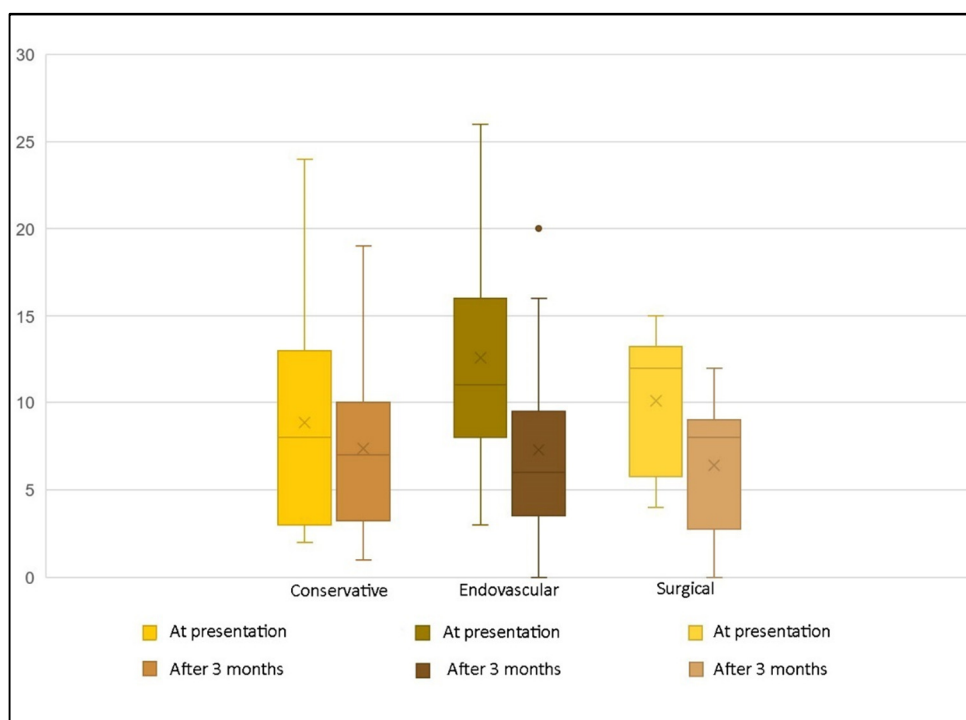


Figure 28: Box and whisker chart showing comparison of mean VCSS score before and after intervention by conservative, endovascular and surgical modalities

2 group comparison was done for the change in VCSS scores using paired T-test and following P-values were obtained.

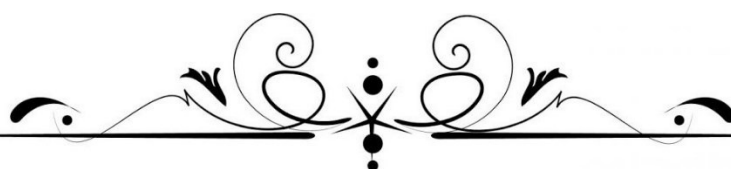
Table 13: 2 group comparison of the change in VCSS using paired T-test

<i>2- group comparison</i>	<i>P value</i>
<i>Conservative vs Endovascular</i>	<i>P<0.01 HS</i>
<i>Conservative vs Surgical</i>	<i>P<0.01 HS</i>
<i>Endovascular vs Surgical</i>	<i>P>0.05 NS</i>

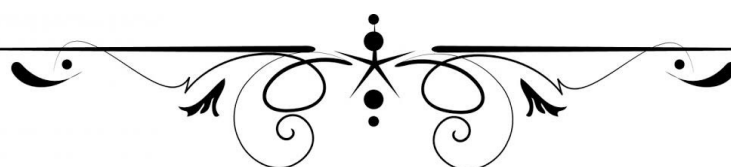
12. Complications: Following complications were seen in the limbs managed by endovascular and surgical methods.

Table 14: Complications encountered in Endovascular/Surgical intervention

Complication encountered	Mode of intervention	Number of limbs
Thrombophlebitis	Endovascular	2
Superficial burns	Endovascular	2
Burnt sheath	Endovascular	1
Local site seroma formation	Surgical	1



DISCUSSION



DISCUSSION

Demographics:

1. Gender: The study consisted of 72 males(72%) and 28 females(28%). In the Edinburgh varicose-vein study the age-adjusted frequency was 39.7% in men and 32.2% in women.⁵ Thus, keeping in line with male gender being more affected with varicose veins, this can be justified as shown by the reference studies.^{20,21}

Since the male gender is more likely to be associated with occupations requiring prolonged standing which is an important risk factor in itself for developing varicose veins. Also the lack of awareness about health, illiteracy among the females might have hindered them from visiting the health care facility.

2. Age distribution: The mean age of presentation in our study was 37.5 years, with a range of 54 years, youngest subject being 18 years of age and the oldest subject of 72 years. Only 2 subjects of age >70 years were present. Maximum number patients were presented in the age group 21-30 years.

These figures are slightly less as compared to reference studies where the maximum age group of presentation was 30-40 years (Campbell et al).⁴⁰ This discrepancy can be partially explained by increased health awareness among young individuals as Jodhpur is hub for defence academies and candidates with varicose veins get rejected in the medical examination. This might also explain the sex wise age distribution in which among younger age group males were more affected than females as young males are more likely to apply for defence services. Other contributory factors may be the small sample size in our study.

3. BMI: In our study, out of the 100 patients, 13 (13%) were obese (BMI > 30). 27 patients were found to be overweight (BMI between 25 -29.9). Total of 40 patients (40%) were having BMI >25.

The results are comparable with study by Shepherd et al⁵⁴ in which among 131 subjects with primary chronic venous disease 6.8 % were obese.⁵⁴

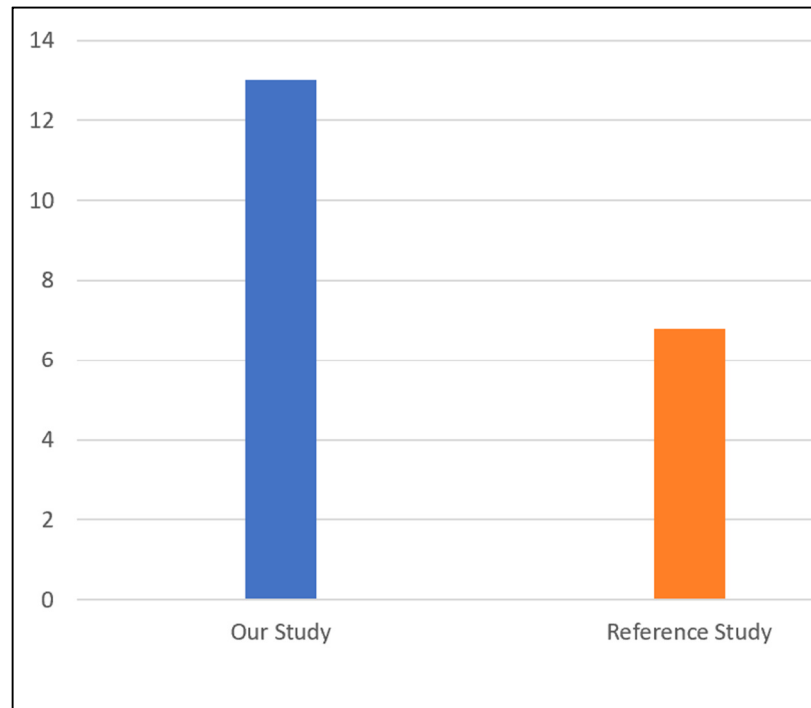


Figure 29: Comparison of mean BMI in our study with reference study

4. Risk factors: Varicose veins are known occupational disease and commonly found in jobs requiring prolonged standing or sitting. In our study history of prolonged standing or sitting was the most important risk factor and was found in 81% of subjects. We found that our study had 38% of shopkeepers, teachers and guards whose occupation required standing for long intervals. 25% were housewives (89.28% of total female patients) which also requires prolonged standing in doing the household work especially in kitchen.

In our study 13% of subjects reported family history of varicose veins which is less compared to other studies. In a study of varicose veins in Japanese women, 42% of subjects with varicose veins had a positive family history.⁴³

Among female population 46.4% developed varicose veins after pregnancy thus showing the importance of pregnancy as a risk factor. In an Italian study of people over 65 years of age, varicose veins developed after a pregnancy in 40.5% of women.⁴⁴

5. Venous territory affected: SFJ and SPJ incompetence was seen in 89 limbs (74.78%) and 21 limbs (17.67%) respectively. In patients showing SFJ and SPJ incompetence GSV and SSV territory was affected respectively Among these limbs, both SFJ and SPJ incompetence was seen in 12 limbs (10.1%). Compared with the study by Shepherd et al⁵⁴, GSV territory

was affected in 79.4% of total limbs and among them both GSV and SSV territory was affected in 12.97% of total limbs which is comparable with our study.

Mean diameter of dilated GSV and SSV was 5.51 mm with S.D. of 1.66 and 3.75 mm with S.D. of 1.39 respectively. According to the study by Rasmussen et al⁵⁸, mean GSV diameter was 7.6 mm with SD of 2.1.

In one limb incompetent GSV was an isolated finding and in one limb SFJ incompetence was associated with dilated GSV and AASV. However, these findings may be under-reported as ultrasound evaluation is user dependent and without extensive evaluation such findings may be missed.

Out of the 100 subjects, 19 had bilateral disease, 49 had varicose veins on left side, while 32 had the disease on the right lower limb.

6. Symptomatology: Most commonly reported symptoms were lower limb heaviness and pain affecting 105 (88.2%) and 103 limbs (86.5%) respectively. Among these, severe pain limiting the daily activities was reported in 53 limbs (44.54%). In comparison with a study conducted by Vuylsteke et al⁵⁶, though the two most common symptoms and signs remain the same, the proportion of subjects affected is less as compared to our study. It was reported to be 70.4% for heaviness and 50.4 % for pain. This discrepancy is due to the different study settings. While the mentioned reference study is an epidemiological study measuring the prevalence of chronic venous disease, our study consisted recruiting varicose veins patients. Thus, the subjects reported to our hospital which is a tertiary care centre only after significant symptoms.

In the clinical signs, skin inflammation, pigmentation and induration was present in almost half of the affected limbs (50.4 %). Ulcer was the least common sign, however presence of ulcer deemed increased VCSS score. The mean VCSS score of limbs with active venous ulceration was 22.2 compared to the mean of 10.52 of the total population. This is in line with the study by Vuylsteke et al⁵⁶ which showed decreasing trend in frequency of signs from lower limb edema to skin changes to ulceration as severity of the disease increase, however the proportion of subjects affected is less as compared to our study. This discrepancy has already been explained above.

7. Severity of disease: According to the CEAP classification in the category C, 36 limbs (36.13%) had complaints of varicose veins only and were classified as C2. Among 54 limbs with severe disease (C4-C6), 35 limbs (29.41%) had skin changes, 10 limbs (10.08%) had healed ulcers and 9 (9.24%) limbs presented with active ulcers.

Table 15: Comparison of frequency of C category according to CEAP classification of our study with the reference study

CEAP classification	<u>Our study (%)</u>	<u>Reference Study (%)</u>
C2	36.13	16.6
C3	15.13	8.9
C4	29.41	40.9
C5	10.08	1.1
C6	9.24	29.9

The above table compares the clinical characteristics according to CEAP classification of our study with the study done by Perrin et al done on 1900 patients by 398 angiologists.⁵⁷

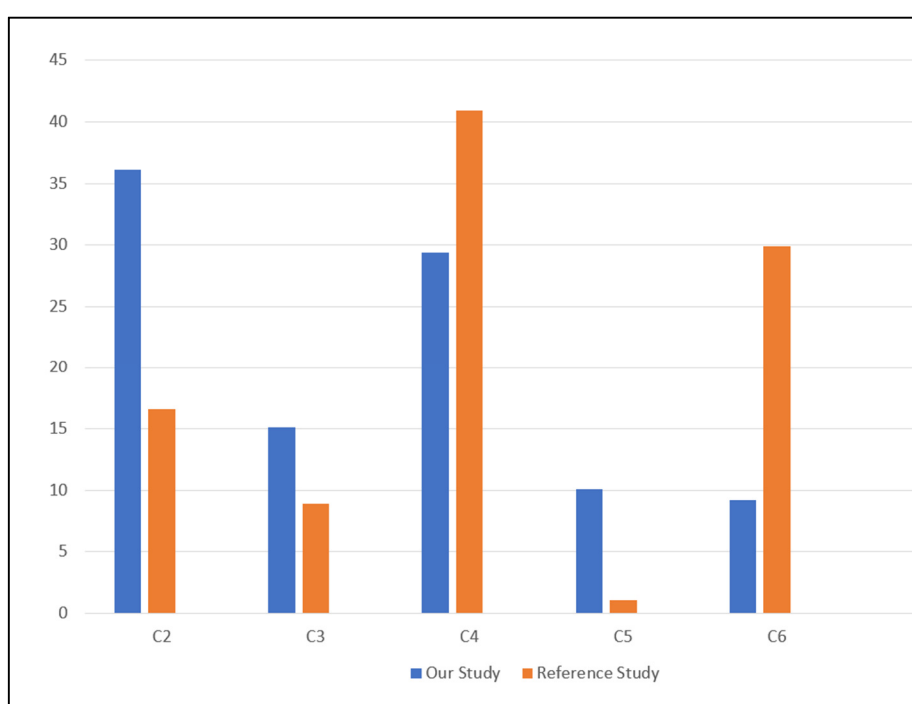


Figure 30: Bar chart showing comparison of frequency of C category limbs in our study and reference study.

In our study C2 category patients had the maximum frequency whereas in the reference study C4 category patients had maximum frequency, this discrepancy may be explained by the fact that our hospital is in the vicinity of defence academies and many young male patients

aspiring to join the defence services visited our institute for management of varicose veins for cosmetic purpose.

8. VCSS score: Baseline mean VCSS score of total limbs was 10.52 before treatment with maximum being 25 and minimum being 2. The mean (SD) VCSS was 8.84 (5.56) for conservative management, 12.6 (5.81) for endovascular and 10.1 (3.98) for surgical group. Compared with the studies by Shepherd et al⁵⁴ and Rasmussen et al⁵⁸ mean (SD) VCSS score was 4.7 (2.1) and 2.68 (2.25) for EVLA group which is quite less compared to our study.⁵⁴ This discrepancy shows that patients presenting to our institute were more severely affected by chronic venous disease. Since our study took place during the times of COVID many patients were not able to visit health facilities due to lockdowns, which resulted in deterioration of their clinical status. These patients presented with worsened clinical status resulting in higher VCSS scores, as proper timely medical intervention was delayed.

9. Response to treatment: In our study, out of 119 limbs 64 (53.78%) were treated conservatively, 45 (37.81%) were treated by endovascular ablation and 10 (8.4%) were treated surgically.

Since our study was observational study and not a randomised clinical trial the treatment modality depended on patient's preference. The operative management of the patients was affected drastically by the COVID situation, as operation theatres were reserved for emergency patients only, for a significant interval of time during the study. This affected the number of patients getting active intervention.

The clinical response was present in all the three modalities of management with decrease in VCSS score by 1.50 in conservative management, 5.31 in endovascular management and 3.9 by surgical management at the end of 3 months which was highly significant.

- Mean improvement score of limbs undergoing conservative management was 1.5 and of endovascular was 5.31, resulting in a statistically significant outcome. Mean improvement score of limbs undergoing conservative management was 1.5 and of surgical was 3.9 which was also statistically significant. Thus, there is clear benefit or superiority of surgical and endovascular management over conservative management alone. Hence, endovascular/surgical should be attempted whenever indicated and/or feasible in cases of varicose veins specially of higher VCSS score because of significantly better outcome.

- Mean improvement score of patients undergoing endovascular management was 1.74, 3.58 and 5.31 and of surgical management was 1.6, 3 and 3.9 at the end of 1 week, 1 month and 3 months follow up respectively, however comparison of change in VCSS score in both groups was not statistically significant. As Rasmussen et al⁵³ demonstrated in their study, the mean change in VCSS was 2.24 and 2.45 in limbs managed with EVLA and surgical stripping respectively at the end of 3 years which was also not statistically significant.⁵⁸ However the baseline mean VCSS was 2.95 and 2.75 for EVLA and surgical group respectively which is lower compared to the baseline mean score of 12.6 and 10.1 respectively in our study. This might explain the better response (i.e. mean change in VCSS) seen in our study compared to Rasmussen et al.

Limitations of our study

- The main limitation of our study was the small follow up time due to the time constraints of the MD course. In patients of chronic venous disease, the recurrence of varicosities after intervention is often seen at longer follow up time which could not be assessed in our study.
- As our study took place during COVID pandemic the operative management of patients was adversely affected and the physical follow up of few of the patients was also affected. Many patients presented with worsening of their signs and symptoms which resulted in increased baseline VCSS score.
- As the study required follow up few subjects were lost to follow up.
- There was no comparison group.

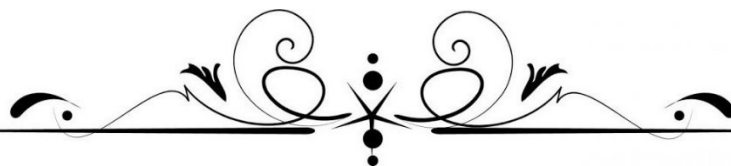


IMAGE GALLERY

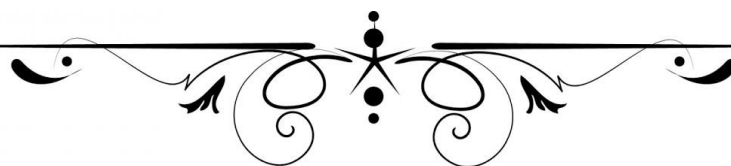


IMAGE GALLERY



Figure 31: C category classification of the varicose veins under CEAP: All the C categories seen in our study

- A:** C1- Telangiectasias or reticular veins.
- B:** C2- Varicose veins.
- C:** C3- Edema.
- D:** C4a- Pigmentation and eczema.
- E:** C4b- Lipodermatosclerosis and atrophie blanche.
- F:** C4c- Corona phlebectatica.
- G:** C5- Healed venous ulcer.
- H:** C6- Active venous ulcer.

Case 1



Figure 32

51 years old female, with complaints of varicose veins associated with severe pain, skin changes and active ulceration of right lower limb. **(Figure A)**

CEAP classification: C6 category

VCSS score: 22

USG evaluation: Incompetent right SFJ with dilated GSV (6.5 mm) with multiple superficial varicosities in GSV territory and oedematous changes in lower third calf. The inter-saphenous vein was dilated and communicating with SSV resulting into varicosities in SSV territory.

Procedure: EVLA of right GSV and SSV

Follow up: At 1 month follow up there was significant decrease in the pain for the patient with VCSS score of 15. On USG evaluation the GSV and SSV were thrombosed. There was decrease in the inflammation, induration and skin pigmentation however active ulcer was still present. **(Figure B)**

At 3 month follow up there was healing of the active ulcer. **(Figure C)**

Case 2

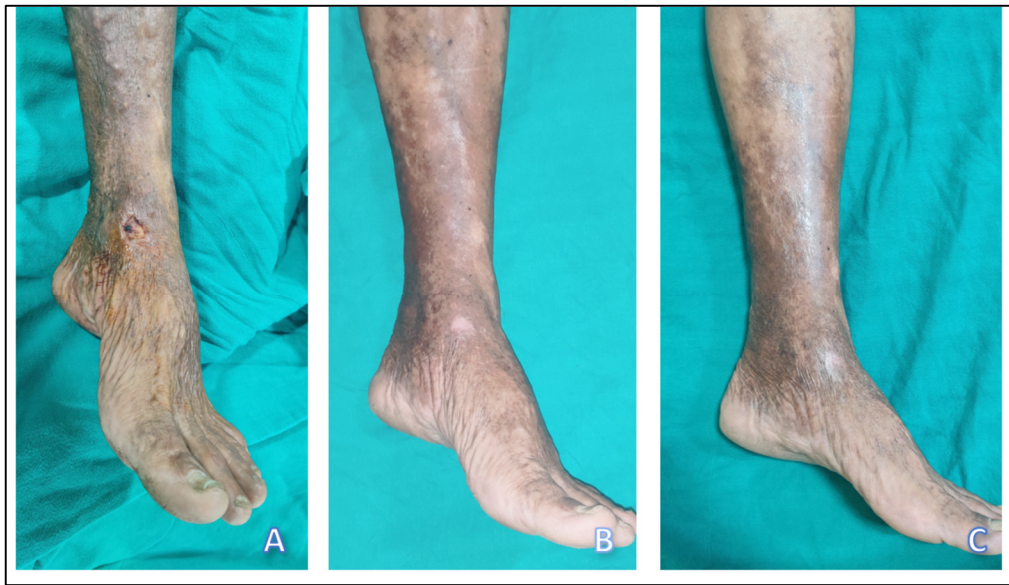


Figure 33

63 years old male, teacher by profession presented with complaints of varicose veins associated with severe pain, skin changes and active ulceration of left lower limb (**Figure A**). H/o Trendelenburg surgery 20 years back for varicose veins was present.

CEAP classification: C6 category

VCSS score: 25

USG evaluation: Post operative status of left SFJ and upper GSV, incompetent left SPJ with dilated lower GSV (5.9 mm) and SSV (5.5 mm) with multiple superficial varicosities in GSV and SSV territories.

Procedure: EVLA of right GSV and SSV with foam sclerotherapy of lower leg varicosities near ankle.

Follow up: At 1 month follow up there was significant decrease in the pain and varicosities for the patient with VCSS score of 15. On USG evaluation the visualized GSV and SSV were thrombosed. There was decrease in the inflammation, induration and skin pigmentation with healing of the active ulcer. (**Figure B**)

At 3 month follow up there was similar findings as 1 month follow up. VCSS score was 14. (**Figure C**)

Case 3

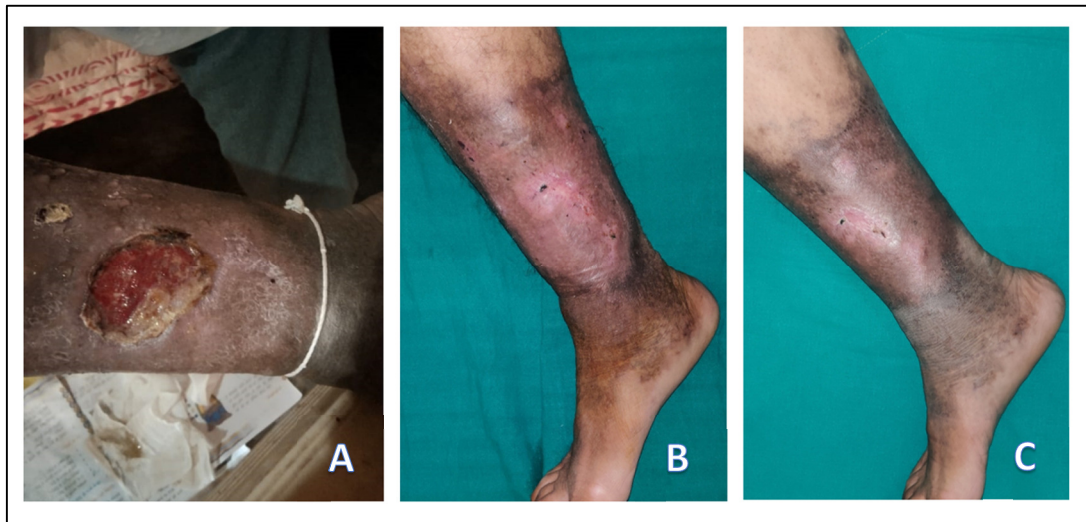


Figure 34

31 years old male, stone worker by profession presented with complaints of ulceration of right leg with maggot infestation. **(Figure A)**. Patient also had associated lower limb edema and skin changes in the form of skin pigmentation, induration and inflammation of right leg. Similar changes were also seen in left leg with no ulceration. Patient was HbsAg positive.

CEAP classification: C6 category

VCSS score: 24

USG evaluation: Incompetent bilateral SFJ with dilated GSV and SSV with multiple superficial varicosities in GSV and SSV territories.

Procedure: EVLA of bilateral GSV and SSV taking universal precautions. Patient was advised regular surgical dressing of the ulcer till the procedure to be done.

Follow up: At 1 month follow up there was significant decrease in the pain and varicosities for the patient with VCSS score of 20. On USG evaluation the visualized GSV and SSV were thrombosed. There was decrease in the inflammation, induration and skin pigmentation with healing of the ulceration. **(Figure B)**

At 3 month follow up there was healing of the ulcer with similar USG findings. VCSS score was 11. **(Figure C)**

Case 4

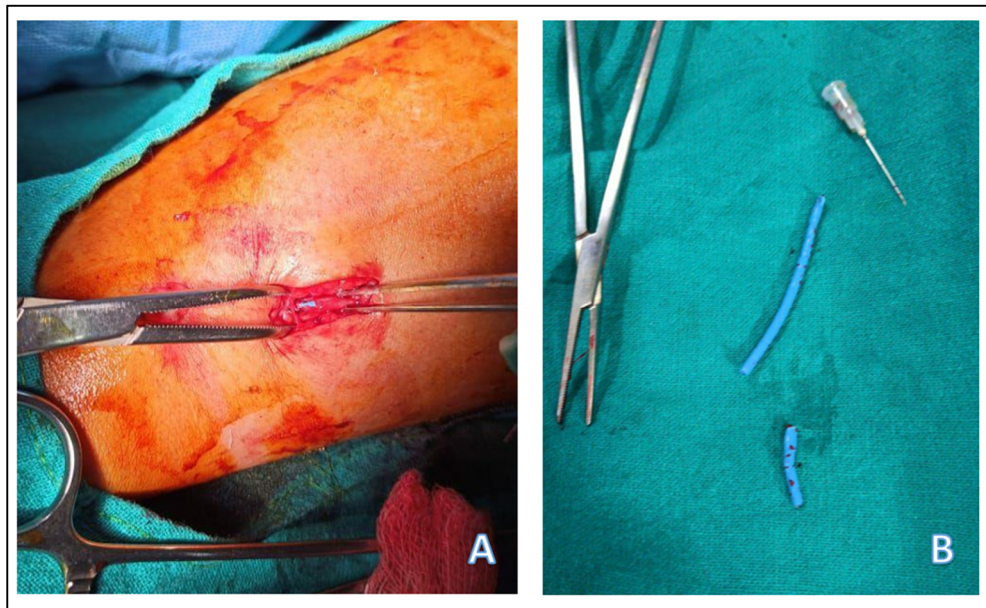


Figure 35

Female aged 43 years, obese, presented with varicose veins of left lower limb. On USG evaluation left SFJ and SPJ were incompetent with dilated GSV and SSV. EVLA of left GSV and SSV was planned.

During the procedure ablation of GSV went smoothly without any complication, however towards the end of the ablation of SSV the sheath was not withdrawn during the firing of laser fibre. This resulted in the burning of sheath in the SSV and ~5 cm of the distal end of sheath was found to be missing. Ultrasound evaluation of the local site was done and the remaining segment was found to be in SSV. Mini incision was given and the remaining segment was visualised in SSV (**Figure A**). It was removed in two pieces by saphenectomy (**Figure B**).

The patient was monitored for the next 24 hours after which she was discharged, as she did not develop any additional problems. On colour Doppler ultrasound performed 1 week and month after discharge, the saphenous vein was observed to be completely occluded and fibrotic.

Case 5

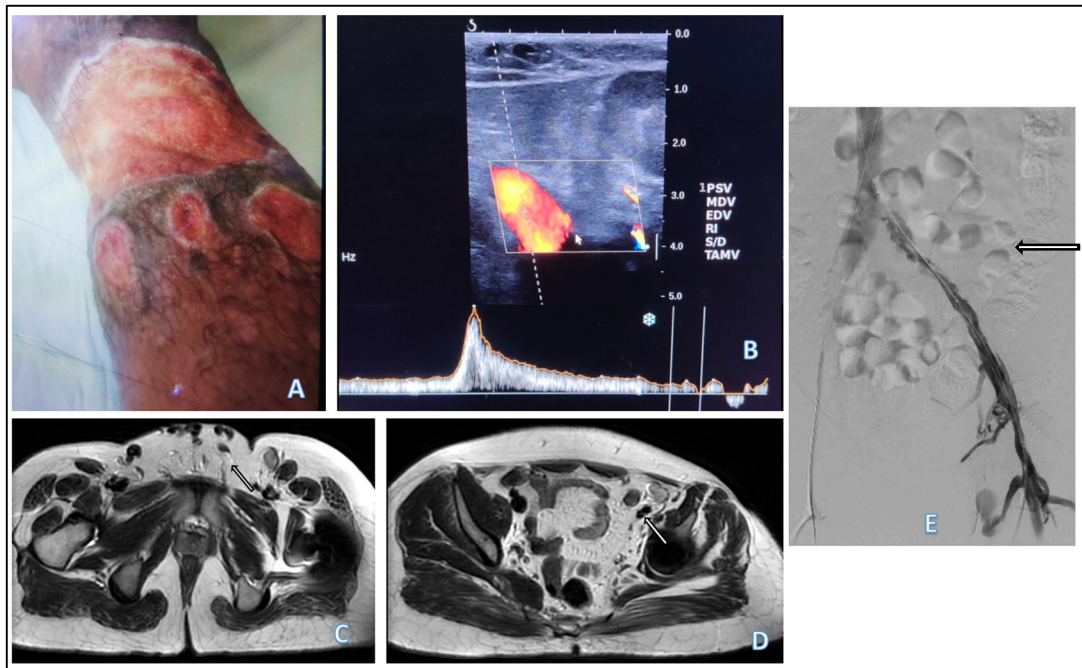


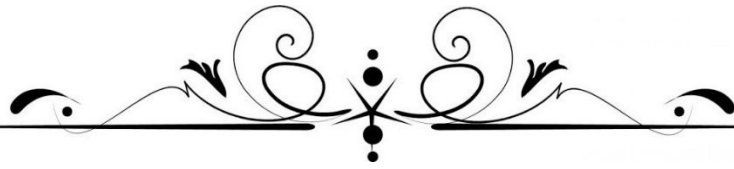
Figure 36

22 years old male presented with complaints of ulceration of left leg for 2 years with multiple superficial varicosities. **(Figure A)** History of trauma with nailing in left femur 3 years back.

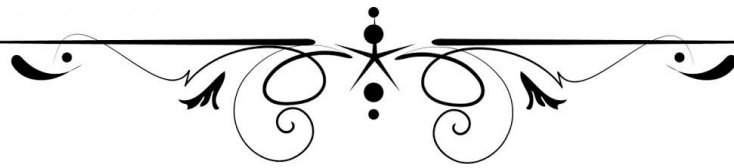
USG evaluation: Continuous reflux was seen at left SFJ with augmentation of the reflux during Valsalva manoeuvre which was an atypical finding. **(Figure B)** Left CFV, SFV and PV showed normal colour flow.

Hence suspicion of central venous abnormality was raised and **MRI pelvis** was done for the patient to rule out any central cause such as pelvic mass. MRI pelvis showed multiple anterior abdominal wall collaterals (arrow) with metallic artifact in head and neck of left femur. **(Figure C)**. Left external iliac vein (arrow) was narrowed in calibre compared to right side. **(Figure D)**. Diagnosis of post traumatic/operative chronic DVT of left external iliac vein was done. Conventional venography showed normal opacification of left CFV with narrowing of iliac vein (arrow) with multiple pelvic collaterals. **(Figure E)**.

EVLA was avoided in this patient as it would have worsened the clinical condition of the patient. This case emphasises the importance of thorough USG evaluation for varicose veins and raising the suspicion of deep/central venous pathology, as it alters the type of interventions for such cases.



CONCLUSION



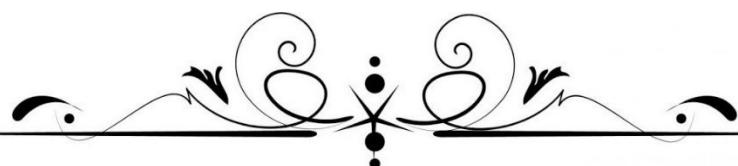
CONCLUSION

Varicose veins are dilated tortuous subcutaneous veins responsible for wide range of symptoms of lower limbs such as heaviness, swelling, pain, cramps and in severe cases causing skin changes and even ulcerations leading to disease and disability worldwide. Obstruction and reflux involving the superficial veins are the main culprits leading to these manifestations. USG is the primary imaging modality for evaluation of varicose veins and thus it is imperative for the vascular sonographer to provide high-quality duplex examination for the planning of lower extremity venous interventions. Treatment includes stockings, ulcer care and surgical/endovascular intervention in resistant cases.

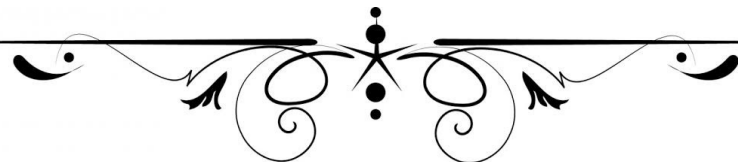
Our present study on primary varicose veins showed:

- Prevalence of risk factors like history of prolonged standing/sitting, obesity, pregnancy and family history.
- Patients with varicose veins of all stages showed ultrasound findings of dilated saphenous veins, incompetent perforators and/or SPJ/SFJ reflux with multiple superficial varicosities.
- All stages of varicose veins responded to treatment, with statistically significant differences between conservative and endovascular/surgical management. Endovascular/surgical management were found superior to conservative medical management alone.
- Surgical/endovascular interventions are associated with minimal complications which are easily manageable.

Varicose veins of lower limbs is a common clinical condition, but if not intervened early by lifestyle changes and conservative management may lead to deterioration of the condition which may require surgical/endovascular intervention. However, surgical/endovascular intervention provides promising outcome in such resistant cases. Literature about varicose veins among Indian population is lacking and hence more such studies need to be undertaken.



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BIBLIOGRAPHY

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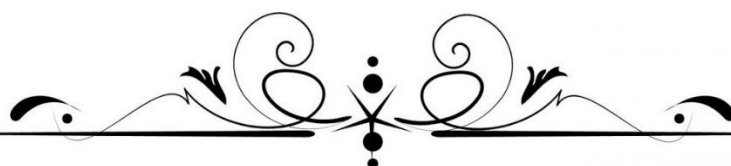
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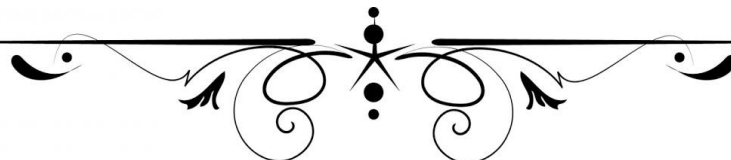
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ANNEXURES



ANNEXURE - 1

Ethical Clearance Certificate



अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2020/2028

Date: 01/01/2020

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: AIIMS/IEC/2019-20/992

Project title: "A study of demographic factors and treatment outcomes in patients with primary varicose veins of lower limb"

Nature of Project: **Research Project**

Submitted as: **M.D. Dissertation**

Student Name: **Dr.Saurabh Badgurjar**

Guide: **Dr.Pushpinder Singh Khara**

Co-Guide: **Dr.Pawan Garg, Dr. Ashok Purnaik, Dr. Sarbesh Tiwari, Dr.Ramkaran Chaudhry & Dr.Nitesh Manohar Gonnade**

This is to inform that members of Institutional Ethics Committee (Annexure attached) met on 23-12-2019 and after through consideration accorded its approval on above project. Further, should any other methodology be used, would require separate authorization.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

On behalf of Ethics Committee, I wish you success in your research.

Enclose:

1. Annexure 1


Dr. Praveen Sharma
Member Secretary
Institutional Ethics Committee
AIIMS, Jodhpur

Annexure 1



Institutional Ethics Committee All India Institute of Medical Sciences, Jodhpur

Meeting of Institutional Ethics committee held on **23-12-2019 at 10:00 AM** at Committee Room,
Admin Block AIIMS Jodhpur.

Following members were participated in the meeting:-

S/No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1.	Dr. F.S.K Barar	MBBS, MD (Pharmacology)	Chairman
2.	Justice N.N Mathur	LLB	Legal Expert
3.	Dr. Varsha Sharma	M.A (Sociology)	Social Scientist
4.	Mr. B.S.Yadav	B.Sc., M.Sc. (Physics), B.Ed.	Lay Person
5.	Dr. K.R.Haldiya	MD (General Medicine)	Clinician
6.	Dr. Arvind Mathur	MBBS, MS (General Medicine)	Clinician
7.	Dr. Surajit Ghatak	MBBS, MS (Anatomy)	Basic Medical Scientist
8.	Dr. Vijaya Lakshmi Nag	MBBS, MD (Microbiology)	Basic Medical Scientist
9.	Dr. Sneha Ambwani	MBBS, MD (Pharmacology)	Basic Medical Scientist
10.	Dr. Kuldeep Singh	MBBS, MD (Paediatric), DM (General Medicine)	Clinician
11.	Dr. Abhinav Dixit	MBBS, MD (Physiology), DNB (Physiology)	Basic Medical Scientist
12.	Dr. Pradeep Kumar Bhatia	MBBS, MD (Anaesthesiology)	Clinician
13.	Dr. Tanuj Kanchan	MBBS, MD (Forensic Medicine)	Basic Medical Scientist
14.	Dr. Pankaj Bhardwaj	MBBS, MD (CM&FM)	Clinician
15.	Dr. Praveen Sharma	M.Sc., Ph.D. (Biochemistry)	Member Secretary


Dr. Praveen Sharma
Member Secretary
 Institutional Ethics Committee
 AIIMS, Jodhpur

ANNEXURE - 2

All India Institute of Medical Sciences Jodhpur, Rajasthan

Informed consent form(Hindi)

Title of the project: A study of demographic factors and treatment outcomes in patients of primary varicose veins of lower limb

Name of the Principal Investigator: Dr. Saurabh Badgurjar

Tel. No: 9013922877

Patient/Volunteer Identification No.: _____

I, _____ S/o or D/o _____
R/o _____

_____ give my full, free, voluntary consent to be a part of the study “**A study of demographic factors and treatment outcomes in patients of primary varicose veins of lower limb**” the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from AIIMS, Jodhpur. I give permission for these individuals to have access to my records.

Date : _____

Place : _____

Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date : _____

Place : _____

Signature of Principal Investigator

Witness 1

2. Witness 2

Signature

Signature

Name: _____

Name: _____

Address : _____

Address : _____

ANNEXURE - 3

All India Institute of Medical Sciences, Jodhpur, Rajasthan

Informed Consent (Hindi)

- थीसिस / निबंध का शीर्षक: पैरों के प्राथमिक वैरिकाज़ नसों वाले रोगियों में जनसांख्यिकीय कारकों और उपचार परिणामों का □ अध्ययन
- पीजी छात्र का नाम: सौरभ बड़गुर्जर टेल न: 9013922877
- रोगी / स्वयं सेवक पहचान संख्या: _____

मैं, _____ एस /ओ या पी /ओ _____

आर /ओ _____

□ अध्ययन "पैरों के प्राथमिक वैरिकाज़ नसों वाले रोगियों में जनसांख्यिकीय कारकों और उपचार परिणामों का □ अध्ययन" का एक भाग बनने के लिए मेरी पूर्ण, स्वतंत्र, स्वैच्छिक सहमति दें, जिसकी प्रक्रिया और प्रकृति मुझे □ पनी पूरी संतुष्टि के लिए □ पनी भाषा में समझाई गई है। मैं पुष्टि करता हूं कि मुझे प्रश्न पूछने का □ वसर मिला है।

मैं समझता हूं कि मेरी भागीदारी स्वैच्छिक है और मुझे किसी भी कारण दिए बिना किसी भी समय □ अध्ययन से बाहर निकलने के मेरे □ अधिकार की जानकारी है।

मैं समझता हूं कि मेरे और मेरे मेडिकल रिकॉर्ड के कत्रित की गई जानकारी को एम्स से जिम्मेदार व्यक्ति द्वारा देखा जा सकता है। मैं इन व्यक्तियों को □ पने □ भिलेखों तक पहुंच के लिए □ नुमति देता हूं

तारीख : _____

जगह: _____ हस्ताक्षर / बाएं □ गूठे का छाप _____

यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त की गई है

तारीख : _____

जगह: _____ पीजी छात्र के हस्ताक्षर _____

गवाह 1 : _____

गवाह 2 : _____

हस्ताक्षर: _____

हस्ताक्षर: _____

तारीख : _____

तारीख : _____

ANNEXURE – 4

Patient Information Sheet

1. Risks to the patients: There's no risk of death or any disability resulting directly due to imaging.
2. Confidentiality: Your participation will be kept confidential. Your medical records will be treated with confidentiality and will be revealed only to doctors/ scientists involved in this study. The results of this study may be published in a scientific journal, but you will not be identified by name.
3. Provision of free treatment for research related injury. Not applicable.
4. Compensation of subjects for disability or death resulting from such injury. Not Applicable
5. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
6. You have complete freedom to participate and to withdraw from research at any time without penalty or loss of benefits to which you would otherwise be entitled.
7. Your participation in the study is optional and voluntary.
8. The copy of the results of the investigations performed will be provided to you for your record.
9. You can withdraw from the project at any time, and this will not affect your subsequent medical treatment or relationship with the treating physician.
10. Any additional expense for the project, other than your regular expenses, will not be charged from you.

ANNEXURE - 5

रोगी सूचना पत्रक

1. रोगियों के लिए जोखिम: इमेजिंग के कारण सीधे मौत या कोई विकलांगता का कोई खतरा नहीं है। कोई हस्तक्षेप या जीवन-धम की प्रक्रिया नहीं की जाएगी।

2. गोपनीयता: आपकी भागीदारी को गोपनीय रखा जाएगा। आपके मेडिकल रिकॉर्ड को गोपनीयता के साथ इलाज किया जाएगा और केवल इस अध्ययन में शामिल डॉक्टरों / वैज्ञानिकों को पता चलेगा। इस अध्ययन के परिणाम एक वैज्ञानिक पत्रिका में प्रकाशित हो सकते हैं, लेकिन आपको नाम से पहचाना नहीं जाएगा।

1. अनुसंधान संबंधी चोट के लिए निः शुल्क उपचार की व्यवस्था। लागू नहीं।

2. ऐसी चोट से उत्पन्न विकलांगता या मृत्यु के लिए विषयों का मुआवजा लागू नहीं है

5. किसी भी समय दण या लाभों के नुकसान के बिना किसी भी समय भाग लेने के लिए व्यक्ति को स्वतंत्रता लेने और अनुसंधान से वापस लेने के लिए स्वतंत्रता, जिसके तहत विषय न्यथा हकदार होगा

6. आपको जुर्माना या लाभ के नुकसान के बिना किसी भी समय भाग लेने और अनुसंधान से वापस लेने की पूरी आजादी है, जिस पर आप न्यथा हकदार होंगे।

7. अध्ययन में आपकी भागीदारी वैकल्पिक और स्वैच्छिक है।

8. प्रदर्शन की जांच की परिणामों की प्रति आपके रिकॉर्ड के लिए आपको उपलब्ध कराई जाएगी।

9. आप किसी भी समय परियोजना से वापस ले सकते हैं, और यह आपके बाद के चिकित्सा उपचार या उपचार चिकित्सक के साथ संबंध को प्रभावित नहीं करेगा।

10. परियोजना के लिए कोई भी अतिरिक्त व्यय, आपके नियमित खर्चों के लावा, आप से शुल्क नहीं लिया जाएगा।

ANNEXURE - 5

MASTER CHART

Age	Gender	Occupation	History of prolonged standing/sitting	BMI Category	Family history of varicose veins in first-degree relatives	Clinical presentation	CEAP Classification	Pain	Varicose veins	Venous Edema	Skin Pigmentation	Inflammation	Induration	No. of active ulcers	Active Ulcer Size	Ulcer Duration	Compression	Total VCSS score	Laterality	SFJ	GSV diameter	Perforators	SFU	SSV diameter	Treatment	Original VCSS score	VCSS follow up 1	VCSS follow up 2	VCSS follow up 3	Developed after pregnancy (in female)	Post intervention complication - If any
23	Male	STUDENT	Yes	Optimal	No	Cosmetic appearance - dilated veins	2	1	2	0	0	0	1	0	0	0	0	3	Right	Competent	3.6	Above knee - 9.2 mm	Competent	2.2	Conservative	3	2				
27	Male	VEGETABLE SELLER	Yes	Optimal	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins, Healed Ulcer	2	1	2	2	1	1	1	0	0	0	2	1	9	Left	Incompetent	2.2	Below knee 3.5	Competent	2.5	Conservative	9	2			
34	Male	CARPENTER	Yes	Optimal	No	Pain, Skin pigmentation	4	2	3	2	1	1	0	0	0	0	0	9	Left	Incompetent	6.3	Below knee - 3.8	Competent	3.5	Conservative	9	2				
19	Female	STUDENT	No	Optimal	Yes	Pain, Cosmetic appearance - dilated veins	2	1	1	0	0	0	0	0	0	0	1	3	Left	Incompetent	6.1	Below knee - 4mm	High Riding	2.5	Conservative	3	3				
34	Male	SHOP OWNER	Yes	Overweight	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	2	3	2	2	2	2	0	0	0	0	14	Right	Competent	6.3	Below knee - 3.4	Competent	3.2	Conservative	14	14				
34	Male	SHOP OWNER	Yes	Overweight	Yes	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	3	3	2	1	1	1	0	0	0	0	11	Left	Incompetent	5.8	Below knee - 3.5	Competent	2.9	Conservative	11	12				
31	Male	SHOP OWNER	Yes	Optimal	No	Pain, Skin pigmentation, Cosmetic appearance - dilated veins	4	1	2	1	1	1	1	0	0	0	3	10	Right	Competent	4.3	Above knee - 3.1, Below knee 3.2, Above Ankle - 3.5	Competent	3.6	Conservative	10	10				
32	Male	COOKING	Yes	Overweight	No	Pain, Ankle swelling, Cosmetic appearance - dilated veins	2	2	2	2	0	2	0	0	0	0	0	8	Left	Incompetent	7.7	Above ankle - 4 mm	High Riding	3.3	Conservative	8	7				
18	Male	STUDENT	Yes	Optimal	No	Cosmetic appearance - dilated veins	2	1	3	0	0	0	0	0	0	0	0	3	4.4	Left	Competent	4.4	Endovascular	16	16						
33	Male	SHOP OWNER	Yes	Overweight	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	0	2	2	3	3	3	0	0	0	2	15	Left	Incompetent	6.8	Nil	High Riding	4.6	Conservative	15	15	3	2		
32	Female	HOUSEWIFE	Yes	Optimal	No	Pain, Ankle swelling, Cosmetic appearance - dilated veins	2	3	3	1	0	0	0	0	0	0	1	8	Right	Competent	3.5	Below knee - 3.2, Above ankle - 2.5	Competent	2.7	Conservative	8	9		Yes		
27	Male	FARMER	Yes	Optimal	No	Pain, Ankle swelling, Cosmetic appearance - dilated veins	2	3	2	2	0	0	0	0	0	0	7	Right	Incompetent	5.3	Below knee - 3.8	High Riding	4.9	Conservative	7	7					
27	Male	FARMER	Yes	Optimal	No	Pain, Ankle swelling, Cosmetic appearance - dilated veins	2	3	2	2	0	0	0	0	0	0	7	Left	High Riding	5.8	Below knee - 3.2	Competent	3.6	Conservative	16	16					
50	Female	HOUSEWIFE	Yes	Overweight	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins, Healed Ulcer	5	3	3	2	2	2	2	0	0	0	3	17	Right	Incompetent	6.4	Below knee - 5.2, Above ankle - 4.5	Competent	6.2	Conservative	17	16		No		
50	Female	HOUSEWIFE	Yes	Overweight	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins, Healed Ulcer	5	3	3	2	2	2	2	0	0	0	3	17	Left	Incompetent	6.2	Below knee - 4.8, Above ankle - 4.4	Competent	5.1	Conservative	17	16		No		
59	Female	HOUSEWIFE	Yes	Overweight	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	3	3	2	2	2	2	0	0	0	1	16	Left	Incompetent	6.5	Nil	High Riding	3.6	Conservative	16	16		No		
68	Female	TEACHER	Yes	Overweight	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	1	1	2	2	2	2	0	0	0	3	13	Left	Competent	6	Nil	Competent	2.3	Conservative	13	8		No		
18	Male	STUDENT	Yes	Optimal	No	Pain, Ankle swelling, Cosmetic appearance - dilated veins	3	2	2	2	0	0	0	0	0	0	2	8	Left	Incompetent	4.7	Below Knee - 3.8	High Riding	2.8	Endovascular	8	6	3	3		
21	Male	STUDENT	Yes	Optimal	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	2	2	2	1	1	1	0	0	0	2	11	Right	Incompetent	5.4	Below knee - 3.7	High Riding	2.9	Endovascular	11	8	6	6		
57	Male	CARPENTER	Yes	Obese	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	2	2	2	0	1	1	0	0	0	9	Left	Competent	5.5	Below knee - 4	Incompetent	4.4	Endovascular	9	8	6	6			
67	Male	CHEMIST	Yes	Overweight	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins, Active Ulcer	6	1	3	2	3	3	3	1	2	3	3	24	Right	Incompetent	7.9	Below knee - 5.5, Above ankle - 4.2	Competent	5	Conservative	24	18		Superficial burn in GSV territory		
25	Male	SHOPKEEPER	Yes	Optimal	No	Cosmetic appearance - dilated veins	2	0	2	0	0	0	0	0	0	0	0	2	Right	Competent	3.3	Above ankle - 2.8	Competent	2.3	Conservative	2	1				
19	Male	STUDENT	No	Optimal	No	Cosmetic appearance - dilated veins	2	0	2	0	0	0	0	0	0	0	0	2	Right	Competent	5.8	Mid thigh - 3.4	High Riding	2.9	Conservative	2	1				
26	Male	SHOP OWNER	Yes	Optimal	No	Cosmetic appearance - dilated veins	2	0	2	0	0	0	0	0	0	0	2	Left	Competent	4	Below knee - 4.1, Above ankle - 5.1	High Riding	3.6	Conservative	2	1					
39	Male	TEACHER	Yes	Optimal	No	Pain, Cosmetic appearance - dilated veins	2	3	2	1	0	0	0	0	0	0	0	6	Left	Incompetent	6.2	Below knee - 4	Competent	3.6	Conservative	6	4				
28	Male	Cloth shop worker	Yes	Optimal	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins, Active Ulcer	6	3	2	2	3	3	3	1	2	2	3	24	Left	Competent	5.9	Above knee - 5, below knee - 5.1, above ankle - 5.3	High Riding	4.1	Conservative	24	18		No		
58	Male	SHOP OWNER	Yes	Optimal	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	3	2	2	3	3	3	0	0	0	0	14	Left	Competent	5.4	Below knee - 5.2	High Riding	3.4	Conservative	14	14	9	8		
51	Female	Teacher	Yes	Overweight	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	2	3	2	1	2	2	0	0	0	0	12	Left	Competent	3.8	Above ankle 3.2	High Riding	2.1	Conservative	12	6		No		
41	Female	House wife	No	Optimal	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	2	3	3	2	1	1	1	0	0	0	0	11	Right	Incompetent	5.5	Nil	High Riding	7.5	Endovascular	11	9	7	6		
41	Female	House wife	No	Optimal	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	2	3	3	2	1	1	1	0	0	0	0	11	Left	Incompetent	6.5	Nil	High Riding	9.5	Conservative	11	11		No		
44	Male	GOVERNMENT SERVICE	Yes	Optimal	No	Pain, Cosmetic appearance - dilated veins	2	3	2	2	0	2	2	0	0	0	0	11	Left	High Riding	4.5	Endovascular	11	11							
32	Male	Kirana shop owner	Yes	Obese	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	5	3	3	3	3	3	3	0	0	0	1	19	Right	Incompetent	5.5	Nil	High Riding	2.1	Endovascular	19	16	13	11		
32	Male	Kirana shop owner	Yes	Obese	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	5	3	3	3	3	3	3	0	0	0	0	1	19	Left	Incompetent	6.5	Nil	High Riding	2.5	Conservative	19	16		No	
37	Female	Housewife	No	Obese	No	Pain, Ankle swelling, Cosmetic appearance - dilated veins	2	3	2	2	0	0	0	0	0	0	0	7	Right	Competent	3.2	Nil	Incompetent	6.5	Conservative	7	5		No		
37	Female	Housewife	No	Obese	No	Pain, Ankle swelling, Cosmetic appearance - dilated veins	2	3	2	2	0	0	0	0	0	0	0	7	Left	Incompetent	5.3	Nil	Competent	2.8	Conservative	7	5		No		
45	Female	Housewife	No	Overweight	Yes	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins, Healed Ulcer	5	2	3	2	2	2	2	0	0	0	2	15	Right	Competent	5.1	Nil	High Riding	4	Conservative	15	14		No		
51	Male	TEACHER	Yes	Optimal	Yes	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	3	3	2	2	2	2	0	0	0	3	17	Right	Incompetent	6	Below knee - 4, Above ankle - 4.2	High Riding	4.5	Endovascular	17	16	13	10		
51	Male	TEACHER	Yes	Optimal	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	3	2	2	2	2	2	0	0	0	3	17	Left	Competent	4.7	Below knee - 3.2, Above ankle - 3.8	High Riding	4.7	Endovascular	17	13	13	9		
48	Female	Housewife	No	Overweight	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	3	2	2	1	1	1	0	0	0	3	13	Left	Competent	4.5	above ankle - 3.5	Incompetent	4	Conservative	13	10		No		
28	Male	Nurse	Yes	Optimal	No	Pain, Ankle swelling, Cosmetic appearance - dilated veins	2	1	1	1	0	0	0	0	0	0	0	3	Right	Incompetent	5.5	below knee - 4	High Riding	3.8	Conservative	3	2		No		
28	Male	Nurse	Yes	Optimal	No	Pain, Ankle swelling, Cosmetic appearance - dilated veins	2	1	1	1	0	0	0	0	0	0	0	3	Left	Incompetent	8.8	below knee 4.4	High Riding	3.9	Conservative	3	2		No		
24	Male	Farmer	Yes	Underweight	No	Pain, Ankle swelling, Cosmetic appearance - dilated veins	2	0	3	2	0	0	0	0	0	0	3	9	Left	Competent	4.28	Below knee - 4.5, above ankle 4.1	Competent	4.28	Conservative	9	5		Yes		
52	Female	HOUSEWIFE	Yes	Obese	Yes	Pain, Cosmetic appearance - dilated veins	2	0	3	1	1	0	1	0	0	0	3	9	Right	Incompetent	8.8	Nil	Competent	3.2	Endovascular	8	7	5	Yes		
52	Female	HOUSEWIFE	Yes	Obese	Yes	Pain, Cosmetic appearance - dilated veins	2	0	3	1	1	0	1	0	0	0	3	9	Left	Incompetent	5.8	Nil	Competent	2.8	Endovascular	9	8	6	5		
21	Male	Student	Yes	Overweight	No	Cosmetic appearance - dilated veins	2	0	3	0	0	0	0	0	0	0	3	7	Right	Competent	3.5	Below knee 3	Competent	2.8	Conservative	3	4		No		
47	Male	CARPENTER	Yes	Overweight	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	2	3	2	1	1	1	0	0	0	0	7	Right	Incompetent	5.8	Endovascular	9	8		6	6		No		
47	Male	CARPENTER	Yes	Overweight	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	1	2	1	1	1	1	0	0	0	0	7	Left	Competent	2.9	Nil	Incompetent	6.1	Endovascular	7	7	6	6		
52	Male	Guest House owner	Yes	Optimal	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	2	2	1	1	2	2	0	0	0	0	10	Right	Incompetent	3.5	Nil	High Riding	3.1	Conservative	10	6		No		
52	Male	Guest House owner	Yes	Optimal	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	2	2	1	1	2	2	0	0	0	0	12	Left	Competent	3.2	Conservative	High Riding	3.2	Conservative	12	6		No		
20	Male	Student	Yes	Optimal	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins, Active Ulcer, Healed Ulcer	5	1	3	1	2	2	2	1	2	1	0	15	Right	Competent	9.7	Below knee 5	Competent	4	Conservative	15	10		No		
25	Male	Student	Yes	Underweight	No	Pain, Cosmetic appearance - dilated veins	2	1	3	0	0	0	0	0	0	0	0	4	Left	Incompetent	11	Below knee 3.1, above ankle 2.7	Competent	3.5	Surgical	4	3	3		Wound site hematoma	
25	Male	Housewife	No	Optimal	No	Pain, Ankle swelling, Cosmetic appearance - dilated veins	2	3	2	2	0	0	0	0	0	0	0	8	Right	Incompetent	3.2	Nil	Incompetent	6.5	Conservative	8	5		No		
42	Female	Housewife	No	Optimal	No	Pain, Ankle swelling, Cosmetic appearance - dilated veins	2	3	2	2	0	0	0	0	0	0	0	9	Left	Competent	3.5	Conservative	9	9		6	6		No		
50	Male	SHOP OWNER	Yes	Optimal	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins, Healed Ulcer	5	1	3	3	3	3	3	0	0	0	0	16	Right	Incompetent	5.6	SSV territory - Below knee - 4.5, Above ankle - 4.8	Competent	4.9	Endovascular	16	14	11	9		
20	Male	Works at Xerox shop	Yes	Optimal	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	2	3	1	1	1	1	0	0	0	3	12	Right	Incompetent	5.5	Nil	High Riding	2.2	Conservative	12	11		No		
20	Male	Works at Xerox shop	Yes	Optimal	No	Pain, Skin pigmentation, Ankle swelling, Cosmetic appearance - dilated veins	4	3	3	1	1	1	1	0	0	0	3	13	Left	Incompetent	5.8	Nil	High Riding	2.5	Conservative	13	12		No		
43	Female	Worker	Yes	Obese	No	Pain, Ankle swelling, Cosmetic appearance - dilated veins	2	1	3	0	0	0	0	0	0	0	0	5	Left	Incompetent	3.5	Conservative	High Riding	2.7	Conservative	5	7		No		
51	Male	SHOP OWNER	Yes	Overweight	No	Pain, Skin pigmentation																									